Menopause: identification and management
Consultation on draft guideline - Stakeholder comments table M - Z

17/11/2023 – 05/01/2024

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Marches Psychological Services Ltd	Evidence Review A	general	general	There are no comparison studies indicating the efficacy of the Treatment As Usual (TAU) groups versus groups where there was no treatment was provided.	Thank you for your comment. There is a 'summary of the evidence' section and the committee discussion of the evidence base that lead to the recommendations is provided in the 'Benefits and harms' section of evidence review A.
Marches Psychological Services Ltd	Evidence Review A	general	general	We are concerned about the quality of the research studies being used to make recommendations for CBT. For example, many studies had low participant numbers, some studies were dated and used self-report measures (Moradi Farsani 2021, Soori 2019, McCurry 2016, Keefer 2005, Ayers 2012, Duijts 2012). Recent ACT papers include data and outcomes from 2022 which have not been included in this guidance - this review is not comprehensive and does not look at good evidence (which is acknowledge in the review, but not in the main guideline - it should be stated in both)	Thank you for your comment. Participant numbers, year of publication and whether studies used self-reported outcome measures were not considered criteria for inclusion or exclusion in the pre-defined protocol, therefore studies have not been excluded on this basis. See the full protocol in Appendix A of Evidence Review A for the full criteria on which studies were assessed as relevant for inclusion. The quality of the evidence is captured using GRADE assessment of outcomes, which can be found in Appendix F of Evidence Review A. Low participant numbers may impact the imprecision of the effect estimate and will be captured in the GRADE assessment. If there are concerns over risk of bias due to self-reported outcomes, these are captured in the risk of bias assessment of each study which can be found in the full evidence tables in Appendix D of Evidence Review A. The committee considered the quality of the evidence when formulating recommendations. This is reflected in the wording used which indicates the recommendation strength. The word 'consider' was used for recommendation 1.4.9 as it is a

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					'weak' recommendation. In 'strong' recommendations for actions that should (or should not) be offered, directive language such as 'offer' is used. For more information on this please see: Developing NICE guidelines: the manual. The committee has revised the wording to ensure clarity about CBT 'as an option: in addition to HRT, for people for whom HRT is contraindicated or for people who prefer not to take HRT'. You have not provided a reference to the ACT papers from 2022 therefore it is not possible to give a detailed response as to why the studies included in that review have not been included in the evidence review.
Marches Psychological Services Ltd	Evidence Review A	general	general	The evidence is questionable with regards to generalisability to the UK demographic with only 3 articles/ research papers cited here taking place in the UK. Studies from countries such as Iran and Saudi Arabia may well not be generalisable given the cultural differences. For example, the studies in this guidance state that it is how vasomotor symptoms are perceived that is the issue (and main measure) not the frequency of the symptom, hence using CBT. However, cross-cultural studies suggest variations in perceptions and experience of menopause in women from different ethnic origins and living in different countries (Avis & Crawford, 2008), not to mention also reporting differences. Caucasian women were found to report more psychological and somatic symptoms than any other ethnic groups, yet some of the samples here were mostly white (McCurry). There is also variation between women within ethnic groups, as well as	Thank you for your comment. The review protocol did not limit inclusion of trials based on country. The included studies all meet the protocol criteria for inclusion. A number of different measures were used which also included number of vasomotor symptoms and effectiveness was not only reported in how symptoms were perceived but also frequency of symptoms. Whilst the approach may differ the principles of CBT are applicable across different cultures. Therefore, it would not be appropriate to restrict the evidence to specific countries.

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				variation across cohorts and generations. Most studies in this guidance have women with a mean age of over 50. Many women experience menopause symptoms far earlier than this.	
Marches Psychological Services Ltd	Evidence Review A	general	general	We would recommend that studies exploring the effect of therapy (not just CBT) with participants from the UK demographic are used to make the recommendations in the guidance.	Thank you for your comment. The current guideline focused on CBT only, for which new evidence was identified. However, based on this and other stakeholder comments, the effects of psychological therapies have been highlighted to the NICE surveillance team as a topic to monitor for emerging evidence.
Marches Psychological Services Ltd	Evidence Review A	general	general	The research papers inclusion criteria are very restrictive for example, non-oncology individuals, professionals in roles with cognitive loading, participants with suicidal ideation, and depression are often excluded but these are common symptoms being experienced in individuals reporting menopausal symptoms. The vast majority of women in the UK do not have cancer when they become menopausal.	Thank you for your comment, The population for this review was broad; women, non-binary and trans people with symptoms associated with menopause. The included populations are a reflection of the available evidence (please see appendix A for the review protocol).
Marches Psychological Services Ltd	Evidence Review A	general	general	The research studies used focus on vasomotor symptoms. This is one cluster of symptoms and there is no research cited for use of CBT for other symptoms where CBT might be more appropriate for example anxiety, cognitive 'brain fog' and memory problems related to menopause etc.	Thank you for your comment. Psychological symptoms i.e. anxiety and low mood were included in the protocol for this review. The section on menopause symptoms of the guideline was not in the scope of the 2024 guideline update. The committee therefore restricted the outcomes based on symptoms that were previously identified for the intervention reviews conducted in 2015.
Marches Psychological Services Ltd	Evidence Review A	general	general	Very short time to follow ups so it is unclear whether effects are maintained e.g.: McCurry 2016, Moradi Farsani 2021.	Thank you for your comment. The review protocol did not restrict for length of follow-up, all relevant evidence irrespective of follow-up length was included. However, this was acknowledged in the 'the quality of evidence' section of evidence review A.

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Marches Psychological Services Ltd	Evidence Review A	general	general	Participants demographics - many of the 14 studies look at cancer patients (who often experience menopause differently for a variety of reasons - medical or surgical, younger, faster speed, and in context of facing cancer diagnosis which influences how symptoms are rated) - these studies should not be used as the basis for a recommendation for the wider population of c. 13 million in the UK.	Thank you for your comment. The committee took into consideration possible differences on impact of CBT on people with and without a history of breast cancer when making the recommendations. This is outlined in 'the committee's discussion and interpretation of the evidence' section of evidence review A: 'The committee considered whether a history of breast cancer would have an impact on the treatment effects of CBT. Since the evidence showed a benefit for CBT in both people with and without a history of breast cancer, the committee agreed that specific recommendations based on a person's history of breast cancer cannot be made from the evidence base.'
Marches Psychological Services Ltd	Evidence Review A	general	general	There is a concern that only CBT has been recommended in this guidance when it is well known that CBT is only effective for around 50% of people at best.	Thank you for your comment. CBT has been offered as a treatment option for certain symptoms associated with menopause based on the benefit of CBT observed for the outcomes vasomotor symptoms, depressive symptoms and sleep. The committee reflected on the wording of the recommendations related to CBT and revised them to ensure clarity about this ' as an option: in addition to other treatments (including HRT), for people for whom other treatments are contraindicated or for people who prefer not to take HRT'. This makes it clear that CBT is not seen as a first line treatment but as an option where this is a preferred choice. Note NG23 has undergone a partial updated in 2024 following the NICE surveillance outcome in 2019 and 2021 as published in the related guideline update scope. The recommendations made previously (NG23 2015) on areas that have not been updated still apply. For the comprehensive list of recommendations see the revised guideline document.

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Marches Psychological Services Ltd	Evidence review A	general	general	Most studies have only wait list control groups and many who have TAU as a control, the TAU is not a similar time-heavy input intervention. In other words, the control groups are not really control groups. It is not possible from these studies to conclude that CBT as an intervention is superior to offering women the opportunity to chat to one another once a week.	Thank you for your comment. A systematic search for evidence was conducted for inclusion into this review. All available evidence that meets the criteria of the protocol have been included.
Marches Psychological Services Ltd	Evidence Review A	010		Fenlon (2020) study - reports a lower problem rating score for vasomotor symptoms for the CBT group vs the control group, but the difference was not clinically significant (the authors pre-stated the score difference that would be clinically significant, the results failed to reach this, but they nonetheless drew the conclusion that it was). This is not robust research that a national guideline should be based on.	Thank you for your comment. The studies included in this review meet the criteria of the pre-defined review protocol. Each study is assessed for methodological robustness which is taken into consideration when assessing the inclusion of the studies as well as rating the quality of the evidence. Studies are then meta-analysed where possible. The effectiveness and clinical significance of the evidence base is independently assessed by the guideline committee based on all of the included studies rather than the individual author's conclusions of each paper. The committee's reasoning is explained in the 'committee's discussion and interpretation of the evidence' section.
Marches Psychological Services Ltd	Evidence Review A	010		Key authors on some of the RCTs (e.g. Fenlon et al 2020) have a conflict of interest since they developed the CBT model for vasomotor symptoms of the menopause	Thank you for your comment. The conflict of interest has now been noted in the data extraction (appendix D). However, since the author did not administer the CBT intervention in the trial, the impact is uncertain, and the evidence has not been further downgraded.
Marches Psychological Services Ltd	Evidence Review A	018	030 - 042	The evidence is described as 'most of the evidence is of very low and low quality' - this should be clearly stated in the main guidelines, not buried in the evidence review which most GPs will not read. The evidence does not justify such a strong recommendation for CBT for ALL	Thank you for your comment. The quality of the evidence is taken into consideration when formulating recommendations. This is reflected in the wording used which indicates the recommendation strength. The word 'consider' was used for recommendation 1.4.9 as it is a

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				'troublesome' symptoms of the menopause right beside HRT.	'weak' recommendation. In 'strong' recommendations for actions that should (or should not) be offered, directive language such as 'offer' is used and the recommendation has been revised to ensure clarity about CBT 'as an option: in addition to HRT, for people for whom HRT is contraindicated or for people who prefer not to take HRT'. For more information on the wording of recommendations see: Developing NICE guidelines: the manual.
Marches Psychological Services Ltd	Evidence Review A and Guidelines	general	general	The reviews do not include or examine support and/or education for families/partners/carers/children. It would seem prudent to include this in the guidance given the impact that menopause can have on relationships.	Thank you for your comment. Assessing the support and/or education for families/partners/carers/children was not in the scope of this guideline update. Evidence for this topic was therefore not searched for, reviewed or discussed with the committee. The committee could therefore not comment on this.
Marches Psychological Services Ltd	Evidence Review A and Guidelines	general	general	We recognise that CBT lends itself to RCTs as is often the therapy model most recommended in NICE guidance. However, it is widely known that CBT is only effective for 50% of people and that RCTs do not reflect "real life". Most people do not have symptoms in isolation or fit into the next boxes required for inclusion in RCTs. We would recommend that other models are explored as well as seeing psychological therapy as a part of treatment, part of a holistic package of care rather than an either or (and making is explicit in the guideline that it should be an adjunct if HRT cannot be prescribed or has already been maximised). The way the guideline is written does not make this clear - as evidenced by the initial responses even from GPs.	Thank you for your comment. The committee reflected on the wording of the recommendations related to CBT and revised them to ensure clarity about this ' as an option: in addition to other treatments (including HRT), for people for whom other treatments are contraindicated or for people who prefer not to take HRT'. This makes it clear that CBT is not a first line treatment but as an option where this is a preferred choice.

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Marches Psychological Services Ltd	Guideline	general	general	We would like to see a recommendation for training for medical professionals and therapists in peri menopause and menopause identification and diagnosis. Many women are still being given misinformation (e.g., refusing HRT where there are no known risks), misdiagnosis e.g., offering antidepressants instead of HRT. There is a real risk CBT is offered quickly instead of HRT unless this training is widely offered and knowledge for prescribing HRT is vastly improved.	Thank you for your comment. Recommendations on training are outside the remit of NICE since these are set by the relevant professional bodies such as the British Menopause Society, the Faculty of Sexual and Reproductive Healthcare or the Royal College of Obstetricians and Gynaecologists. The committee revised the CBT recommendation to clarify that this is recommended as an option (1) alongside of other treatments (including HRT) (2) to people for whom other treatments are contraindicated or (3) to those who prefer not to have other treatments. The committee decided that it was important that for people experiencing menopause who are suspected to have, or are diagnosed, with depression a link to the NICE guideline on depression in adults is provided so that recommendations in the menopause guideline are followed alongside the recommendations on the treatment of depression.
Marches Psychological Services Ltd	Guideline	general	general	We would like to see a recommendation for training for therapists in CBT for perimenopause and menopause. In addition, therapists and all staff assessing and working with individuals whose difficulties might be related to hormonal changes and menopause. CBT for menopausal symptoms is distinctly different to other forms of CBT so this must be made clear to avoid women being offered 'general' CBT which will be ineffective and a waste of public money	Thank you for your comment. Training of therapists is outside the scope of NICE guidelines because it is the remit of academic institutions or Royal colleges. The committee could therefore not comment on this.
Marches Psychological Services Ltd	Guideline	006	019	The language used throughout the document is undermining, invalidating and minimises the experiences of the individual's and the impact this can have e.g.: "troublesome". This is used	Thank you for your comment. Based on this and other feedback, the committee reflected on this wording and consequently, 'troublesome' has been removed from the guideline. NICE takes the

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				repeatedly in the guidelines. These symptoms can impact on individuals leaving their jobs for example which can hardly be described as 'troublesome', (900,000 women reported to have left their jobs due to menopausal symptoms): https://publications.parliament.uk/pa/cm5803/cmselect/cmwomeq/91/report.html	reports of the debilitating symptoms, the considerable concern it causes and the impact that symptoms associated with the menopause have , seriously. Whilst an update of the list of symptoms and experiences (including experiences at work) was outside the current scope of 2024 guideline update and therefore, no evidence review was conducted, the NICE surveillance tea regularly checks for new evidence for topics within guidelines to see where further work is needed. Apart from the removal of the word 'troublesome' the committee decided that without further evidence, they could not comment on this.
Marches Psychological Services Ltd	Guideline	014	005	The guidance states to consider CBT for troublesome vasomotor symptoms. The research this recommendation is based on is lacking clinical validity (see points below regarding evidence review A)	Thank you for your comment. The committee considered the quality of the evidence when formulating recommendations. This is reflected in the wording used which indicates the recommendation strength. The word 'consider' was used for recommendation 1.4.9 as it is a 'weak' recommendation. In 'strong' recommendations for actions that should (or should not) be offered, directive language such as 'offer' is used. For more information on this please see: Developing NICE guidelines: the manual. The committee has revised the wording to ensure clarity about CBT 'as an option: in addition to HRT, for people for whom HRT is contraindicated or for people who prefer not to take HRT'. This has been done to clarify that CBT is an option rather than a first line treatment instead of HRT.
Meno Martha International Menopause Directory	Guideline	General	General	Menopause Evidence-based Information Meno Martha International Menopause Directory is the world's only evidence-based international menopause directory.	Thank you for your response.

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				Meno Martha International Menopause Directory has published over 1,000 health topics and blogs showcasing evidence-based information by Menopause Societies and International Sources.	
Menopause Mandate	Guideline	General		As a campaigning organisation, it's key that we reflect the patient's perspective in our response to these draft guidelines. We asked the members of our community to share their feedback via social media and email. XXX people (women?) responded. The key themes are summarised below and supplemented with verbatim quotes from respondents to humanise our submission. **CBT** The vast majority of responses related to the CBT aspect of the guideline. While the majority have said there is definitely a space for CBT, it is not enough to manage severe hormonal symptoms of menopause and many women were concerned about the emphasis placed on CBT as an alternative to HRT: *"There is a place for CBT but by no means does it resolve or improve some of the devastating symptoms that have a purely hormonal basis, such as vasomotor symptoms, heavy periods, and rapid onset, severe anxiety and depression."* *"It doesn't and cannot replace the hormones that you have lost. I honestly thought we were moving forward with*	Thank you for your comment. The committee reflected on the wording related to CBT. They revised the recommendation to emphasise that CBT is an option (1) in addition to HRT (2) for people for whom HRT is contraindicated or (3) for people who prefer not to take HRT. With regards to ignoring scientific evidence, the evidence reviews conducted for this guideline followed rigorous NICE methods and processes, with details outlined in a supplement available on the website (supplement 1 - methods), consistent with the NICE guideline manual. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). The committee noted that there are long waiting times for CBT. They also noted that people currently trained in providing this kind of therapy may not be familiar with menopause-specific CBT so training on this may incur costs and increase waiting times in the short term. However, online and group CBT may be easier and less costly to adapt to be menopause specific. There are also resources available to train people in providing menopause-specific CBT (that could also inform

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				the help and advice women were receiving NICE needs to catch up or other women are going to continue to suffer." *"Whilst I am a massive advocate of alternative therapies for many things, CBT cannot address the decline in hormones that result in night sweats and the sleep deprivation that comes with it, mood swings, brain fog, joint pain and many other symptoms that affect the mental health and quality of life of many women, their families & work colleagues. These draft guidelines completely ignore the considerable scientific research that shows HRT also helps to prevent against osteoporosis and cardiovascular disease and instead over emphasises the fear of breast cancer akin to what happened in the 1990s where scientific data was inaccurately reported."* Others were concerned about the current availability of CBT on the NHS and questioned whether it was realistic for this recommendation to be supported. *"Mental health services are already overwhelmed - so women will just sit on waiting lists and add pressure to the services. It also has to potential to push some women into economic inactivity - I was on the verge of leaving my NHS role before starting HRT."* *"It's just unrealistic when you look at the waitlist plus for time poor women it's hard enough finding time for doctor's*	the adaptation of online CBT), which could facilitate implementation. Your comment will be considered by NICE where relevant support activity is being planned. In the information and support section of the guideline there is already an emphasis on sharing information about 'lifestyle changes and interventions that can support health and wellbeing' which is important in this context. However, effectiveness of specific lifestyle changes in the management of menopause were outside the scope of the 2024 guideline update. With regards to populations that may need different approaches to CBT we have revised the related recommendation in the section on 'discussing management options' to include that it should be explained what CBT is (including menopause-specific CBT) and to talk about the available options, taking into account the person's preferences and needs. Such needs could include making reasonable adjustments for people with specific needs such as people with ADHD or neurodivergent people. However, it has been made explicit that CBT has been recommended as an additional options so if people feel that it would not work for them they do not have to take up this option. In relation to surgical menopause we have emphasised that people who are likely to experience menopause as a result of medical or surgical treatment should be offered support and information about menopause and fertility and that this should be done before and after they have

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				appointments let alone talking therapy!! I would love to see more emphasis on what lifestyle changes can be made and for women to have more support and access to movement/diet advice. These changes create long term health benefits and are accessible immediately." Women who have been diagnosed with cancer and women with ADHD were particularly keen to mention that CBT would not work for them. *"Women with ADHD most commonly suffer the worst menopausal symptoms. Oestrogen plays a vital and very specific role in the brains of ADHD women and we utilise and require higher levels of oestrogen."* *"I am a strong advocate for CBT and have had various CBT over the years, firstly to help with depression and PMS in my early 20's and more recently I had cognitive behavioural hypnotherapy to help me through my cancer treatment which was genuinely amazing and transformational. CBT is a great life skill, and I am sure has far reaching benefits for many varied health conditions however I can absolutely testify that it DOES NOT in any way get rid of many of the most challenging symptoms of menopause."* HRT Many wanted NICE to highlight the (proven) benefits of HRT and move away from the fear that has been there for decades.	their treatment. It is also emphasised that they should have the opportunity to discuss fertility, both before and after they have their treatment, with a healthcare professional with expertise in fertility as well as have an opportunity to discuss menopause, both before and after they have their treatment, with a healthcare professional with expertise in menopause. The committee made research recommendations related to the topics that were in the scope of the 2024 guideline update, such as the impact of type of progestogen or route of administration of systemic HRT on specific health outcomes.

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				"There's a place for other treatments, and women who can't or don't want to have HRT deserve guidance and support. But this seemed intent on undermining HRT. Being in surgical menopause, as I am, means HRT including testosterone is very important to me. I'm lucky I have good GP support at the moment but a lot of women don't. I'm scared one day I might not too. We need official guidance to reflect accurate and up to date information. We need it to not drive fear. Some women urgently need it to back up that they need replacement hormones, not make it less likely their GP or other practitioner will prescribe for them. Whatever the intent behind the guidance I fear it will set a lot of people back if it goes ahead." *"The guidelines fail menopausal women by focusing on one "add-on" treatment (CBT) while repeatedly referring to HRT in negative terms. HRT is the central treatment option for menopause. Altogether an ignorant and patriarchal nonsense, which was so distressing to see in this century from the UK medical fraternity."* *"At 59 I read Davina's book on Menopause. I immediately asked my GPs for a bone scan - I have Osteoporosis. They offered me bisphosphonates despite recent covid related swallowing and choking issues. They refused me HRT on the grounds I*	

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				was too old. I now pay privately for HRT. I'm hoping it's not too late to improve my bone density. Please, please NICE concentrate on educating GPs on the scientifically proven benefits of HRT and NOT on CBT which will do nothing for the very serious physical effects of reduced oestrogen levels." *"I have read the recent NICE overview on HRT/CBT etc. and while I did recognise that the text said that HRT was "unlikely to increase or decrease overall life expectancy", it did not highlight any of the benefits of HRT which are many and are PROVEN. This is very disappointing considering that we are still at a delicate stage of awareness and many women will still hold the idea that HRT is harmful."* "*I had a hysterectomy with my ovaries removed at 28 I was left for over 10 years without proper HRT treatment I feel let down by doctors. I've educated myself and have since been put on HRT in recent times I'm starting to get my life back but for the 1st ten years after my hysterectomy I have lost those years to crippling symptoms. I need and deserve my HRT!"* *"HRT saved my health and sanity, but, like thousands of other women, I had to fight for it. Am sure CBT has its place, but I worry stressed out, and sometimes, unexperienced GPs will prescribe it as an easy way to deal with*	

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				menopausal symptoms… Menopausal symptoms can be devasting and cause long term health issues for many women. It saddens me immensely that NICE, once again, have failed to recognise the impact that HRT can have for women struggling with acute peri and menopausal symptoms." **More research** Many said there was a need for clarity and more research into women's health and clear, effective options for treatment of the menopause… and that this seemed to be a one size fits all solution. *"We need a top to bottom shake up of menopause care - more research to address areas of weak/insufficient evidence; acknowledgment of the severity of the symptoms & life implications for some (not all) women; education of medical care providers, who sometimes know very little; consistent access to HRT alongside other options as appropriate; better availability of testosterone and understanding of the full range of benefits it offers to women; and particular attention to the research and menopause care/options for women who have already experienced oestrogen positive breast cancer and ensuing hormonal treatment."* *"The situation is gravely concerning and if these guidelines go through will have a massive impact on a great many women and their families. These*	

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				proposals are a huge backward step ignoring a large body of scientific research and how can they come from an organisation meant to be responsible for care excellence? I suspect there is a cost saving driver behind these but it is a false economy." *"As a 56 year old woman who has suffered severe physical and psychological symptoms through peri/ menopause for the last 9 years and whose close female family members historically suffered even more dramatic debilitating symptoms, I cannot stress strongly enough the need for more research into women's health and clear, effective options for treatment of the menopause. This must happen for future generations of women."*	
Menopause Mandate	Guideline	General		• In general, there is a lot of emphasis on risks of HRT and less on the benefits. Guidelines should be more balanced on the risks and benefits of HRT to enable health care professionals (HCP) have a more balanced discussion with patients. o For most women HRT is the most effective method of management of menopause symptoms and this is not reflected in this guidance. o Reading the from the perspective of a HCP with little or no knowledge of the	Thank you for your comment. For the draft guideline, the committee opted for a verbal format complemented by tables, providing estimates of absolute numbers. This decision was made to facilitate conversations between clinicians and individuals, enabling shared decision-making regarding menopause management. Based on the absolute numbers in the tables of appendix in the consultation version of the guideline (including numbers for fragility fractures) a discussion aid document has been developed which includes data visualisation as well as a verbal description of what the numbers mean. This discussion aid has undergone user-testing and was refined based on user feedback. Descriptions of the underlying

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				menopause, management of the menopause with HRT would seem to be an option that should be approached with great caution. This does not accurately reflect the absolute numbers of women who will be diagnosed with breast cancer as a result of taking HRT balanced against the absolute numbers of women who will not be diagnosed with osteoporosis or osteoporotic related fractures as a result of taking HRT. ○ Absolute numbers are not mentioned in the guidance body (excluding tables) except for ovarian cancer. It would be useful to see absolute numbers used throughout the body of the document for easy reference and to reflect risks and benefits. Risks should be discussed in the context of other lifestyle related risk – particularly of breast cancer. • It is difficult to discuss the duration that HRT will be taken for at the outset and more specific guidance of why this is included is needed in the body of the guidance. A guide to points needed to be covered in the discussion around duration would be helpful for	concepts and calculation are also provided. This includes estimates and uncertainties. Absolute numbers for ovarian cancer remain included in the related rationale section because the statement emphasises that both the baseline is very low and that the risk increases very slightly. It is stated in the guideline that healthcare professionals should tailor the information about benefits and risks to the person's age, individual circumstances and potential risk factors and that information should be provided about lifestyle changes and interventions that can support health and wellbeing. The recommendation related to discussing the duration of HRT treatment has been revised to say that healthcare professionals should discuss (a) the possible duration of treatment at the outset (b) at every review, rediscuss the benefits and risks of continuing treatment (see the section on reviewing treatment for anyone) and (c) should explain that symptoms may return when HRT is stopped and discuss the option of restarting treatment if necessary. The use of the word 'troublesome' has been removed throughout the guideline. In relation to experiences of menopause, NICE takes the reports of the debilitating symptoms, the considerable concern they cause, and the impact menopause has seriously. Whilst an update of the list of symptoms and experiences (including cognitive symptoms) was outside the current scope of this update and therefore no evidence review was conducted. The topic of symptoms and

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				practitioners who are not experienced in managing the menopause • As a menopause specialist this guideline is difficult to read and difficult to interpret – see specific comments - and so it's highly likely that GPs and lay people will also find it difficult. • The language used to describe menopause symptoms and their impact is vague and patronising at times including the use of 'troublesome' and 'bothersome'. It does not recognise the well evidenced breadth of the impact that symptoms can have on all aspects of a woman's life. • The guidance correctly highlights awareness that women from ethnic minority backgrounds may experience menopause at a younger age. There is known poor uptake of HRT in this diverse group. A call for research would be therefore welcomed into the clarification of discrepancies and the reasons behind variations in HRT uptake – as well as access to menopause care – to help more women manage symptoms and long term health consequences of the menopause. • More research is needed in experience of the menopause, presentation and management for women with disabilities and this should include women with learning disabilities – both underserved populations of women.	experience of the menopause has been logged with NICE surveillance team which checks regularly for new evidence for topics within guidelines to see where further work is needed. Access and uptake of HRT was not in the scope of the 2024 guideline update. The evidence was therefore not systematically reviewed. The committee could therefore not comment on this nor could they make a research recommendation for this. At the time when the scope of the 2024 guideline update was agreed, there was no substantive new evidence that would change the recommendation related to testosterone. However, NICE recognises the importance of this issue and has worked with the NIHR to prioritise funding for research on the matter. The recommendations related to CBT and sleep has been revised to now also emphasise that it is an option (1) in addition to other treatments (including HRT) (2) for people for whom other treatments are contraindicated or (3) for people who prefer not to try other options. Other NICE guidance cannot be referred to because the related guidance is not specific to sleep problems associated with the menopause. The effectiveness of other alternative treatments or management options apart from HRT were not in the scope of the 2024 guideline update and the committee could therefore not comment on these.

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				• The demand for testosterone therapy is high in the community throughout the UK. This is the source of many referrals to NHS specialist menopause clinics (anecdotally) with significant cost to the NHS. A formal recommendation for off license prescribing and monitoring would be welcomed to help guide GPs in prescribing testosterone for women with low libido and we believe this would come with significant financial savings. • The section on sleep is inadequate. Chronic insomnia is experienced by 60% of women or more. A reference to the NICE guidance on sleep would be helpful. This is an area of medicine where there is little or no training and so NICE have an important role in the provision of evidence based guidance. • It is recognised that cognitive behavioural therapy (CBT) has a role to play in management of the menopause. The guidelines should consistently state the symptoms that CBT can help manage to avoid confusion. It should be stated that CBT is not suitable for all women. • There is good evidence that hypnosis can help manage symptoms of the menopause transition. The section on alternatives is inadequate in comparison to available products that many women use.	

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				• There is no mention of the evidence around benefits of lifestyle intervention. • A more thorough examination of other prescribable alternatives to HRT would be helpful. • Persistent use of the word 'people' has been reported to be alienating for many. It would be better to explain that document is inclusive and is meant for women, transmen and non binary People registered female at birth, but the vast body of research has been carried on out women. • There is nowhere in the guidance that addresses the full spectrum of menopause symptoms and lists of symptoms are used inconsistently. It would be better to have a list of acknowledged symptoms at the beginning of the guidance that could be referred to throughout for consistency. • Ensure resources are in place throughout the UK to support delivery of the recommendations in the guidelines – e.g. - CBT service availability/waiting lists - HRT availability - 'healthcare professionals with expertise in menopause' (as defined by the BMS)	
Menopause Mandate	Guideline	006	014	Rec 1.2.1 This comment does not acknowledge the fact that some women have a premature surgical or medical menopause which may not be perceived as 'normal' by those suffering. I	Thank you for your comment. This has been revised to say 'in most people' it is a normal life transition. The objective of this recommendation is very general about providing information. There is

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				am concerned that the frequently more severe symptoms of often premature surgical or medical menopause may not be taken seriously, or simply dismissed.	a specific recommendation related to menopause as a result of medical or surgical treatment within the same section to highlight specifically the information and support that is needed in these circumstances.
Menopause Mandate	Guideline	006	014	Rec 1.2.1 add 'that for some women, can impact all aspects of their life'	Thank you for your comment. This has been revised to say it is a life transition. The objective of this recommendation is about providing general information about the menopause. NICE recognises and takes seriously the reports of the debilitating symptoms, the considerable concern it causes and the impact menopause can on daily activities. Whilst an update of the list of symptoms and experiences was outside the current scope of the 2024 guideline update (and therefore no evidence review was conducted), the NICE surveillance team checks regularly for new evidence for topics within guidelines to see where further work is needed.
Menopause Mandate	Guideline	006	022	Rec 1.2.2 The word 'troublesome' does not reflect the life changing and severe symptoms that many women experience.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
Menopause Mandate	Guideline	007	002	Rec 1.2.2 Please consider adding cognitive symptoms as they affect so many and have impact on women's ability to work in particular (73% according to Fawcett Society research - https://www.fawcettsociety.org.uk/Handlers/Download.ashx?IDMF=9672cf45-5f13-4b69-8882-1e5e643ac8a6).	Thank you for your comment. NICE takes the reports of the debilitating symptoms, the considerable concern they cause, and the impact that symptoms associated with the menopause have, seriously. Whilst an update of the list of symptoms and experiences (including cognitive symptoms) was outside the current scope of the 2024 guideline update and therefore no evidence review was conducted, the NICE surveillance team checks regularly for new evidence for topics within guidelines to see where further work is needed.

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Menopause Mandate	Guideline	007	009	Rec 1.2.9 please consider adding other non-hormonal prescribable alternatives to HRT on or off license, for example oxybutynin, clonidine.	Thank you for your comment. Based on the page and line number, this appears to refer to recommendation 1.2.3. The committee considered this and other feedback and decided that the examples in the bullet points caused confusion. They were often misunderstood as recommendations rather than examples. They were therefore removed.
Menopause Mandate	Guideline	007	019	Rec 1.2.9 I would like to see stronger language used around the recommendation to 'offer support' and provide information for women likely to experience a surgical menopause. This is an underserved population, information is often NOT given. Highlighting this need within the guideline may help people get the information and support they need.	Thank you for your comment. In NICE style the wording 'offer' and 'discuss' are strong instructions to carry out the associated action. It is therefore expected that information should be provided, and referral offered.
Menopause Mandate	Guideline	008	012	Rec 1.3.1 Identifying perimenopause mentions only 'new onset vasomotor symptoms' (and changes in menstrual cycle) – it would be helpful to add the other physical and psychological symptoms of menopause (see 1.2.2) Please consider reviewing this definition.	Thank you for your comment. Defining perimenopause was not in the scope of this guideline update. Evidence for this topic was not searched for and not reviewed and discussed with the committee. The committee could therefore not comment on this.
Menopause Mandate	Guideline	009	012	Typo – should read 1.7 and not 1.8	Thank you for your comment. this has been amended.
Menopause Mandate	Guideline	009	014	Please consider saying women, transmen and non binary people registered female at birth rather than people.	Thank you for your comment. The wording 'women, trans men and non-binary people registered female at birth' is used when there is a need to make it explicit that all these groups are covered. Elsewhere, 'people with symptoms associated with the menopause' is used to make recommendations easier to read.
Menopause Mandate	Guideline	009	015	Please consider saying women, transmen and non-binary people registered female at birth rather than people.	Thank you for your comment. The wording 'women, trans men and non-binary people registered female at birth' is used when there is a need to make it explicit that all these groups are

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					covered. Elsewhere, 'people with symptoms associated with the menopause' is used to make recommendations easier to read.
Menopause Mandate	Guideline	010	020	Rec 1.4.2 There is emphasis on 'duration' throughout. Most women do not know how long they will continue to take HRT for when they start it. There is no evidence for stopping after an arbitrary length of time or at an arbitrary age. Do you mean 'inform women that the small risks of HRT are related to the length of time HRT is taken for' – and also 'while HRT is taken, there are benefits see section XXXX' – you need to be more specific as most GPs and other Health Care Professionals (HCP) may not appreciate the nuance of this statement and guidance of how to discuss this is important. Please consider differentiating here the difference in discussion for younger women taking HRT for POI vs women transitioning the menopause at an average age. As mentioning later in the guidance, it is important that women with POI take HRT at least until the average age of the menopause. Anecdotally, many women are advised to stop HRT after 5 years even when starting at a young age as there may be misunderstanding as to the risk and benefit ratio differences according to age. This puts younger women at greater risk of osteoporosis, heart disease and possibly dementia.	Thank you for your comment. The focus of this section is on discussing HRT as an option emphasising that this should be an individualised plan. This is particularly highlighted in the sentence underneath the recommendations which talks about 'tailoring the information about benefits and risks to the person's age, individual circumstances and potential risk factors'. Duration is only one aspect of this list and would be something that people would usually want to know about when they decide whether to have a treatment. The recommendation has links to other sections which discuss the benefits and harms in more detail. A further link was added to this section to the management of premature ovarian insufficiency so that the duration until natural age of menopause is taken into account during these discussions.
Menopause Mandate	Guideline	010	027	Rec 1.4.3 Please specify the recommendation re duration	Thank you for your comment. This has been rephrased to read 'discuss the possible duration of treatment at the outset', followed by 'rediscuss the benefits and risks or continuing treatment at every

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					review'. The committee agreed not to set arbitrary limits or cut-offs.
Menopause Mandate	Guideline	011	001	Rec 1.4.3 Most GPs will not know the likelihood of symptoms returning when HRT is stopped. Better to inform and say 'symptoms of the menopause may return when HRT is stopped. The only way of knowing if symptoms will return is to stop the HRT. If symptoms recur, the possibility of restarting HRT should be discussed along with the risks related to duration of use… as per text line 030, 040 and 050	Thank you for your comment. This has been rephrased to read 'discuss the possible duration of treatment at the outset', followed by 'rediscuss the benefits and risks or continuing treatment at every review'. The word 'likelihood' has been removed and the final bullet has been reworded to address this concern: 'explain that symptoms may return when HRT is stopped and discuss the option of restarting treatment if necessary'.
Menopause Mandate	Guideline	011	007	Rec 1.4.4 There is little or no access to CBT through the NHS – or very long waiting times. Please specify what 'troublesome symptoms' that you mean CBT is suitable for (these are listed in 1.4.9). Please reconsider the use of the word troublesome which is open to interpretation – better to say 'possible treatment for symptoms, mild, moderate or severe…'. Please acknowledge that CBT may not be suitable for all women. There is a need for consistency with regards to recommendations for use of CBT. The inconsistency may cause confusion and concern from women and less likely to take up CBT as a consequence.	Thank you for your comment. The committee acknowledged in the impact section of the guideline that there are long waiting times for CBT. They also noted that people currently trained in providing this kind of therapy may not be familiar with menopause-specific CBT and training on this may incur costs and increase waiting times in the short term. However, online and group CBT may be easier and less costly to adapt to menopause-specific CBT. There are also resources available to train people in providing menopause-specific CBT (and could also inform the adaptation of online CBT), which could facilitate implementation. Your comment will be considered by NICE where relevant support activity is being planned. In section 1.5 on symptom management (evidence showed it to be effective in the management of vasomotor symptoms, depressive symptoms and sleep problems) wording has been revised to ensure clarity about CBT 'as an option: in addition to other treatments (including HRT), for people for whom other treatments are contraindicated or for people who prefer not to take HRT'. The wording

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					troublesome has been removed from the guideline. The section referred to in the comment is related to discussing CBT treatment rather than the symptoms for which it is recommended which are addressed in section 1.5 on symptom management. The wording in relation to discussing CBT treatment has been revised to ensure that information is provided about what CBT is (including menopause-specific CBT) and that preferences and needs should be taken into account.
Menopause Mandate	Guideline	012	013	Rec 1.4.8 Please reconsider the word troublesome which is patronising, does not reflect the severity of symptoms some women experience and is open to interpretation	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
Menopause Mandate	Guideline	014	005	Rec 1.4.16 Please reconsider the word troublesome which is patronising, does not reflect the severity of symptoms some women experience and is open to interpretation	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
Menopause Mandate	Guideline	015	004	Rec 1.4.19 Please reconsider the word troublesome which is patronising, does not reflect the severity of symptoms some women experience and is open to interpretation. Please specify symptoms. Please acknowledge that symptoms can progress if not actively managed.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline. Symptom management apart from genitourinary symptoms was not within the scope of the guideline and the committee could therefore not comment on symptom progression.
Menopause Mandate	Guideline	015	009	Rec 1.4.20 Please reconsider the word troublesome which is patronising, does not reflect the severity of symptoms some women experience and is open to interpretation.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.

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Menopause Mandate	Guideline	015	014	Rec 1.4.20 Please give an idea of how much oestrogen is absorbed. Some GPs will read this and assume that women cannot use if there are other factors that may make HRT potentially more risky (history of venous thromboembolic disease, for example). This is based on my experience of answering 50+ advice and guidance requests every month. 'Small' – please replace with 'extremely small and not measurable by most hospital-based labs' or equivalent more accurate wording.	Thank you for your comment. This bullet point was reworded to say that vaginal oestrogen is absorbed locally - a minimal amount is absorbed into the bloodstream (when compared with systemic HRT), but this is unlikely to have a significant effect throughout the body. It is then described in the rationale section that 'the committee agreed to highlight this because it means that there is no need to combine low-dose vaginal oestrogens with systemic progestogen treatment to protect the person against endometrial hyperplasia and cancer'.
Menopause Mandate	Guideline	015	019	Rec 1.4.21 Please clarify this comment – are you suggesting increasing beyond licensed doses? Most GPs prescribe the maximum dose. Please explain 'standard therapeutic range'. Please consider also using alternative vaginal preparation and consider alternative diagnoses (lichen sclerosus is often undiagnosed and mistaken for atrophic vaginitis particularly in phone consultations). Please also consider recommending examination is needed if the vaginal oestrogen does not relieve genitourinary symptoms.	Thank you for your comment. The committee reflected on this and decided that there was generally no clear consensus about the standard therapeutic range in relation to vaginal oestrogen. The committee therefore decided to remove this recommendation. The guideline contains recommendations about reviewing treatment and recommends that treatment for symptoms associated with the menopause should be reviewed at 3 months to assess efficacy and tolerability and annually thereafter, unless there are clinical indications for an earlier review (such as treatment ineffectiveness, side effects or adverse events). It is also recommended to 'refer people to a healthcare professional with expertise in menopause if treatments do not improve their menopause symptoms or they have ongoing side effects.' This means that if symptoms are not resolved after vaginal oestrogen is prescribed treatment is reviewed and other differential diagnoses could be considered.
Menopause Mandate	Guideline	015	022	Rec 1.4.22 Please reconsider the word troublesome which is patronising, does not	Thank you for your comment. Based on this and other feedback the committee reflected on this

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				reflect the severity of symptoms some women experience and is open to interpretation.	wording and consequently 'troublesome' has been removed from the guideline.
Menopause Mandate	Guideline	015	026	Rec 1.4.23 Please consider commenting on need for appropriate moisturisers and lubricants for the vagina – in terms of pH and osmolarity – this could form a new section as per work by Nick Panay et al.	Thank you for your comment. The pH level and osmolarity of moisturisers and lubricants was not in the scope of this review question. This means that different levels of pH and osmolarity were not compared with each other to investigate the impact on genitourinary outcomes associated with the menopause. The article by Panay was not included because it did not meet protocol criteria (it was a narrative review). The committee could therefore not comment on this.
Menopause Mandate	Guideline	015	001	I would like to see a recommendation that a genitourinary symptoms should be proactively sought out. There is good evidence to show they are under reported with significant morbidity, and they progress with time.	Thank you for your comment. It was not in the scope of the 2024 guideline update to identify opportunities for proactive discussions and therefore they could not recommend details related to this. However, the guideline recommends a person-centred approach with tailored discussions including information about symptoms.
Menopause Mandate	Guideline	016	011	Please reconsider the word troublesome which is patronising, does not reflect the severity of symptoms some women experience and is open to interpretation.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
Menopause Mandate	Guideline	016	015	Please reconsider the word troublesome which is patronising, does not reflect the severity of symptoms some women experience and is open to interpretation.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
Menopause Mandate	Guideline	017	011	Please give an idea of how much oestrogen is absorbed. Some GPs will read this and assume that women cannot use if other factors such as previous VTE.	Thank you for your comment. This bullet point was reworded to say that vaginal oestrogen is absorbed locally - a minimal amount is absorbed into the bloodstream (when compared with systemic HRT), but this is unlikely to have a significant effect throughout the body. It is then described in the rationale section that 'the

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					committee agreed to highlight this because it means that there is no need to combine low-dose vaginal oestrogens with systemic progestogen treatment to protect the person against endometrial hyperplasia and cancer'.
Menopause Mandate	Guideline	017	022	Rec 1.4.22 – the link takes to a recommendation for systemic HRT. A separate recommendation should be given for local oestrogen use where it should be acknowledged that treatment may need to continue for 3-6 months before improvement is noticed, and if symptoms are not improving to consider alternative diagnoses.	Thank you for your comment. There are 2 recommendations in the NICE guideline urinary incontinence and pelvic organ prolapse in women related to HRT. One states, 'do not offer systemic hormone replacement therapy to treat urinary incontinence' and the other recommendation 'offer intravaginal oestrogens to treat overactive bladder symptoms in postmenopausal women with vaginal atrophy'. The guideline already contains a recommendation related to the review of each treatment at 3 months to assess efficacy and tolerability and annually thereafter, unless there are clinical indications for an earlier review (such as treatment ineffectiveness, side effects or adverse events).
Menopause Mandate	Guideline	018	018	The evidence presented compares with usual treatment but there is no specification of what this is. There is little evidence (which is acknowledged) for effectiveness. There is no acknowledgement that CBT may not be suitable for some people. There should be other recommendations for management of depressive symptoms including lifestyle changes. There is a risk that GPs will offer CBT only and there is very poor availability though the NHS.	Thank you for your comment. The wording has been revised to ensure clarity about CBT 'as an option: in addition to other treatments, for people for whom other treatments are contraindicated or for people who prefer not to have other treatments'. The committee acknowledged in the impact section of the guideline that there are long waiting times for CBT. They also noted that people currently trained in providing this kind of therapy may not be familiar with menopause-specific CBT and training on this may incur costs and increase waiting times in the short term. However, online and group CBT may be easier and less costly to adapt to menopause-specific CBT. There are also resources available to train people in providing

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					menopause-specific CBT (and could also inform the adaptation of online CBT), which could facilitate implementation. In the 'information and support' section of the guideline it is recommended that healthcare professionals should provide information on 'interventions, or changes the person can make to support their health and wellbeing'. Your comment will be considered by NICE where relevant support activity is being planned. In the 'information and support' section of the guideline it is recommended to provide information on 'interventions, or changes the person can make to support their health and wellbeing'.
Menopause Mandate	Guideline	019	002	Rec 1.4.37 There should be other recommendations for sleep. Sleep is a symptom for which there is little training. Other interventions should be considered under this heading, for which there is evidence, - e.g. HRT, lifestyle factors, alternative therapies (such as hypnosis, for which there is evidence), SSRIs. Sleep is a common symptom with good evidence for morbidity. This section does not adequately address or guide HCP in managing women with sleep disorders in the menopause.	Thank you for your comment. Apart from CBT other management options for sleep problems associated with the menopause were not in the scope of the 2024 guideline update. However, the committee acknowledged that there are other options that may be used (including HRT). They have therefore reworded the recommendation to reflect this. It now states that CBT could be used as an option (1) in addition to other treatments (including HRT), or (2) for people for whom other treatments are contraindicated or (3) for people who prefer not to have other treatments. Given the constraints of the scope they could not be more specific than this.
Menopause Mandate	Guideline	019	015	Rec 1.5.1 Please acknowledge that women who have had a subtotal hysterectomy or hysterectomy after endometriosis need to consider whether a progestogen is needed.	Thank you for your comment. The committee discussed that choice between oestrogen-only and combined HRT may be different for people with a sub-total hysterectomy. They decided that they could not be prescriptive about the type of HRT to be used for people who have had a sub-total hysterectomy because their condition is clinically

					complex and they had not reviewed evidence about the effect of HRT on risk of endometrial cancer for this group. They acknowledged that people who were going to have, or had had, a sub-total hysterectomy would be under the care of a specialist who could discuss HRT options tailored to their needs (or a relevant specialist within the MDT). Due to a lack of evidence, no specific recommendation was made for sub-total hysterectomy; however, the term "total" was added before "hysterectomy" in guidance regarding the offer of oestrogen-only HRT to those who have had a hysterectomy. This addition alerts healthcare professionals to consider other factors for patients with a sub-total hysterectomy. The committee also noted that some people have a hysterectomy for a condition that may be affected by HRT, such as endometriosis. The committee did not review evidence related to such conditions. They recognised that the decision about the type of HRT that best balances benefits and risks for the person may be affected by that condition (for example endometriosis) or having had a subtotal hysterectomy. For this reason, they added a recommendation highlighting that advice from a healthcare professional with specialist knowledge of that condition may be needed when making this choice. Due to this stakeholder comment and other related comments, this topic has been logged with NICE surveillance so that it can be considered for a possible update to either the Menopause or the Endometriosis guideline in future.

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Menopause Mandate	Guideline	019	016	Rec 1.5.2 Lowest effective dosage for what? For symptom control or bone protection (where there is a history of osteoporosis)? Please clarify this point.	Thank you for your comment. The committee recommended the lowest effective dosage which would be reviewed in 3 months to assess efficacy and tolerability and annually thereafter (as highlighted in a different recommendation on reviewing treatments). All dosages would be within licensed ranges and a statement has now been added to emphasise this. The guideline does not specifically recommend HRT for bone protection (where there is a history of osteoporosis). The 2015 guideline mentioned in the context of premature ovarian insufficiency that both HRT and combined oral contraceptives offer bone protection. However, it is unclear whether this would require different dosages.
Menopause Mandate	Guideline	021	015	Rec 1.5.11 specialist psychology services are aspirational – please specify whether this would include liaison psychiatry to help prevent rejection of referrals. I am concerned that this recommendation, while laudable, creates false hope.	Thank you for your comment. As stated in the rationale, the committee agreed that it is common practice to provide psychological support to people. While a potential referral will have a resource impact, the committee agreed that specialist psychological services will lead to improvements in quality of life and reduce future contacts with health services. Your comment will be considered by NICE where relevant support activity is being planned.
Menopause Mandate	Guideline	021	020	Please consider the use of the word 'troublesome' to reflect the severity and significance of symptoms that many women experience. Troublesome could be perceived as being glib and patronising.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
Menopause Mandate	Guideline	021	022	This statement contradicts that of the British Menopause Society/International Menopause Society and my concern is that it will cause more confusion.	Thank you for your comment. The committee noted that high-quality evidence showed no difference in mortality with either oestrogen-only or combined HRT. A decrease in all-cause mortality was reported for 1 isolated subgroup (women

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					starting oestrogen-only HRT aged between 50 and 59). In isolation, it was a statistically significant figure. But in a wider context, it cannot be interpreted as good evidence of a different effect in this group. This is because: • there was not any identifiable pattern of changes in risk happening as people age and • the statistical subgroup analysis shows that this observed decrease could be accounted for by the play of random chance and therefore does not represent a real difference between age groups. As a result, the committee did not refer to this decrease in the recommendation. The rationale section has been updated with this information.
Menopause Mandate	Guideline	023	Table 1	The statement on breast cancer risk being increased LESS with transdermal preparations compared with oral – this is based on 1 study and contradicts Table 2 where there is no difference. There is no biological plausibility for this and it will cause confusion and anxiety amongst women who do not absorb oestradiol adequately from transdermal doses. No other study – Women's Health Initiative, Collaborative Group on Hormonal Factors in Breast Cancer data or Million Women Study - shows this difference. Its inclusion needs justifying.	Thank you for your comment. The statement has been removed and a research recommendation was added aimed to clarify matters related to different routes of administration.
Menopause Mandate	Guideline	023	Table 1	I understand the limitations of papers showing a difference in risk for different progestogens, but the MWS and others have shown there IS. This contradicts statements made by the BMS and will cause confusion and potential harm.	Thank you for your comment. The committee considered all the evidence that was relevant and included in the review. They agreed that there was insufficient evidence to support any differences in the risk of breast cancer with difference progestogens, and making a recommendation on limited evidence would cause more harm. The committee agreed that more evidence was required to make any robust recommendations

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					and agreed to make a research recommendation to support further work in the area. The committee's discussion of the evidence section in Evidence Report D has been updated to provide more detail regarding different preparations of combined HRT. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). However, they highlighted that RCT and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. These and other evidence reviews have been revised to implement these changes accordingly.
Menopause Mandate	Guideline	026	Table 1	Risk of dementia. This data is not clear – no causal link has been proven. This will cause anxiety. Is the data clear that the risk is only when starting HRT over the age of 65? My understanding was that it is not clear if the risk is associated with starting or continuing HRT beyond 65. This will cause great anxiety to the many women who need to continue to take HRT for symptom control.	Thank you for your comment. For ages below 65 there was no clear evidence whether or not HRT increased the risk of dementia. One study showed no difference whereas another study showed an increase in the incidence of dementia. Given these discrepancies and potential for confounding in observational data, the committee based this recommendation on the available RCT data with participants that started HRT over the age of 65 and decided not to comment on people initiating HRT earlier. Where data were divided by duration of use the pattern was unclear with one study showing no difference and the other an increase. The committee therefore decided not to comment

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					on duration of HRT use beyond the age of 65. This is described in the rationale section. The committee decided to retain the 2015 research recommendation on the effects of HRT on dementia.
Menopause Mandate	Guideline	035	004	Rec 1.6.4 Please make it clear that a lack of evidence does not indicate a lack of benefit – reading this section, this is the implication. There is evidence suggesting that the benefits of HRT for under 40s do not stop at 40. This section reads negatively. I am concerned that younger women with an early menopause will be under served. HRT will not be encouraged with increasing mortality (cardiovascular disease and osteoporosis) and morbidity (including psychological) as a result. This is also important as women from different ethnic backgrounds may be more likely to have an early menopause and these populations have already been shown to have lower uptake of HRT.	Thank you for your comment. The section on early menopause has been revised and only the message to explain to people experiencing early menopause that, for them, the benefits and risks of either taking or not taking HRT are likely to lie between those for people with premature ovarian insufficiency and those for people aged 45 or over has been retained from the consultation version. In accordance with the systematic review protocol only evidence on breast cancer was identified but it was decided that this highlighted that further research is necessary to clarify the benefits and risks. The committee also noted that the focus of this topic was too narrow to cover early menopause adequately and suggested several topics that based on stakeholder feedback which were logged with the NICE surveillance team for future consideration in an update. This also includes the topic of the impact of early menopause itself on various health outcomes and what the best options are to manage potential negative impact. However, this was not part of the 2024 guideline update and so the committee could not comment on this.
Menopause Mandate	Guideline	037	008	Terms used. There is often confusion in primary care around the terms topical oestrogen and vaginal oestrogen and local oestrogen. This has led to harm as Oestrogel has been described anecdotally as 'topical' and so a progestogen has not been given, resulting in endometrial	Thank you for your comment. The committee decided that it would be readily understood what vaginal oestrogen refers to and therefore this terminology was used throughout the guideline rather than local. The terminology topical oestrogen is otherwise not used and therefore

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				hyperplasia. Please consider adding to this section clarification of these terms.	would not require a definition in the guideline. In other parts the terminology transdermal has been used to make a clear distinction between this and oral. The definition of systemic HRT includes gel as a part of so this and a recommendation has been made that people with a uterus if they wish to take HRT should be offered combined HRT.
Menopause Mandate	Guideline	038	013	Recommendations for research. The mention of testosterone is brief in rec 1.4.38. The demand for testosterone therapy is high in the community throughout the UK. Please guide on the need for more research into other potential benefits of testosterone. Many women report improvements to cognition and mood and more research is needed to clarify any benefits to other symptoms of the menopause, as well as other long term benefits or risks.	Thank you for your comment. At the time when the scope of the 2024 guideline update was agreed, there was no substantive new evidence that would change the recommendation related to testosterone. However, NICE recognises the importance of this issue and has worked with the NIHR to prioritise funding for research on the matter.
Menopause Mandate	Guideline	038	013	Recommendations for research. Rec 1.3.3 correctly states awareness that women from ethnic minority backgrounds may experience menopause at a younger age. There is known poor uptake of HRT in this diverse group. A call for research would be therefore welcomed into the clarification of discrepancies and the reasons behind variations in HRT uptake – as well as access to menopause care – to help more women manage symptoms and long term health consequences of the menopause.	Thank you for your comment. The topic of uptake of HRT in people from ethnic minority backgrounds was not in the scope of the 2024 update. In accordance with NICE processes research recommendations can only be made on topics that are systematically searched for and reviewed. The suggested research recommendation could therefore not be added.
Menopause Mandate	Guideline	038	013	Recommendations for research. More research is needed in experience of the menopause, presentation and management for women with disabilities and this should include women with learning disabilities.	Thank you for your comment. The 2024 update of the guideline did not include a systematic review of the experience of the menopause (including presentation and management for women with disabilities and this should include women with

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					learning disabilities). In accordance with NICE processes research recommendations can only be made on topics that are systematically searched for and reviewed. The suggested research recommendation could therefore not be added.
Menopause Mandate	Guideline	043	017	'the use of HRT in people experiencing early menopause' – should read as 'the use of HRT in people experiencing early or *premature* menopause'	Thank you for your comment. There is early menopause (menopause experienced between ages 40 to 44) and premature ovarian insufficiency (menopause experienced before the age of 40). Diagnosing and managing premature ovarian insufficiency in people under 40 is covered in section 1.7 of the guideline. Therefore, using the phrase people experiencing early or premature menopause is likely to cause confusion.
Menopause Mandate	Guideline	076	001	There is no mention of women who experience medical menopause – eg through use of chemotherapy or radiotherapy.	Thank you for your comment. The need to consider evidence for the people that are more likely to develop early menopause has been acknowledged. The committee have highlighted the following subgroups to the NICE surveillance team for incorporation into future menopause guideline updates when considering early menopause; spontaneous versus iatrogenic, people with disabilities (physical or mental, people with rare illnesses or underlying conditions), ethnic minorities, specific disorders (for example, diabetes), medical menopause for example due to medical suppression of ovarian function (e.g., using GnRH analogues in the treatment of endometriosis or PMDD), people on chemotherapy/radiotherapy and surgical (hysterectomy, oophorectomy).
Menopause Mandate	Guideline	076	007	This is a very limited mention of menopause symptoms – there is nowhere in the guidance that addresses the full spectrum of menopause symptoms	Thank you for your comment. Whilst an update of the list of symptoms and experiences was outside the current scope of this update and therefore no evidence review was conducted, the NICE

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					surveillance team checks regularly for new evidence for topics within guidelines to see where further work is needed.
Menopause Mandate	Guideline	087		Appendix A – It would be useful to understand the figures given on the tables better by adding the papers the data refers to and the confidence limits to put these figures into context.	Thank you for your comment. For the draft guideline, the committee opted for a written format complemented by tables, providing estimates of absolute numbers from a single source rather than from two different study types. This differs from the approach used in the published version of NG23. This decision was made to facilitate conversations between clinicians and individuals, enabling shared decision-making regarding Menopause management. The appendix has been used to produce a discussion aid document including visualisation of the data. This provides details about the type of evidence data originated from, how to interpret the numbers and information about uncertainty. It also links to the relevant evidence reviews which contain details of the estimates from different study types (and the relevant sources) as well as the confidence intervals. It also includes links to a separate supplement file which provides the details of each calculation. This discussion aid has undergone user-testing and was refined based on user feedback.
Menopause Support CIC	guideline	general	general	Many of the women that we support, strongly object to the frequent use of the word 'troublesome' throughout the document. This feels dismissive/demeaning and patronising when we know that there can be significant impacts to quality of life for many.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
Menopause Support CIC	guideline	general	general	There is widespread concern from women that we support that CBT will be offered instead of HRT, when HRT is first line treatment. Many	Thank you for your comment. The wording of the recommendation has been revised to make it explicit that this is an option which could be in

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				already experience barriers to accessing HRT in general practice and view this as another potential barrier.	addition to HRT, for people in whom HRT is contraindicated or for those who prefer not to take HRT.
Menopause Support CIC	guideline	general	general	There is concern amongst those that we support that where CBT may be an appropriate intervention, that access to trained therapists is limited and sometimes non-existent, depending upon postcode. It is also important to consider that CBT does not work for everyone and is not an appropriate therapeutic tool for some of those individuals who are neurodiverse.	Thank you for your comment. The committee acknowledged in the impact section of the guideline that there are long waiting times for CBT. They also noted that people currently trained in providing this kind of therapy may not be familiar with menopause-specific CBT and training on this may incur costs and increase waiting times in the short term. However, online and group CBT may be easier and less costly to adapt to menopause-specific CBT. There are also resources available to train people in providing menopause-specific CBT (and could also inform the adaptation of online CBT), which could facilitate implementation. Your comment will be considered by NICE where relevant support activity is being planned. In section 1.5 on symptom management (evidence showed it to be effective in the management of vasomotor symptoms, depressive symptoms and sleep problems) wording has been revised to ensure clarity about CBT 'as an option: in addition to other treatments (including HRT), for people for whom other treatments are contraindicated or for people who prefer not to take HRT'. The wording in relation to discussing CBT treatment has been revised to ensure that information is provided about what CBT is (including menopause-specific CBT) and that preferences and needs should be taken into account. These needs would include making adjustments for people who are neurodiverse.
Menopause Support CIC	guideline	general	general	Not enough emphasis on assessing cardiovascular and osteoporosis risk as	Thank you for your comment. The guideline already recommends that advice on bone health

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				standard. Specific emphasis on ongoing monitoring of this in those with P.O.I., young surgical menopause. The document is not in line with ESHRE POI guidance.	should be given to all people experiencing menopause and bone health should be discussed with them at review appointments. It also recommends that potential risk factors should be taken into consideration. Overall assessment of menopause and risk factors related to this were outside of the scope of the 2024 guideline update. The committee could therefore not be specific about what should be assessed or monitored. The premature ovarian insufficiency section was not updated and the section on early menopause only considered the effect of either taking or not taking HRT on specific health outcomes. All recommendations in the previous guideline on symptom management apply to the early menopause group, too, because this is how the guideline was divided in 2015 (above and below the age of 40). The ages were therefore clarified in the section headings. The committee recognised that definitions of premature ovarian insufficiency and other guidelines related to this commonly also now include the age group of 40 to 44 within this. The committee acknowledged that the question on early menopause was narrow and that other questions would have been relevant to making clinical decisions. They have therefore logged prevalence of early menopause, health consequences of early menopause and management of early menopause with the NICE surveillance team so that these can be considered for future updates.
Menopause Support CIC	guideline	general	general	Transdermal HRT does not increase risk of VTE and this should be more specific if risk factors rather than the use of the word 'consider'	Thank you for your comment. The impact of HRT on risk of VTE was not in the scope of the 2024 guideline update. Evidence for this topic was therefore not searched for, reviewed or discussed with the committee. The committee could therefore

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					not comment on this. Some stakeholders have provided a list of related references, and this has been passed on to the NICE surveillance team to consider for a future update.
Menopause Support CIC	guideline	general	general	In many areas the document does not reflect current British Menopause Society data which is concerning.	Thank you for your comment. The methodology of developing guidance published by the British Menopause Society and guidelines published by NICE differs. The evidence reviews in this guideline followed rigorous NICE methods and processes, with details outlined in a supplement available on the website (supplement 1 - methods), consistent with the NICE guideline manual. Evidence was systematically reviewed and discussed with a committee consisting of experts and lay people. NICE also commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation).
Menopause Support CIC	guideline	general	general	It would be useful to include some information about considering lifestyle; nutrition, exercise, stress management, sleep etc	Thank you for your comment. The guideline recommends the provision of information about lifestyle changes and interventions that can support health and wellbeing. The committee agreed that nutrition, exercise, stress management and sleep would fall into this category.
Menopause Support CIC	guideline	general	general	HRT decreases risk of cardiovascular disease if started within the window of opportunity. This is not clear from the document.	Thank you for your comment. The committee specified in the protocol that, where data allowed, the evidence would be stratified by different ages at first use of HRT, and different times between HRT first use and the start of menopause. The committee discussed the subgroup analysis from the RCT data for age at first use and the time since menopause at first use, and since there were no statistically significant subgroup differences, they could not conclude that there was a reduced

					incidence of heart disease related events when HRT was used at a particular age, or a specific time period following the start of menopause. The committee also considered the observational study evidence, which was also stratified by the same subgroups where possible. They discussed that evidence from one study supported a reduced risk in coronary heart disease which was specific to a younger age group, however this pattern was not reflected in another observational study which also presented subgroup data. Since there were inconsistent results between the observational studies as well as between study types, and no statistically significant subgroup differences in the RCT evidence, the committee could not reach the conclusion that there was a reduced risk of coronary heart disease depending on the age at first use, or the time since menopause when HRT was first used. This is discussed in more detail in the committee's discussion of the evidence section in Evidence Review C. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). With regards to the conclusion related to coronary heart disease the independent review concluded 'If considering each forest plot individually, there were subgroups where evidence suggests that HRT appears to be associated with cardiovascular benefits, which have been noted in the stakeholder comments. However, we agree with the committee’s interpretation of the evidence, based on the limited power in these analyses to detect subgroup differences, and lack of interpretable trends of effects.' To address the issue of 'limited power' highlighted in this

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					independent review a research recommendation was made to increase the evidence base. However, they highlighted that RCT, and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. These and other evidence reviews have been revised to implement these changes accordingly.
Menopause Support CIC	guideline	general	general	30% risk reduction of Type 2 diabetes with HRT, this is not clear from the document.	Thank you for your comment. Evidence related to Type 2 diabetes was not reviewed because it was not within the scope of the 2024 guideline update. The committee could therefore not comment on this.
Menopause Support CIC	guideline	general	general	Continuous HRT has decreased risk of endometrial cancer, this is not clear from the document.	Thank you for your comment. The relevant wording has been revised from 'does not increase' to 'decreases' with continuous combined HRT.
Menopause Support CIC	guideline	general	general	Mortality has been shown to be lower in those taking HRT which is not clear from the document.	Thank you for your comment. The committee based their recommendations on the evidence included in Evidence Review H. See appendix D of the evidence review for details of the evidence that supports this recommendation, and the committee's discussion of the evidence section for the explanation on why the committee made the decision to recommend that HRT does not increase or decrease life expectancy.
Menopause Support CIC	guideline	general	general	The whole document feels quite alarming and does not feel balanced. We suspect that most GPs would continue to feel apprehensive about	Thank you for your comment. The guideline recommends offering HRT for some symptoms, for example vasomotor symptoms. This has not

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				prescribing HRT after reading this and that is not fair to them or to the vast majority of those experiencing menopause.	changed since the 2015 guideline. One of the reasons the 2015 guideline required updating was the pharmacovigilance risk assessments by the MHRA and the EMA, concerning the impact of HRT on the risk of breast cancer. NICE is required to consider the impact of regulatory guidance from MHRA in its guidance and as such the additional information on breast cancer does change the balance of risks and benefits from that in the original 2015 guideline. There were other outcomes where the systematically reviewed evidence also showed an increased risk and the committee agreed that people should be made aware of these. However, this has to be seen in the context of absolute numbers and based on the numbers in the appendix of the consultation version of the guideline (with tables of absolute numbers) a discussion aid document has been developed which includes data visualisation as well as a verbal description of what the numbers mean. Descriptions of the underlying concepts and calculation are also provided. This includes estimates and uncertainties. This discussion aid has undergone user-testing and was refined based on user feedback.
Menopause Support CIC	guideline	015	004	The section on GSM feels unclear. Healthcare professionals should be encouraged to actively ask about these symptoms. We know that up to 80% of people experiencing menopause will have symptoms but only 10% seek help. Data indicates a potential 52% risk reduction in UTIs with proper management of GSM.	Thank you for your comment. The committee recommended a person centered approach and in the 'information and support' section it is described that information should be shared about the symptoms associated with the menopause (including genitourinary symptoms). This will give the person the opportunity to discuss the symptoms they experience with the healthcare professional and make a shared decision about treatment choices.

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Menopause Support CIC	guideline	016	001	1.4.24 Prasterone is not widely available.	Thank you for your comment. Prasterone has only been recommended when all other options have been exhausted.
Menopause Together Ltd	Guideline	General	General	We have issue with the term "troublesome symptoms" which is used throughout the draft guideline. This term significantly understates the often life-changing and devastating impact of symptoms on women's lives. It would be more accurate to state that symptoms can range from mild, to troublesome to life changing for some women. We strongly urge that this phrasing, which is highly insulting to the real-life experiences of women, is reviewed to more accurately reflect the extent of impact on many women's lives.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline. NICE takes the reports of the debilitating symptoms, the considerable concern it causes and the impact menopause has seriously. Whilst an update of the list of symptoms and experiences was outside the current scope of the 2024 guideline update (and therefore no evidence review was conducted), the NICE surveillance team checks regularly for new evidence for topics within guidelines to see where further work is needed. Apart from the removal of the word 'troublesome' the committee decided that without further evidence they could not comment on this.
Menopause Together Ltd	Guideline	General	General	Since the results of the Women's Health Initiative study were prematurely published and the trial stopped in 2004 the number of women prescribed HRT has fallen from about 50% to less than 10% for women from 45 to 60. Even when results were published in 2012 to state that the benefits outweighed the risks for women starting HRT before age 60, there remains a reluctance on the part of many general practitioners to prescribe HRT and women remain fearful that it will raise their risks of serious disease. The whole document is written to highlight the negatives rather than positives and this is more	Thank you for your comment. The guideline recommends offering HRT for some symptoms, for example vasomotor symptoms. This has not changed since the 2015 guideline. One of the reasons the 2015 guideline required updating was the pharmacovigilance risk assessments by the MHRA and the EMA, concerning the impact of HRT on the risk of breast cancer. NICE is required to consider the impact of regulatory guidance from MHRA in its guidance and as such the additional information on breast cancer does change the balance of risks and benefits from that in the original 2015 guideline. There were other outcomes where the systematically reviewed evidence also showed an increased risk and the committee agreed that people should be made

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				likely to raise concerns and anxiety than allay fears in both the prescriber and patient.	aware of these. However, this has to be seen in the context of absolute numbers and based on the numbers in the appendix of the consultation version of the guideline (with tables of absolute numbers) a discussion aid document has been developed which includes data visualisation as well as a verbal description of what the numbers mean. Descriptions of the underlying concepts and calculation are also provided. This includes estimates and explanations that there are uncertainties around these.
Menopause Together Ltd	Guideline	General	General	Throughout the document there is greater emphasis on the risks associated with HRT rather than on the benefits. "Increased risk" is used with very little explanation as to the degree of increased risk. If the risk of an adverse outcome is very small, even if that risk is doubled it is still a very small risk.	Thank you for our comment. Conclusions about increased risks with HRT were based on systematically reviewed evidence. The evidence reviews in this guideline followed rigorous NICE methods and processes, with details outlined in a supplement available on the website (supplement 1 - methods), consistent with the NICE guideline manual. Absolute numbers of incidence of health outcomes per 1000 people were presented in the appendix of the consultation version of the guideline. Based on the numbers in this appendix a discussion aid document has been developed which includes data visualisation as well as a verbal description of what the numbers mean. Descriptions of the underlying concepts and calculation are also provided. This will facilitate a clearer understanding of the size of the effects in the shared decision-making process between the person and the healthcare professional. This discussion aid has undergone user-testing and was refined based on user feedback.
Menopause Together Ltd	Guideline	General	General	The draft refers to using the "lowest effective dose" which has led prescribers to be cautious in using higher dose of HRT and women being	Thank you for your comment. The committee recommended the lowest effective dosage which would be reviewed in 3 months to assess efficacy

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				denied effective treatment. HRT is highly effective at reducing menopause symptoms, reducing the risks of heart disease and osteoporosis. We would suggest that the guidance should state that women should be started on an appropriate dose of HRT and then the dose should be increased in order to provide relief of vasomotor symptoms.	and tolerability and annually thereafter (as highlighted in a different recommendation on reviewing treatments). All dosages would be within licensed ranges and a statement has now been added to emphasise this. The guideline does not specifically recommend HRT for bone protection (where there is a history of osteoporosis). The 2015 guideline mentioned in the context of premature ovarian insufficiency that both HRT and combined oral contraceptives offer bone protection. However, it is unclear whether this would require different dosages.
Menopause Together Ltd	Guideline	006 - 007		1.2.2 It states that the menopause is a normal life transition which is commonly associated with symptoms and that lifestyle changes can support health and wellbeing. There is little discussion on the severity and impact of symptoms that at least 30% of women experience – symptoms which can be utterly life changing for these women. The symptoms are broadly described as Vasomotor GUSM Mood MSK Sexual difficulties However there is no mention of cognitive symptoms – and this is a cause of concern for our members, many of whom report that impairment to cognitive functioning caused by their symptoms can have the greatest impact on their ability to sustain employment and function well.	Thank you for your comment. NICE takes the reports of the debilitating symptoms, the considerable concern they cause, and the impact that symptoms associated with the menopause have, seriously. Whilst an update of the list of symptoms and experiences (including in their work environment) was outside the current scope of the 2024 guideline update and therefore no evidence review was conducted, the NICE surveillance team checks regularly for new evidence for topics within guidelines to see where further work is needed.

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Menopause Together Ltd	Guideline	006	General	The draft document starts by advising that care should be based on individual needs and acknowledges that symptoms will change over time. There should be shared decision making after patient has been given information regarding benefits and risks. It acknowledges the need to provide information for women who are approaching the menopause. This is to be welcomed and highlights the need for healthcare professionals to have up-to-date and correct information on HRT to share with women.	Thank you for your comment in support of this.
Menopause Together Ltd	Guideline	007	019	We welcome the recommendation that women who will experience menopause as a result of medical or surgical treatment should be referred to a menopause specialist before their menopause-inducing treatment and before they start to experience problems.	Thank you for your comment in support of this.
Menopause Together Ltd	Guideline	008	General	The guidelines suggest referral for women with a history of breast cancer and family history of breast cancer to a menopause specialist. For women who have a history of breast cancer there needs to be greater access to menopause specialists. For women who have a family history of breast cancer, they may have an associated increased risk of breast cancer but that is independent of any risk associated with HRT. "Prevent Breast Cancer" an organisation run by the breast screening clinic at the Nightingale Centre, Wytheshawe has the largest family history clinic in the UK and has led research for many years. They acknowledge the benefits of HRT and are	Thank you for your comment. This recommendation is related to an initial discussion with the person. Therefore, it would be most relevant to refer to a healthcare professional with expertise in menopause in the first instance who could, if needed, refer on or seek advice from oncology.

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				happy to recommend that women with a family history of breast cancer can take HRT safely for up to five years. For women who carry the BRCA 1 and BRCA2 gene mutations and have risk reducing oophorectomies, there is no increased risk of breast cancer if they take HRT. The draft document states that there is an increased risk of breast cancer when HRT is taken for less than one year. We would request clarification on this as any breast cancer diagnosed within this time frame most likely predates the start of HRT. We understand that research would suggest that taking HRT for up to five years is not associated with any significant increased risk of breast cancer. The draft document does state that sequential HRT has a lower breast cancer risk than continuous HRT but there is no recommendation that sequential HRT would be a preferred option for women who are at increased risk of breast cancer.	
Menopause Together Ltd	Guideline	013	005	Why recommend referral of women with risk factors of VTE to a haematologist before starting treatment when transdermal HRT will not increase risk of VTE?	Thank you for your comment. The impact of HRT on risk of VTE was not in the scope of the 2024 guideline update. Evidence for this topic was therefore not searched for, reviewed or discussed with the committee. The committee could therefore not comment on this. Some stakeholders have provided a list of related references and this has been passed on to the NICE surveillance team to consider for a future update.
Menopause Together Ltd	Guideline	015	General	There is no recommendation that women should continue using vaginal oestrogen post-	Thank you for your comment. The recommendation was reworded to say 'for as long

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				menopausal long term and yet it stated that symptoms will return when treatment is stopped and treatment should continue as long as symptoms last. The document acknowledges that systemic absorption of vaginal oestrogen is small. Specialists from BMS often state that if vaginal oestrogen is used for one year, the amount of oestrogen absorbed is equivalent to taking one oral contraceptive pill in a year. This information provides important reassurance for women, including those with a history of breast cancer that vaginal oestrogen is not going to increase the risk of breast cancer or breast cancer recurrence. This information should be made clearly available to women and prescribers.	as it is needed'. This does not set a limit and it is described in the 'reviewing treatment' section that the 'efficacy and tolerability' should be reviewed at 3 months and then annually thereafter unless there are clinical indications for an earlier review (such as treatment ineffectiveness, side effects or adverse events). It is also stated in another recommendation (which has been revised) that healthcare professionals should 'explain that symptoms may return when HRT is stopped and discuss the option of restarting treatment if necessary'. Therefore, vaginal oestrogen can be taken as long as is needed and if symptoms return after stopping, they could restart treatment if they wanted to. The recommendation related to absorption has also been reworded to highlight that vaginal oestrogen is absorbed locally - a minimal amount is absorbed into the bloodstream (when compared with systemic HRT), but this is unlikely to have a significant effect throughout the body. In the section referring to people with a history of breast cancer, the committee made changes to the order of recommendations so that considerations of adjuvant treatments are being made early in shared decision making. They also revised the recommendation related to safety considerations for clarity. This would give this section a more logical flow and greater clarity about safety. The rationale of the guideline and

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					the committee discussion section of the evidence were revised accordingly. A visual summary was produces for the management of genitourinary symptoms to clarify treatment options and facilitate decision making.
Menopause Together Ltd	Guideline	018	General	As an organisation which has more than 8000 women in our online support group, we know that a significant proportion of these women experience depressive symptoms – ranging from mild low moods, right through to significant reduction in mental health. Many of these women describe the positive impact of HRT on depressive symptoms. We welcome the draft guidelines suggesting that women with mild depressive symptoms associated with the menopause should be started on HRT rather than antidepressants and also welcome the fact that it also states that antidepressants and clonidine should not be used routinely for treating vasomotor symptoms. The draft guideline only makes reference to offering HRT "to alleviate mild depressive symptoms" – but we would encourage this to be widened out to all women with depressive symptoms associated with perimenopause or menopause. There is already significant evidence available to demonstrate that large numbers of women are inappropriately offered anti-depressants instead of HRT to treat the low moods associated with menopause. We, therefore, feel strongly that this needs greater	Thank you for your comment. The effectiveness of HRT in the management of depressive symptoms associated with the menopause was not in the scope of the 2024 guideline update. Evidence for this topic was not searched for, reviewed or discussed with the committee. The committee could therefore not comment on this. The CBT recommendation has been rephrased to clarify that this is an option in addition to other treatments, or for people for whom other treatments are contraindicated or who prefer not to have other treatments.

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				prominence in the guideline to discourage the practice of anti-depressants instead of HRT. The guideline also makes reference to the benefits of CBT for depressive (and other) symptoms. Whilst this is helpful, we are concerned that may women will be offered CBT instead of HRT (even where they want HRT). The availability of CBT within local health services is virtually inaccessible due to demand and lengthy waiting lists. We feel strongly that it should be made very clear that CBT should be offered IN ADDITION TO and not instead of HRT.	
Menopause Together Ltd	Guideline	019	General	The use of Testosterone "for low sexual desire" is an area of great concern to our members. GPs are reluctant to prescribe this even where it is recommended for low sexual desire. Greater guidance needs to be offered to prescribing health professionals on how and what to prescribe. There is also significant anecdotal evidence about the broader benefits of testosterone for women in dealing with symptoms such as mental clarity, brain fog, and cognitive functioning. It is hugely disappointing that the draft guideline offers no guidance on the broader use of Testosterone. Women, who have been prescribed Testosterone, often report that this was the "missing link" to their wellbeing and cognitive functioning. This is an area that we strongly urge you to consider for inclusion in the new guidelines.	Thank you for your comment. At the time when the scope of the 2024 guideline update was agreed, there was no substantive new evidence that would change the recommendation related to testosterone. It was therefore not included in the update and the committee could not comment on this. However, NICE recognises the importance of this issue and has worked with the NIHR to prioritise funding for research on the matter.

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Menopause Together Ltd	Guideline	021	013	Offering psychological support to women experiencing early menopause is a really important factor – however we would have concerns that this is limited to those aged 40-44 years old. Surely this should be offered to any women under the age of 44 with no lower age limit?	Thank you for your comment. Since this review was specifically targeted at early menopause, the age cut-offs were applied to capture this particular population.
Menopause Together Ltd	Guideline	026	General	All the research for increased risk relates to women starting HRT over 65 years old. There is no increased risk for the women who start HRT prior to age 65. There are very very few women who are starting HRT over the age of 60 so this statement needs to be presented in a way that reassures women that HRT is not associated with increased risk of HRT, unless it is started after age 65.	Thank you for your comment. For ages below 65 there was no clear evidence whether or not HRT increased the risk of dementia. One study showed no difference whereas another study showed an increase in incidence of dementia. Given these discrepancies and potential for confounding in observational data, the committee based this recommendation on the available RCT data with participants that started HRT over the age of 65 and decided not to comment on people initiating HRT earlier. This is described in the rationale section. The committee decided to retain the 2015 research recommendation on the effects of HRT on dementia.
Menopause Together Ltd	Guideline	041	General	The recommendations for research are welcomed, but we would also welcome research into the following areas: Impact of HRT on depressive symptoms – the rationale being that this will provide clear evidence to inform future practice and ensure women are offered the most appropriate treatments for their symptoms. We would also strongly encourage research into the broader benefits of testosterone on women's symptoms – the rationale being this would provide the evidence needed to support	Thank for your comment. The surveillance and scoping process for the 2024 guideline update did not identify substantive new evidence likely to change the existing recommendations on the impact of HRT on depressive symptoms or testosterone. These was therefore not prioritised for the 2024 update. However, NICE discussed the need for research in relation to testosterone use for menopausal symptoms with the National Institute for Health and Care Research (NIHR) and they prioritised funding for urgent research in this area.

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				prescribing of testosterone to alleviate a broader range of symptoms.	
Mumsnet	Guideline	General	General	The language used in the guidance is patronising. The use of the term "troublesome symptoms" fails to reflect the life-changing difficulties experienced by women who have left jobs, unable to cope, or suffered severe physical and mental health problems until they were offered HRT. In a survey in 2022, 28% of those women who told us they were considering leaving work said they were enjoying work less because of the menopause, and 11% of those who had left said it was because of the menopause. Describing the symptoms that prompt these life changes as 'troublesome' is deeply offensive and suggests a failure to grasp the scale of the effect they can have on women	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline. NICE takes the reports of the debilitating symptoms, the considerable concern it causes and the impact menopause has seriously. Whilst an update of the list of symptoms and experiences was outside the current scope of the 2024 guideline update (and therefore no evidence review was conducted), the NICE surveillance team checks regularly for new evidence for topics within guidelines to see where further work is needed. Apart from the removal of the word 'troublesome' the committee decided that without further evidence they could not comment on this.
Mumsnet	Guideline	General	General	We are worried that this guidance emphasises risk (239 mentions) over benefits (39 mentions) and may do women a disservice by fear mongering. It mentions breast cancer 150 times, and osteoporosis - which HRT can help prevent - only five times.	Thank you for your comment. The emphasis of wording is part of this being a partial rather than a complete guideline update. The scope of the 2024 guideline update included the assessment of the impact of HRT on specific health outcomes compared to people not taking HRT. Within the scope there were 3 different types of cancer. Osteoporosis was not updated. Therefore, the word cancer was mentioned more than osteoporosis. The identified evidence identified more risks than benefits for the outcomes in the update and therefore the word risk appears more than the word benefit.
Mumsnet	Guideline	General	General	We were worried by the tone and choice of negative evidence around HRT lowering risk of cardiovascular disease, Type 2 diabetes, colon cancer etc. We would urge NICE to take a look	Thank you for your comment. Type 2 diabetes and colon cancer were not part of the 2024 guideline update. The evidence reviews in this guideline followed rigorous NICE methods and processes,

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				at this document from The Menopause Charity's clinical advisory panel, "Transforming Women's Long-term Health" which is extensively footnoted. https://www.themenopausecharity.org/2023/10/18/transforming-womens-long-term-health/	with details outlined in a supplement available on the website (supplement 1 - methods), consistent with the NICE guideline manual. The committee concluded that coronary heart disease is not increased by combined or oestrogen-only HRT and overall, life expectancy is unlikely to change with the use of combined or oestrogen-only HRT even if some individual health outcome risks are increased. Both of these are positive messages. The link cited in the comment relates to information that focuses on specific individual findings rather than a systematic review of the literature as carried out by NICE.
Mumsnet	Guideline	General	General	There is a large body of evidence that a toxic combination of entrenched misogyny, misinformation and lack of knowledge already makes it difficult for women in perimenopause and menopause to access the HRT medication that they are entitled to. We believe that these draft guidelines will exacerbate this problem. The guidelines emphasise the negative over the positive effects. They will make doctors even more reluctant to prescribe HRT, and they will make women more fearful of asking for and/or accepting it. We are also deeply worried by the suggestion of offering (largely unavailable) CBT and unproven alternative therapies to women who are suffering with the debilitating effects of low hormones. Lack of research and information around health issues that specifically affect women is an important factor in the often poor treatment that they experience. We think it's imperative that women are properly informed of their treatment	Thank you for your comment. One of the reasons the 2015 guideline required updating was the pharmacovigilance risk assessments by the MHRA and the EMA, concerning the impact of HRT on the risk of breast cancer. NICE is required to follow regulatory guidance from MHRA in its guidance and as such the additional information on breast cancer was important to summarise. The evidence reviews in this guideline followed rigorous NICE methods and processes, with details outlined in a supplement available on the website (supplement 1 - methods), consistent with the NICE guideline manual. The identified evidence for the topics that were in the 2024 guideline update identified some risks with combined or oestrogen-only HRT and the committee agreed that these should be taken into account when making treatment choices. They also decided that there were gaps in the evidence (such as for types of progestogen as well as different routes of administration) and the committee made research recommendations for these topics. The recommendations related to CBT have been revised to clarify that CBT could be an

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				options for symptoms of perimenopause and menopause, and this should include explicit information about the safest forms of HRT - something this document does not do. Our medical advisors believe that only limited evidence has been taken into account on this and the long-term health benefits of the safer forms of HRT. We urge NICE to reconsider its recommendations, and take time to bring more menopause experts, endocrinologists and neuroscientists on board to give women the up-to-date and comprehensive advice and information that they deserve.	option (1) in addition to other treatments (including HRT) (2) for people for whom other treatments are contraindicated or (3) for people who prefer not to have other options. The committee consisted of a range of experts and lay people who would be involved in shared decisions about treatment choices.
Mumsnet	Guideline	007	003	We believe that the priorities suggested in this guidance will be detrimental to the health of women, and that the medical advice fails to give doctors (and women) clear information on the safest forms of Hormone Replacement Therapy. The first line of advice *1.2.3. (page 7)* prioritises "non-hormonal" treatment, and appears to put that and Cognitive Behavioural Therapy on a par with HRT as a possible treatment.	Thank you for your comment. Recommendation 1.2.3 is in the information section and highlights that all options should be discussed with examples given for each category of treatment. However, the committee reflected on this and related feedback and has removed the examples because they agreed that they were causing confusion and were misunderstood to be recommendations. The categories of options were also now put into alphabetical order so that no particular priority of treatment is suggested.
Mumsnet	Guideline	007	006 - 007	We note there is a useful section (p15) on the Genitourinary Symptoms of Menopause, which many Mumsnet users tell us they experience, and it recommends vaginal oestrogen as a first-line treatment. Why, then, at the start of the guidance (1.2.3. page 7), is the very first suggestion for everyone: "*non-hormonal, for example, non-hormonal vaginal lubricants and moisturisers"?* This is extremely confusing for women and medical professionals. We have also seen the latest good news on the safe use	Thank you for your comment. Recommendation 1.2.3 is in the information section and highlights that all options should be discussed with examples given for each category of treatment. However, the committee reflected on this and related feedback and have removed the examples because they agreed that they were causing confusion and were misunderstood to be recommendations. The categories of options were also now put into

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				of vaginal oestrogen in breast cancer patients, which is not mentioned in the guidance. (https://jamanetwork.com/journals/jamaoncology/article-abstract/2811413)	alphabetical order so that no particular priority of treatment is suggested. In the people with a personal history of breast cancer section related to genitourinary symptoms associated with menopause, the committee made changes to the order of recommendations so that considerations of adjuvant treatments are being made early in shared decision making. They aslo revised the recommendation related to safety considerations for clarity. This would give this section a more logical flow and greater clarity about safety. The rationale of the guideline and the committee discussion section of the evidence were revised accordingly. A visual summary was produces for the management of genitourinary symptoms to clarify treatment options and facilitate decision making.
Mumsnet	Guideline	008	015	On p8 1.3.1. perimenopause is defined as "*if they have new onset vasomotor symptoms and any changes in their menstrual cycle".* We are very aware from Mumsnet users that this is not everyone's experience of perimenopause, and indeed mood swings, heart palpitations and even vaginal dryness are extremely common symptoms – even in women who do not yet have hot flushes. This definition seems unnecessarily narrow, and may result in women in need of medical help being turned away.	Thank you for your comment. Defining perimenopause was not in the scope of the 2024 guideline update. Evidence for this topic was not searched for and not reviewed and discussed with the committee. The committee could therefore not comment on this.
Mumsnet	Guideline	014	010	While we very much support lifestyle changes and access to additional therapies for women, we were puzzled that diet and regular exercise were not top line recommendations. Instead, there is this (p14 1.4.18): "*Explain to people*	Thank you for your comment. The NICE medicines advisory team was consulted in relation to this comment. They advised that this does not need to be separately pointed out because the recommendation already states that 'safety is

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				with menopause symptoms that there is some evidence that isoflavones or black cohosh may relieve vasomotor symptoms associated with the menopause." Black cohosh has a known potential risk of liver damage – and women would have to pay for it privately. This is from a Gov.UK report: "Worldwide, the liver reactions reported vary from abnormal liver-function tests and jaundice to liver failure. Just over half of the reactions reported resulted in admission to hospital. The limited evidence available suggests that the reactions occurred within three months of starting black cohosh." (https://assets.publishing.service.gov.uk/media/5df7610ce5274a08f78bca34/Black_cohosh_and_liver_injury.pdf)	uncertain' which would include this issue. Also, the MHRA in the report also requested that all relevant herbal products state this risk in their product information, so it is listed and is well known.
Mumsnet	Guideline	023	003	On page 23 it says:**"** *Combined HRT increases the risk of breast cancer compared with not taking HRT".* For women reading the document, it is not clear what this means. Does combined mean the old oral HRT with synthetic progestins and equine oestrogens (derived from pregnant horses 'urine) which caused all the headlines of increased breast cancer risk over 20 years ago, or could combined mean the combination of progesterone and estradiol in Bijuve, or a transdermal patch or gel plus Utrogestan progesterone, which have never been shown to have an increased risk of breast cancer? We know that the flawed study in 2002 is still having an impact on women. In a 2019 survey 40% of Mumsnet users told us that press stories about HRT risks make them anxious and less likely to consider taking HRT. We are astonished that the guidance is not updated with the latest knowledge, and doesn't clearly	Thank you for your comment. The recommendation relates to any combined HRT preparations. The evidence for breast cancer outcomes can be found in Evidence Review D. Where the evidence allowed, the data was separated by oestrogenic constituent and progestogenic constituent. The committee agreed that from the evidence there was an increased risk across most combined HRT preparations and chose not to make separate recommendations depending on type. The committee also addressed that more data on some of the newer progestogens is required before they could comment on the risks of these and made a research recommendation. They also discussed the evidence for the mode of administration, and since the risk of breast cancer is increased in both oral and transdermal, they again chose not to make separate recommendations. For more detail on the committee's discussion please see the

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				direct women to the safest forms of HRT. This is a missed opportunity for clarity that may limit the choices of thousands of women.	committee's discussion of the evidence section in Evidence Review D. In line with NICE methodology all evidence available, that meets the criteria set out in the protocol of the review has been included. Therefore, in the context of this review question and protocol all guidance has been updated with the latest published studies.
Mumsnet	Guideline	049	011	In the section "How the recommendations might affect practice", it says that the increased use of CBT: *"would benefit the NHS because people may not need other treatments which would require regular reviews and ongoing prescriptions, such as hormone replacement therapy (HRT)." (p49, line 11)*. We have heard from thousands of Mumsnet and Gransnet users over the years who already struggle to access HRT, despite experiencing menopause and perimenopause symptoms which have a significant effect on their everyday life. In a 2021 survey, nearly four in ten women seeking treatment for perimenopause symptoms say their GP told them they'd just have to learn to live with it, while 26% of those who sought help for menopause symptoms say they visited their GP three times or more before being prescribed appropriate medication. We know that many of our users already have to fight to get access to the HRT they are entitled to, and we think this guidance will make it even harder for women to access it. We worry that women will be turned away from HRT as a first-line treatment for menopause symptoms, when it also lowers risk of many long-term conditions like osteoporosis. We also know	Thank you for your comment. This text and any mention of this being a cost saving option has been removed.

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				from our users that the NHS waiting lists for CBT are up to a year in some areas, and that a few sessions of CBT would be much more expensive than the £120 a year cost to the NHS of the safest HRT (micronized progesterone and transdermal oestrogen).	
Mumsnet	Guideline	062	019	Later, the NICE document does say (p62): "*All types of progestogen were associated with an increased risk of breast cancer, although there was limited evidence assessing the risk of breast cancer with micronised progesterone. Overall, there was insufficient evidence to say whether one type (for example micronised progesterone) may be safer than others and therefore the committee made a research recommendation to address this*." We were puzzled by this statement, since it conflicts with best practice at major NHS and private menopause clinics which recommend transdermal oestrogen and micronised progesterone first line, as does the **British Menopause Society**, quoted here: *"Evidence from large observational studies and case-controlled studies suggests that micronised progesterone and dydrogesterone are unlikely to increase the risk of venous thrombosis and are associated with a lower risk of breast cancer compared to that noted with oral progestogens[progestins]."* https://thebms.org.uk/publications/consensus-statements/bms-whcs-2020-recommendations-on-hormone-replacement-therapy-in-menopausal-women/	Thank you for your comment. The statements by British Menopause Society and others about micronised progesterone and dydrogesterone are associated with a lower risk of breast cancer are based on a study by Fournier et al. 2008 using the so-called E3N cohort. Some of the participants of this particular publication of the E3N cohort have been included in the individual patient data (IPD) from the Collaborative Group on Hormonal Factors in Breast, Cancer (CGHFB) published in 2019, which has been included in our review. It was considered that not all participants of the E3N have been included in the CGHFBC. However, where there are separate publications with overlapping follow-up periods, and no disaggregation of participants, we have not included because this would be double counting of participants in the E3N cohort. As per our processes and methods, we do not reanalyse any existing IPD data as NICE does not generally have the same access to the individual participant data, and therefore the data has been used as it has been published. Due to the large size of the IPD data from the CGHFB, we have prioritised this for inclusion in the review. Fournier 2014 was included as this study had a later follow-up period of the E3N cohort that was not covered by CGHFB. However, since the data from the Fournier 2014 publication did include participants that were in the meta-analysis from CGHFB, the

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					results were analysed separately. In the 2014 publication of the E3N study there was an increased risk of breast cancer with micronised progesterone, but the committee considered that the number of cases of breast cancer with those using micronised progesterone were few and agreed that this supported a recommendation to highlight that there was insufficient evidence to support any differences in the risk of breast cancer with micronised progesterone. The committee agreed that more evidence was required to make any robust recommendations for micronised progesterone and made a research recommendation. The impact of transdermal combined HRT was outside the scope of the 2024 guideline update and the committee could therefore not comment on this.
My Menopause Centre	Guideline	General	General	As a menopause specialist this guideline is difficult to read and difficult to interpret – see specific comments - and so it's highly likely that GPs, other health care professionals and lay people will also find it difficult.	Thank you for your comment. Based on the numbers in the appendix of the consultation a discussion aid document has been developed which includes data visualisation as well as a verbal description of what the numbers mean. Descriptions of the underlying concepts and calculation are also provided. This discussion aid has undergone user-testing and was refined based on user feedback.
My Menopause Centre	Guideline	General	General	• In general, there is a lot of emphasis on risks of HRT and less on the benefits. Guidelines should be more balanced on the risks and benefits of HRT to enable health care professionals (HCP) have a more balanced discussion with patients. ○ For most women HRT is the most effective method of management of menopause	Thank you for your comment. Recommendations related to offer HRT for vasomotor symptoms and the recommendation to consider it for depressive symptoms have not changed in the 2024 guideline update. Neither has the information on osteoporosis which shows a decrease of incidence of fragility fractures with HRT. One of the reasons the 2015 guideline required updating was the pharmacovigilance risk assessments by the MHRA

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				symptoms, and this is not reflected in this guidance. ○ Reading the from the perspective of a HCP with little or no knowledge of the menopause, management of the menopause with HRT would seem to be an option that should be approached with great caution. This does not accurately reflect the absolute numbers of women who will be diagnosed with breast cancer as a result of taking HRT balanced against the absolute numbers of women who will not be diagnosed with osteoporosis or osteoporotic related fractures as a result of taking HRT. Absolute numbers are not mentioned in the guidance body (excluding tables) except for ovarian cancer. It would be useful to see absolute numbers used throughout the body of the document for easy reference and to reflect risks and benefits. Risks should be discussed in the context of other lifestyle related risk – particularly of breast cancer.	and the EMA, concerning the impact of HRT on the risk of breast cancer. NICE is required to consider the impact of regulatory guidance from MHRA in its guidance and as such the additional information on breast cancer does change the balance of risks and benefits from that in the original 2015 guideline. The guideline adopts a person-centred approach emphasising that the information about benefits and risks of HRT should be tailored to the person's age, individual circumstances and potential risk factors - see the 'discussing management options' section. Based on the numbers in the appendix of the consultation version of the guideline (with tables of absolute numbers) a discussion aid document has been developed which includes data visualisation as well as a verbal description of what the numbers mean. Descriptions of the underlying concepts and calculation are also provided. This includes estimates and explanations that there are uncertainties around these. This discussion aid has undergone user-testing and was refined based on user feedback.
My Menopause Centre	Guideline	General	General	1. It is difficult to discuss the duration that HRT will be taken for at the outset and more specific guidance of why this is included is needed in the body of the guidance. A guide to points needed to be covered in the discussion around duration would be helpful for	Thank you for your comment. The wording of this recommendation has been rephrased to read 'discuss the possible duration of treatment at the outset', followed by 'rediscuss the benefits and risks or continuing treatment at every review'. Therefore, it is a general discussion about the potential duration which would then be revisited at review.

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				practitioners who are not experienced in managing the menopause.	
My Menopause Centre	Guideline	General	General	2. The demand for testosterone therapy is high in the community throughout the UK. This is the source of many referrals to NHS specialist menopause clinics (anecdotally) with significant cost to the NHS. A formal recommendation for off license prescribing and monitoring would be welcomed to help guide GPs in prescribing testosterone for women with low libido and we believe this would come with significant financial savings.	Thank you for your comment. At the time when the scope of the 2024 guideline update was agreed, there was no substantive new evidence that would change the recommendation related to testosterone. However, NICE recognises the importance of this issue and has worked with the NIHR to prioritise funding for research on the matter.
My Menopause Centre	Guideline	General	General	3. A more thorough examination of other prescribable alternatives to HRT would be helpful.	Thank you for your comment. The effectiveness of other possible alternatives to HRT (apart from CBT) in the management of symptoms associated with the menopause was not in the scope of the 2024 guideline update. Evidence for this topic was not searched for, reviewed or discussed with the committee. The committee could therefore not comment on this. The NICE surveillance team is regularly looking for evidence related to topics in guidelines which can be considered for future updates.
My Menopause Centre	Guideline	General	General	4. It is recognised that cognitive behavioural therapy (CBT) has a role to play in management of the menopause. The guidelines should consistently state the symptoms that CBT can help manage to avoid confusion. It should be stated that CBT is not suitable for all women.	Thank you for your comment. The wording of the recommendation has been revised to make it explicit that this is an option which could be in addition to HRT, for people in whom HRT is contraindicated or for those who prefer not to take HRT. The guideline recommends a person-centred approach where discussions are tailored to the individual and their preference or risk factors. The recommendation related to discussions about CBT has been updated to include that the person's

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					preferences and needs should be taken into account. If the person's preferences and needs may mean that CBT is not suitable for them then this can be discussed during the shared decision-making process.
My Menopause Centre	Guideline	General	General	5. The section on sleep is inadequate. Chronic insomnia is experienced by 60% of women or more. A reference to the NICE guidance on sleep would be helpful. This is an area of medicine where there is little or no training and so NICE have an important role in the provision of evidence-based guidance.	Thank you for your comment. Apart from CBT other management options for sleep problems associated with the menopause were not in the scope of the 2024 guideline update. However, the committee acknowledged that there are other options that may be used (including HRT). They have therefore reworded the recommendation to reflect this. It now states that CBT could be used as an option (1) in addition to other treatments (including HRT), or (2) for people for whom other treatments are contraindicated or (3) for people who prefer not to have other treatments. Given the constraints of the scope they could not be more specific than this. The only NICE guidance related to insomnia is a medical technology guidance related to the digital self-help programme sleepio. It is unclear whether the effectiveness is generalisable to sleep problems associated with the menopause. Therefore, the committee decided not to cross refer to this.
My Menopause Centre	Guideline	General	General	6. There is good evidence that hypnosis can help manage some symptoms of the menopause transition.	Thank you for your comment. The effectiveness of hypnotherapy in the management of symptoms associated with the menopause was not in the scope of the 2024 guideline update. Evidence for this topic was not searched for, reviewed or discussed with the committee. The committee could therefore not comment on this. The NICE surveillance team is regularly looking for evidence related to topics in guidelines which can be considered for future updates.

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My Menopause Centre	Guideline	General	General	7. The section on alternatives is inadequate in comparison to available products that many women use.	Thank you for your comment. The effectiveness of other alternatives to HRT in the management of symptoms associated with the menopause was not in the scope of the 2024 guideline update. Evidence for this topic was not searched for, reviewed or discussed with the committee. The committee could therefore not comment on this. The NICE surveillance team is regularly looking for evidence related to topics in guidelines which can be considered for future updates.
My Menopause Centre	Guideline	General	General	8. There is no mention of the evidence around benefits of lifestyle intervention.	Thank you for your comment. There is a recommendation stating that information should be shared about lifestyle changes and interventions that can support health and wellbeing. However, the effectiveness of lifestyle interventions on symptoms associated with the menopause was not in the scope of the 2024 guideline update. Evidence for this topic was not searched for, reviewed or discussed with the committee. The committee could therefore not comment on this. The NICE surveillance team is regularly looking for evidence related to topics in guidelines which can be considered for future updates.
My Menopause Centre	Guideline	General	General	9. The guidance correctly highlights awareness that women from ethnic minority backgrounds may experience menopause at a younger age. There is known poor uptake of HRT in this diverse group. A call for research would be therefore welcomed into the clarification of discrepancies and the reasons behind variations in HRT uptake – as well as access to menopause care – to help more women manage symptoms and long-term	Thank you for your comment. Uptake of HRT was not in the scope of the 2024 guideline update or a topic of the original guideline. Given that no evidence was searched for or reviewed, the committee could not make a research recommendation about this.

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				health consequences of the menopause.	
My Menopause Centre	Guideline	General	General	• More research is needed in experience of the menopause, presentation and management for women with disabilities and this should include women with learning disabilities – both underserved populations of women. 10. We welcome inclusion on need for more research on women from ethnic minorities. We would like to see recommendations for research into other groups of women under represented at clinic trials – for example older women and women with multiple co-morbidities.	Thank you for your comment. The impact and experience of menopause and the support needs was a topic that was referred to by many stakeholders and NICE takes reports of the impact on people with learning disabilities seriously. Since this was not part of the 2024 guideline update, the committee could not comment on this. However, the cited references have been passed on to the NICE surveillance team so that they can be considered for future updates. All research recommendations that were made in the 2024 guideline update have highlighted that research in groups that are underrepresented is particularly welcome to encourage diversity in research populations.
My Menopause Centre	Guideline	General	General	11. The language used to describe menopause symptoms and their impact is vague and patronising at times including the use of 'troublesome' and 'bothersome'. It does not recognise the well evidenced breadth and depth of the impact that symptoms can have on all aspects of a woman's life.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
My Menopause Centre	Guideline	General	General	• Persistent use of the word 'people' has been reported to be alienating for many. It would be better to explain that document is inclusive and is meant for women, transmen and non-binary 12. people registered female at birth, but the vast body of research has been carried on out women.	Thank you for your comment. The introduction to the guideline lists the groups it covers. The rationale section provides more detail about the population covered by the evidence.
My Menopause Centre	Guideline	General	General	13. There is nowhere in the guidance that addresses the full spectrum of	Thank you for your comment. Whilst an update of the list of symptoms was outside the current scope

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				menopause symptoms and lists of symptoms are used inconsistently. It would be better to have a list of acknowledged symptoms at the beginning of the guidance that could be referred to throughout for consistency.	of the 2024 guideline update and therefore no evidence review was conducted, the NICE surveillance team checks regularly for new evidence for topics within guidelines to see where further work is needed.
My Menopause Centre	Guideline	General	General	• There are challenges to the implementation of the following recommendations in particular, but it is key that resources – which will require funding - are in place throughout the UK (i.e. no 'postcode lottery') to support delivery of the final recommendations in the guidelines: o CBT service availability/waiting lists o Sufficient 'healthcare professionals with expertise in menopause' (as defined by the BMS) within the NHS 14. HRT availability	Thank you for your comment. The committee acknowledged in the impact section of the guideline that there are long waiting times for CBT. They also noted that people currently trained in providing this kind of therapy may not be familiar with menopause-specific CBT and training on this may increase waiting times in the short term. However, online and group CBT may be easier to adapt to menopause-specific CBT. There are also resources available to train people in providing menopause-specific CBT (and could also inform the adaptation of online CBT), which could facilitate implementation. Your comment will be considered by NICE where relevant support activity is being planned. The definition of 'healthcare professional with expertise in menopause' is not mandating that these professionals are in tertiary centres. They have been defined as professionals with specialist knowledge, skills and training (for example as recognised by the British Menopause Society, the Faculty of Sexual and Reproductive Healthcare or the Royal College of Obstetricians and Gynaecologists) who can advise and support colleagues in managing complex menopause-related needs and risk factors affecting decision making....'. Therefore, this could also be GPs or other relevant healthcare professionals with a special interest in menopause who have

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					undertaken further training. This increases the pool of such healthcare professionals. Addressing HRT availability was outsider the scope of the 2024 guideline update and the committee could therefore not comment on this.
My Menopause Centre	Guideline	006	014	15. Rec 1.2.1 This comment does not acknowledge the fact that some women have a premature surgical or medical menopause which may not be perceived as 'normal' by those suffering. I am concerned that the frequently more severe symptoms of often premature surgical or medical menopause may not be taken seriously, or simply dismissed.	Thank you for your comment. This has been revised to say 'in most people' it is a normal life transition. The objective of this recommendation is very general about providing information. There is a specific recommendation related to menopause as a result of medical or surgical treatment within the same section to highlight specifically the information and support that is needed in these circumstances.
My Menopause Centre	Guideline	006	014	16. Rec 1.2.1 add 'that for some women, can impact all aspects of their life'.	Thank you for your comment. This has been revised to say 'in most people' it is a normal life transition. The objective of this recommendation is very general about providing information and not specifically related to impact.
My Menopause Centre	Guideline	006	022	17. Rec 1.2.2 The word 'troublesome' does not reflect the life changing and severe symptoms that many women experience.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
My Menopause Centre	Guideline	007	002	18. Rec 1.2.2 Please consider adding cognitive symptoms as they affect so many and have impact on women's ability to work in particular (73% according to Fawcett Society research - https://www.fawcettsociety.org.uk/Handlers/Download.ashx?IDMF=9672cf45-5f13-4b69-8882-1e5e643ac8a6).	Thank you for your comment. NICE takes the reports of the debilitating symptoms, the considerable concern they cause, and the impact that symptoms associated with the menopause have, seriously. Whilst an update of the list of symptoms and experiences (including cognitive symptoms and the impact on employment) was outside the current scope of the 2024 guideline update and therefore no evidence review was conducted, the NICE surveillance team checks

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					regularly for new evidence for topics within guidelines to see where further work is needed.
My Menopause Centre	Guideline	007	009	19. Rec 1.2.9 please consider adding other non-hormonal prescribable alternatives to HRT on or off license, for example oxybutynin, clonidine.	Thank you for your comment. Based on the page and line number, this appears to refer to recommendation 1.2.3. The committee considered this and other feedback and decided that the examples in the bullet points caused confusion. They were often misunderstood as recommendations rather than examples. They were therefore removed.
My Menopause Centre	Guideline	007	019	20. Rec 1.2.9 I would like to see stronger language used around the recommendation to 'offer support' and provide information for women likely to experience a surgical menopause. This is an underserved population, information is often NOT given. Highlighting this need within the guideline may help people get the information and support they need.	Thank you for your comment. In NICE style the wording 'offer' and 'discuss' are strong instructions to carry out the associated action. It is therefore expected that information should be provided and referral offered.
My Menopause Centre	Guideline	008	012	21. Rec 1.3.1 Identifying perimenopause mentions only 'new onset vasomotor symptoms' (and changes in menstrual cycle) – it would be helpful to add the other physical and psychological symptoms of menopause (see 1.2.2) Please consider reviewing this definition.	Thank you for your comment. Identifying perimenopause and menopause was not in the scope of the 2024 guideline update. Evidence for this topic was not searched for and not reviewed and discussed with the committee. The committee could therefore not comment on this.
My Menopause Centre	Guideline	009	012	22. Typo – should read 1.7 and not 1.8	Thank you for your comment. This has been amended.
My Menopause Centre	Guideline	009	014	23. Please consider saying women, transmen and non-binary people	Thank you for your comment. The wording 'women, trans men and non-binary people registered female at birth' is used when there is a

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				registered female at birth rather than people.	need to make it explicit that all these groups are covered. Elsewhere, 'people with symptoms associated with the menopause' is used to make recommendations easier to read.
My Menopause Centre	Guideline	009	015	24. Please consider saying women, transmen and non-binary people registered female at birth rather than people.	Thank you for your comment. The wording 'women, trans men and non-binary people registered female at birth' is used when there is a need to make it explicit that all these groups are covered. Elsewhere, 'people with symptoms associated with the menopause' is used to make recommendations easier to read.
My Menopause Centre	Guideline	010	020	25. Rec 1.4.2 There is emphasis on 'duration' throughout. Most women do not know how long they will continue to take HRT for when they start it. There is no evidence for stopping after an arbitrary length of time or at an arbitrary age. Do you mean 'inform women that the small risks of HRT are related to the length of time HRT is taken for'? You need to be more specific as most GPs and other Health Care Professionals (HCP) may not appreciate the nuance of this statement and guidance of how to discuss this is important. Please consider differentiating here the difference in discussion for younger women taking HRT for POI vs women transitioning the menopause at an average age. As mentioned later in the guidance, it is important that women with POI take HRT at least until the average age of the menopause. Anecdotally, many women are advised to stop HRT after 5 years even when	Thank you for your comment. This has been rephrased to read 'discuss the possible duration of treatment at the outset', followed by 'rediscuss the benefits and risks or continuing treatment at every review'. This does not suggest arbitrary limits or cut offs. Age is mentioned as an important issue to consider in the preceding recommendation. This includes the following 'Tailor the information about benefits and risks to the person's age, individual circumstances and potential risk factors.' The POI section has its own recommendation about topics to discuss and therefore a cross reference to this section has been added.

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				starting at a young age as there may be misunderstanding as to the risk and benefit ratio differences according to age. This puts younger women at greater risk of osteoporosis, heart disease and possibly dementia.	
My Menopause Centre	Guideline	010	027	26. Rec 1.4.3 Please specify the recommendation re duration.	Thank you for your comment. This has been rephrased to read 'discuss the possible duration of treatment at the outset', followed by 'rediscuss the benefits and risks or continuing treatment at every review'. Therefore, it is a general discussion about the potential duration which would then be revisited at review.
My Menopause Centre	Guideline	011	001	27. Rec 1.4.3 Most GPs will not know the likelihood of symptoms returning when HRT is stopped. Better to inform and say 'symptoms of the menopause may return when HRT is stopped. The only way of knowing if symptoms will return is to stop the HRT. If symptoms recur, the possibility of restarting HRT should be discussed along with the risks related to duration of use… as per text line 030, 040 and 050'.	Thank you for your comment. This has been rephrased to read 'discuss the possible duration of treatment at the outset', followed by 'rediscuss the benefits and risks or continuing treatment at every review'. The word 'likelihood' has been removed and the final bullet has been reworded to address this concern: 'explain that symptoms may return when HRT is stopped and discuss the option of restarting treatment if necessary'.
My Menopause Centre	Guideline	011	007	Rec 1.4.4 There is little or no access to CBT through the NHS – or very long waiting times. Please specify what 'troublesome symptoms' that you mean CBT is suitable for (these are listed in 1.4.9). Please reconsider the use of the word 'troublesome' which is open to interpretation – better to say 'possible treatment for symptoms, mild, moderate or severe…'. Please acknowledge that CBT may not be suitable for all women.	Thank you for your comment. The committee acknowledged in the impact section of the guideline that there are long waiting times for CBT. They also noted that people currently trained in providing this kind of therapy may not be familiar with menopause-specific CBT and training on this may incur costs and increase waiting times in the short term. However, online and group CBT may be easier and less costly to adapt to menopause-specific CBT. There are also resources available to train people in providing menopause-specific

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				28. There is a need for consistency with regards to recommendations for use of CBT. The inconsistency may cause confusion and concern from women and less likely to take up CBT as a consequence.	CBT (and could also inform the adaptation of online CBT), which could facilitate implementation. Your comment will be considered by NICE where relevant support activity is being planned. In section 1.5 on symptom management (evidence showed it to be effective in the management of vasomotor symptoms, depressive symptoms and sleep problems) wording has been revised to ensure clarity about CBT 'as an option: in addition to other treatments (including HRT), for people for whom other treatments are contraindicated or for people who prefer not to take HRT'. The wording troublesome has been removed from the guideline. The section referred to in the comment is related to discussing CBT treatment rather than the symptoms for which it is recommended which are addressed in section 1.5 on symptom management. The wording in relation to discussing CBT treatment has been revised to ensure that information is provided about what CBT is (including menopause-specific CBT) and that preferences and needs should be taken into account.
My Menopause Centre	Guideline	012	013	Rec 1.4.8 Please reconsider the word troublesome which is patronising, does not reflect the severity of symptoms some women experience and is open to interpretation.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
My Menopause Centre	Guideline	014	005	Rec 1.4.16 Please reconsider the word troublesome which is patronising, does not reflect the severity of symptoms some women experience and is open to interpretation.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
My Menopause Centre	Guideline	015	004	Rec 1.4.19 Please reconsider the word troublesome which is patronising, does not reflect the severity of symptoms some women experience and is open to interpretation.	Thank you for your comment. The word 'troublesome' has been removed from the guideline.

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				Please specify symptoms. Please acknowledge that symptoms can progress if not actively managed.	
My Menopause Centre	Guideline	015	009	Rec 1.4.20 Please reconsider the word troublesome which is patronising, does not reflect the severity of symptoms some women experience and is open to interpretation.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
My Menopause Centre	Guideline	015	014	Rec 1.4.20 Please give an idea of how much oestrogen is absorbed. Some GPs will read this and assume that women cannot use if there are other factors that may make HRT potentially more risky (history of venous thromboembolic disease, for example). This is based on my experience of answering 50+ advice and guidance requests every month. 'Small' – please replace with 'extremely small and not measurable by most hospital-based labs' or equivalent more accurate wording.	Thank you for your comment. This bullet point was reworded to say that vaginal oestrogen is absorbed locally - a minimal amount is absorbed into the bloodstream (when compared with systemic HRT), but this is unlikely to have a significant effect throughout the body. It is then described in the rationale section that 'the committee agreed to highlight this because it means that there is no need to combine low-dose vaginal oestrogens with systemic progestogen treatment to protect the person against endometrial hyperplasia and cancer'.
My Menopause Centre	Guideline	015	019	Rec 1.4.21 Please clarify this comment – are you suggesting increasing beyond licensed doses? Most GPs prescribe the maximum dose. Please explain 'standard therapeutic range'. Please consider also using alternative vaginal preparations and consider alternative diagnoses (lichen sclerosus is often undiagnosed and mistaken for atrophic vaginitis particularly in phone consultations). Please also consider recommending examination is needed if the vaginal oestrogen does not relieve genitourinary symptoms.	Thank you for your comment. The committee reflected on this and decided that there was generally no clear consensus about the standard therapeutic range in relation to vaginal oestrogen. The committee therefore decided to remove this recommendation. The guideline contains recommendations about reviewing treatment and recommends that treatment for symptoms associated with the menopause should be reviewed at 3 months to assess efficacy and tolerability and annually thereafter, unless there are clinical indications for an earlier review (such as treatment ineffectiveness, side effects or adverse events). It is also recommended to 'refer people to a healthcare professional with expertise in menopause if treatments do not improve their

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					menopause symptoms or they have ongoing side effects.' This means that if symptoms are not resolved after vaginal oestrogen is prescribed treatment is reviewed and other differential diagnoses could be considered.
My Menopause Centre	Guideline	015	022	Rec 1.4.22 Please reconsider the word troublesome which is patronising, does not reflect the severity of symptoms some women experience and is open to interpretation.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
My Menopause Centre	Guideline	015	026	Rec 1.4.23 Please consider commenting on need for appropriate moisturisers and lubricants for the vagina – in terms of pH and osmolarity – this could form a new section as per work by Nick Panay et al.	Thank you for your comment. The pH level and osmolarity of moisturisers and lubricants was not in the scope of this review question. This means that different levels of pH and osmolarity were not compared with each other to investigate the impact on genitourinary outcomes associated with the menopause. The article by Panay was not included because it did not meet protocol criteria (it was a narrative review). The committee could therefore not comment on this.
My Menopause Centre	Guideline	015	001	I would like to see a recommendation that genitourinary symptoms should be proactively sought out. There is good evidence to show they are under reported with significant morbidity, and they progress with time.	Thank you for your comment. The committee recommended a person centered approach and in the 'information and support' section it is described that information should be shared about the symptoms associated with the menopause (including genitourinary symptoms). This will give the person the opportunity to discuss the symptoms they experience with the healthcare professional and make a shared decision about treatment choices.
My Menopause Centre	Guideline	016	011	Please reconsider the word troublesome which is patronising, does not reflect the severity of symptoms some women experience and is open to interpretation.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
My Menopause Centre	Guideline	016	015	Please reconsider the word troublesome which is patronising, does not reflect the severity of	Thank you for your comment. Based on this and other feedback the committee reflected on this

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				symptoms some women experience and is open to interpretation.	wording and consequently 'troublesome' has been removed from the guideline.
My Menopause Centre	Guideline	017	011	Please give an idea of how much oestrogen is absorbed. Some GPs will read this and assume that women cannot use if other factors such as previous VTE.	Thank you for your comment. This bullet point was reworded to say that absorption is minimal and not clinically significant. It is then described in the rationale section that 'the committee agreed to highlight this because it means that there is no need to combine low-dose vaginal oestrogens with systemic progestogen treatment to protect the person against endometrial hyperplasia and cancer'.
My Menopause Centre	Guideline	017	022	Rec 1.4.22 – the link takes to a recommendation for systemic HRT. A separate recommendation should be given for local oestrogen use where it should be acknowledged that treatment may need to continue for 3-6 months before improvement is noticed, and if symptoms are not improving to consider alternative diagnoses.	Thank you for your comment. The link is leading to a section within the NICE guideline on Urinary incontinence and pelvic organ prolapse in women: management that includes a recommendation to 'offer intravaginal oestrogens to treat overactive bladder symptoms in postmenopausal women with vaginal atrophy.' Therefore, it refers to local rather than systemic HRT. The menopause guideline also contains recommendations related to reviewing treatments which states that the 'efficacy and tolerability' should be reviewed at 3 months and then annually thereafter unless there are clinical indications for an earlier review (such as treatment ineffectiveness, side effects or adverse events). There is also a recommendation to 'refer people to a healthcare professional with expertise in menopause if treatments do not improve their menopause symptoms or they have ongoing side effects'. These would cover situations where treatments may take a longer time period to show improvement and if symptoms persist a healthcare professional with expertise in menopause could consider alternative treatments or diagnoses.

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My Menopause Centre	Guideline	018	018	The evidence presented compares with usual treatment but there is no specification of what this is. There is little evidence (which is acknowledged) for effectiveness. There is no acknowledgement that CBT may not be suitable for some people. There should be other recommendations for management of depressive symptoms including lifestyle changes. There is a risk that GPs will offer CBT only and there is very poor availability though the NHS.	Thank you for your comment. The wording has been revised to ensure clarity about CBT 'as an option: in addition to other treatments, for people for whom other treatments are contraindicated or for people who prefer not to have other treatments'. The committee acknowledged in the impact section of the guideline that there are long waiting times for CBT. They also noted that people currently trained in providing this kind of therapy may not be familiar with menopause-specific CBT and training on this may incur costs and increase waiting times in the short term. However, online and group CBT may be easier and less costly to adapt to menopause-specific CBT. There are also resources available to train people in providing menopause-specific CBT (and could also inform the adaptation of online CBT), which could facilitate implementation. Your comment will be considered by NICE where relevant support activity is being planned. In relation to lifestyle, in the 'information and support' section of the guideline it is recommended that healthcare professionals should provide information on 'interventions, or changes the person can make to support their health and wellbeing'.
My Menopause Centre	Guideline	019	002	Rec 1.4.37 There should be other recommendations for sleep. Sleep is a symptom for which there is little training. Other interventions should be considered under this heading, for which there is evidence, - e.g. HRT, lifestyle factors, alternative therapies (such as hypnosis, for which there is evidence), SSRIs. Sleep is a common symptom with good evidence for morbidity. This section does not	Thank you for your comment. Apart from CBT other management options for sleep problems associated with the menopause were not in the scope of the 2024 guideline update. However, the committee acknowledged that there are other options that may be used (including HRT). They have therefore reworded the recommendation to reflect this. It now states that CBT could be used as an option (1) in addition to other treatments (including HRT), or (2) for people for whom other

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				adequately address or guide HCP in managing women with sleep disorders in the menopause.	treatments are contraindicated or (3) for people who prefer not to have other treatments. Given the constraints of the scope they could not be more specific than this.
My Menopause Centre	Guideline	019	015	Rec 1.5.1 Please acknowledge that women who have had a subtotal hysterectomy or hysterectomy after endometriosis need to consider whether a progestogen is needed.	Thank you for your comment. The committee discussed that choice between oestrogen-only and combined HRT may be different for people with a sub-total hysterectomy. They decided that they could not be prescriptive about the type of HRT to be used for people who have had a sub-total hysterectomy because their condition is clinically complex, and they had not reviewed evidence about the effect of HRT on risk of endometrial cancer for this group. They acknowledged that people who were going to have, or had had, a sub-total hysterectomy would be under the care of a specialist who could discuss HRT options tailored to their needs (or a relevant specialist within the MDT). Due to a lack of evidence, no specific recommendation was made for sub-total hysterectomy; however, the term "total" was added before "hysterectomy" in guidance regarding the offer of oestrogen-only HRT to those who have had a hysterectomy. This addition alerts healthcare professionals to consider other factors for patients with a sub-total hysterectomy. The committee also noted that some people have a hysterectomy for a condition that may be affected by HRT, such as endometriosis. The committee did not review evidence related to such conditions. They recognised that the decision about the type of HRT that best balances benefits and risks for the person may be affected by that condition (for

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					example endometriosis) or having had a subtotal hysterectomy. For this reason, they added a recommendation highlighting that advice from a healthcare professional with specialist knowledge of that condition may be needed when making this choice. Due to this stakeholder comment and other related comments, this topic has been logged with NICE surveillance so that it can be considered for a possible update to either the Menopause or the Endometriosis guideline in future.
My Menopause Centre	Guideline	019	016	Rec 1.5.2 Lowest effective dosage for what? For symptom control or bone protection (where there is a history of osteoporosis)? Please clarify this point.	Thank you for your comment. The committee recommended the lowest effective dosage which would be reviewed in 3 months to assess efficacy and tolerability and annually thereafter (as highlighted in a different recommendation on reviewing treatments). All dosages would be within licensed ranges and a statement has now been added to emphasise this. The guideline does not specifically recommend HRT for bone protection (where there is a history of osteoporosis). The 2015 guideline mentioned in the context of premature ovarian insufficiency that both HRT and combined oral contraceptives offer bone protection. However, it is unclear whether this would require different dosages.
My Menopause Centre	Guideline	021	015	Rec 1.5.11 specialist psychology services are aspirational – please specify whether this would include liaison psychiatry to help prevent rejection of referrals. I am concerned that this recommendation, while laudable, creates false hope.	Thank you for your comment. As stated in the rationale, the committee agreed that it is common practice to provide psychological support to people. While a potential referral will have a resource impact, the committee agreed that specialist psychological services will lead to improvements in quality of life and reduce future contacts with health services. Your comment will

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					be considered by NICE where relevant support activity is being planned.
My Menopause Centre	Guideline	021	020	Please consider the use of the word 'troublesome' to reflect the severity and significance of symptoms that many women experience. Troublesome could be perceived as being glib and patronising.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
My Menopause Centre	Guideline	021	022	This statement contradicts that of the British Menopause Society/International Menopause Society and my concern is that it will cause more confusion.	Thank you for your comment. The committee noted that high-quality evidence showed no difference in mortality with either oestrogen-only or combined HRT. A decrease in all-cause mortality was reported for 1 isolated subgroup (women starting oestrogen-only HRT aged between 50 and 59). In isolation, it was a statistically significant figure. But in a wider context, it cannot be interpreted as good evidence of a different effect in this group. This is because: • there was not any identifiable pattern of changes in risk happening as people age and • the statistical subgroup analysis shows that this observed decrease could be accounted for by the play of random chance and therefore does not represent a real difference between age groups. As a result, the committee did not refer to this decrease in the recommendation. The rationale section has been updated with this information.
My Menopause Centre	Guideline	023	Table 1	The statement on breast cancer risk being increased LESS with transdermal preparations compared with oral – this is based on 1 study and contradicts Table 2 where there is no difference. There is no biological plausibility for this and it will cause confusion and anxiety amongst women who do not absorb oestradiol adequately from transdermal doses. No other study – Women's Health Initiative, Collaborative	Thank you for your comment. The statement has been removed and a research recommendation was added aimed to clarify matters related to different routes of administration.

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				Group on Hormonal Factors in Breast Cancer data or Million Women Study - shows this difference. Its inclusion needs justifying.	
My Menopause Centre	Guideline	023	Table 1	I understand the limitations of papers showing a difference in risk for different progestogens, but the MWS and others have shown there IS. This contradicts statements made by the BMS and will cause confusion and potential harm.	Thank you for your comment. The committee considered all the evidence that was relevant and included in the review. They agreed that there was insufficient evidence to support any differences in the risk of breast cancer with difference progestogens, and making a recommendation on limited evidence would cause more harm. The committee agreed that more evidence was required to make any robust recommendations, and agreed to make a research recommendation to support further work in the area. The committee's discussion of the evidence section in Evidence Report D has been updated to provide more detail regarding different preparations of combined HRT. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). However, they highlighted that RCT and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. These and other evidence reviews have been revised to implement these changes accordingly.

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My Menopause Centre	Guideline	026	Table 1	Risk of dementia. This data is not clear – no causal link has been proven. This will cause anxiety. Is the data clear that the risk is only when starting HRT over the age of 65? My understanding was that it is not clear if the risk is associated with starting or continuing HRT beyond 65. This will cause great anxiety to the many women who need to continue to take HRT for symptom control.	Thank you for your comment. For ages below 65 there was no clear evidence whether or not HRT increased the risk of dementia. One study showed no difference whereas another study showed an increase in the incidence of dementia. Given these discrepancies and potential for confounding in observational data, the committee based this recommendation on the available RCT data with participants that started HRT over the age of 65 and decided not to comment on people initiating HRT earlier. Where data were divided by duration of use the pattern was unclear with one study showing no difference and the other an increase. The committee therefore decided not to comment on duration of HRT use beyond the age of 65. This is described in the rationale section. The committee decided to retain the 2015 research recommendation on the effects of HRT on dementia.
My Menopause Centre	Guideline	035	004	Rec 1.6.4 Please make it clear that a lack of evidence does not indicate a lack of benefit – reading this section, this is the implication. There is evidence suggesting that the benefits of HRT for under 40s do not stop at 40. This section reads negatively. I am concerned that younger women with an early menopause will be under served. HRT will not be encouraged with increasing mortality (cardiovascular disease and osteoporosis) and morbidity (including psychological) as a result. This is also important as women from different ethnic backgrounds may be more likely to have an early menopause and these populations have already been shown to have lower uptake of HRT.	Thank you for your comment. The section on early menopause has been revised and only the message to explain to people experiencing early menopause that, for them, the benefits and risks of either taking or not taking HRT are likely to lie between those for people with premature ovarian insufficiency and those for people aged 45 or over has been retained from the consultation version. In accordance with the systematic review protocol only evidence on breast cancer was identified but it was decided that this highlighted that further research is necessary to clarify the benefits and risks. The committee also noted that the focus of this topic was too narrow to cover early menopause adequately and suggested several topics that based on stakeholder feedback which were logged with the NICE surveillance team for

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					future consideration in an update. This also includes the topic of the impact of early menopause itself on various health outcomes and what the best options are to manage potential negative impact. However, this was not part of the 2024 guideline update and so the committee could not comment on this.
My Menopause Centre	Guideline	037	008	Terms used. There is often confusion in primary care around the terms topical oestrogen and vaginal oestrogen and local oestrogen. This has led to harm as Oestrogel has been described anecdotally as 'topical' and so a progestogen has not been given, resulting in endometrial hyperplasia. Please consider adding to this section clarification of these terms.	Thank you for your comment. The committee decided that it would be readily understood what vaginal oestrogen refers to and therefore this terminology was used throughout the guideline rather than local. The terminology topical oestrogen is otherwise not used and therefore would not require a definition in the guideline. In other parts the terminology transdermal has been used to make a clear distinction between this and oral. The definition of systemic HRT includes gel as a part of so this and a recommendation has been made that people with a uterus if they wish to take HRT should be offered combined HRT.
My Menopause Centre	Guideline	038	013	Recommendations for research. The mention of testosterone is brief in rec 1.4.38. The demand for testosterone therapy is high in the community throughout the UK. Please guide on the need for more research into other potential benefits of testosterone. Many women report improvements to cognition and mood and more research is needed to clarify any benefits to other symptoms of the menopause, as well as other long-term benefits or risks.	Thank for your comment. The surveillance and scoping process for the 2024 guideline update did not identify substantive new evidence likely to change the existing recommendations on testosterone. Therefore, reviewing evidence on testosterone in relation to menopause care was not prioritised. However, NICE discussed the need for research in relation to testosterone use for menopausal symptoms with the National Institute for Health and Care Research (NIHR) and they prioritised funding for urgent research in this area.
My Menopause Centre	Guideline	038	013	Recommendations for research. Rec 1.3.3 correctly states awareness that women from ethnic minority backgrounds may experience menopause at a younger age.	Thank you for your comment. The topic of uptake of HRT in people from ethnic minority backgrounds was not in the scope of the 2024 guideline update. In accordance with NICE processes research

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				There is known poor uptake of HRT in this diverse group. A call for research would be therefore welcomed into the clarification of discrepancies and the reasons behind variations in HRT uptake – as well as access to menopause care – to help more women manage symptoms and long-term health consequences of the menopause.	recommendations can only be made on topics that are systematically searched for and reviewed. The suggested research recommendation could therefore not be added.
My Menopause Centre	Guideline	038	013	Recommendations for research. More research is needed in experience of the menopause, presentation and management for women with disabilities and this should include women with learning disabilities.	Thank you for your comment. Experience of the menopause and how it could vary in different groups of people was not in the scope of the 2024 guideline update. In accordance with NICE processes research recommendations can only be made on topics that are systematically searched for and reviewed. The suggested research recommendation could therefore not be added.
My Menopause Centre	Guideline	043	017	'The use of HRT in people experiencing early menopause' – should read as 'The use of HRT in people experiencing early or *premature* menopause'	Thank you for your comment. There is early menopause (menopause experienced between ages 40 to 44) and premature ovarian insufficiency (menopause experienced before the age of 40). Diagnosing and managing premature ovarian insufficiency in people under 40 is covered in section 1.7 of the guideline. Therefore, using the phrase people experiencing early or premature menopause is likely to cause confusion.
My Menopause Centre	Guideline	076	001	There is no mention of women who experience medical menopause – e.g. through use of chemotherapy or radiotherapy.	Thank you for your comment. The need to consider evidence for the people that are more likely to develop early menopause has been acknowledged. The committee have highlighted the following subgroups to the NICE surveillance team for incorporation into future menopause guideline updates when considering early menopause; spontaneous versus iatrogenic, people with disabilities (physical or mental, people with rare illnesses or underlying conditions), ethnic

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					minorities, specific disorders (for example, diabetes), medical menopause for example due to medical suppression of ovarian function (e.g., using GnRH analogues in the treatment of endometriosis or PMDD), people on chemotherapy/radiotherapy and surgical (hysterectomy, oophorectomy).
My Menopause Centre	Guideline	076	007	This is a very limited mention of menopause symptoms – there is nowhere in the guidance that addresses the full spectrum of menopause symptoms.	Thank you for your comment. Whilst an update of the list of symptoms and experiences was outside the scope of the 2024 guideline update and therefore no evidence review was conducted, the NICE surveillance team checks regularly for new evidence for topics within guidelines to see where further work is needed.
My Menopause Centre	Guideline	087		Appendix A – It would be useful to understand the figures given on the tables better by adding the papers the data refers to and the confidence limits to put these figures into context.	Thank you for your comment. For the draft guideline, the committee opted for a written format complemented by tables, providing estimates of absolute numbers from a single source rather than from two different study types. This differs from the approach used in the published version of NG23. This decision was made to facilitate conversations between clinicians and individuals, enabling shared decision-making regarding Menopause management. The appendix has been used to produce a discussion aid document including visualisation of the data. This provides details about the type of evidence data originated from, how to interpret the numbers and information about uncertainty. It also links to the relevant evidence reviews which contain details of the estimates from different study types (and the relevant sources) as well as the confidence intervals. It also includes links to a separate supplement file which provides the details of each calculation. This discussion aid has undergone

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					user-testing and was refined based on user feedback.
National Institute of Medical Herbalists	Guideline	General	General	We wish to enquire as to why the current draft guidance has not updated or reviewed the evidence relating to the use of herbal medicine in managing menopausal symptoms. Specifically sections 1.4.7 and 1.4.18 As these sections are shaded in grey we can not submit comments according to your guidelines. However, we wish to draw to your attention that since 2015, research in this area has considerably moved on. Specifically in relation to Black Cohosh and St John's Wort, a 2020 meta-analysis, published in the journal Climacteric, has concluded that: As benefits clearly outweigh risks, iCR/iCR+HP should be recommended as an evidence-based treatment option for natural climacteric symptoms. With its good safety profile in general and at estrogen-sensitive organs, iCR as a non-hormonal herbal therapy can also be used in patients with hormone-dependent diseases who suffer from iatrogenic climacteric symptoms. iCR - isopropanolic Cimicifuga racemosa extract (Black Cohosh) HP - Hypericum poerforatum (St John's Wort) Full text: https://www.tandfonline.com/doi/full/10.1080/13697137.2020.1820477	Thank you for your comment. The effectiveness of herbal medicines in the management of symptoms associated with the menopause was not in the scope of the 2024 guideline update. Evidence for this topic was therefore not searched for, reviewed or discussed with the committee. The committee could therefore not comment on this. The references listed have been checked and none of them meet the criteria set out in the protocols for the evidence reviews that were updated.

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				The Spanish Menopause Society has since duly updated its guidelines on Black Cohosh in 2022: There is evidence that iCR is an effective and safe therapeutic option for the treatment of VMS and psychological symptoms in climacteric women. This responds to the increasing demand for the use of non-hormonal therapies [4]. Given that the benefits outweigh the risks, iCR can be recommended to symptomatic climacteric women. Furthermore, given its safety profile in hor-mone-dependent organs, it may also be recommended for women with hormone-sensitive tumors suffering from iatrogenic VMS. It should be noted that according to the latest NICE guidelines on economic modelling, this is considered the most cost-effective alternative for treating climacteric symptoms in non-hysterectomized women and the second option in hysterectomized ones [56]. However, in conclusion, women should always be advised to use this treatment under medical supervision. Full text: https://www.tandfonline.com/doi/abs/10.1080/09513590.2022.2056591 We hope to receive a response from you and would be very happy to provide research support and guidance on the use of herbal medicines for menopause treatment. We are the oldest and largest register of professional medical herbalists in the UK.	

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Neuro-Informed Ltd	Guideline	General		The recommendation to use CBT may increase already high levels of stigma around menopause rather than recognising the known impact of lower estrogen levels on brain health.	Thank you for your comment. A systematic review of the evidence has been conducted and this showed CBT to be effective in the management of vasomotor symptoms, depressive symptoms and sleep problems. The committee reflected on the wording of the recommendations and revised it to clarify that CBT is an option (1) in addition to other treatments (including HRT) (2) for people in whom other treatments are contraindicated or (3) for people who prefer not to have other treatments.
Neuro-Informed Ltd	Guideline	General		While CBT may be of benefit to some people experiencing some symptoms of peri/menopause, it will not address the underlying cause which is a reduction in sex hormones. Women receiving CBT without HRT will miss out on the protection which it provides against osteoporosis and other chronic health conditions.	Thank you for your comment. HRT is still recommended in the guideline for vasomotor symptoms. The committee reflected on the wording of the recommendations related to CBT and updated it to make it explicit that this was not recommended as a first line treatment. It is now stated that it is an option (1) in addition to other treatments (including HRT) (2) for people in whom other treatments are contraindicated or (3) for people who prefer not to have other treatments. The committee recommended an approach that is tailored to the individual considering benefits and risks of each treatment in a shared decision-making process.
Neuro-Informed Ltd	Guideline	General		In providing training to women of peri/menopausal age, feedback from delegates highlighted that only 12% of women who could benefit from HRT were using it. 22% of participants described menopausal symptoms being 'dismissed' by their GP. 50% of women felt they had to hide their symptoms at work. Many experienced symptoms which they did not realise were associated with menopause. This points to a much greater need for	Thank you for your comment. Raising awareness by sharing information about the menopause was outside the scope of the guideline. NICE agrees that a greater understanding of the menopause and its impact could have a positive impact. The NICE surveillance team regularly checks for evidence related to guideline topics so that they could be considered for future updates.

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				education about the menopause for women, workplaces and GPs,	
Neuro-Informed Ltd	Guideline	General		ADHD does not appear to be mentioned in the menopause guidelines, however there is evidence that menopause has significant cognitive impact for women with ADHD and more research is required "More research is also required to elucidate the interaction of hormones, ADHD symptoms and stimulant medication on functioning during key times of hormonal change (e.g. during the menstrual cycle, pregnancy and the postpartum period, and menopause)"	Thank you for your comment. The impact and experience of menopause and the support needs was a topic that was referred to by many stakeholders and NICE takes reports of the impact on neurodivergent people (including those with ADHD) seriously. However, the committee asked the NICE surveillance team to log information and support as a topic to look for evidence. This could then be considered for future updates. The committee decided that interaction of hormones, ADHD symptoms and stimulant medication on functioning during key times of hormonal change (e.g. during the menstrual cycle, pregnancy and the postpartum period, and menopause) would be a topic more pertinent to an ADHD guideline rather than the menopause guideline.
Neuro-Informed Ltd	Guideline	General		I have heard extensively from women experiencing perimenopausal symptoms as a result of my work in training, development and brain health education. Women report challenges to accessing HRT with their doctor being dismissive of their symptoms. A recommendation to introduce CBT is likely to increase stigma rather than address the true underlying mechanism of estrogen deficits.	Thank you for your comment. The guideline recommends HRT for vasomotor symptoms, so it is expected that this is offered to women for this indication after a discussion about the benefits and risks, unless contraindicated. The recommendations related to CBT for vasomotor symptoms has been revised to clarify that this is an option (1) in addition to HRT (2) for people for whom HRT is contraindicated or (3) who prefer not to take HRT. Similar wording is used for CBT for depressive symptoms and sleep problems. The evidence showed that this was effective, and the committee therefore agreed that it should be an option.
Neuro-Informed Ltd	Guideline	General		At the age of 40 (when symptoms begin), many women are beginning to reach more senior levels in their career. 20% of women report	Thank you for your comment. NICE takes reports of the significant impact of menopause seriously. This was not a topic which was in the scope for the

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				leaving their job as a direct result of peri/menopausal symptoms. This impacts their finances, household, family, relationships, social connections, self esteem, cognitive engagement, mental health. The majority of these factors are also risk factors for dementia.	2024 guideline update. The NICE surveillance team regularly checks for evidence for topics in guidelines to be considered for future updates.
Neuro-Informed Ltd	Guideline	General		**There is evidence that Menopause impacts women's work. This has significant cost implications for families** In a study by the Fawcett Society, "44% of women said their ability to work had been affected, comprising 18% of women who said that their symptoms currently affected their ability to do their jobs, and 26% in the past. 61% said that they had lost motivation at work due to their symptoms, and 52% said they had lost confidence. " **"One in ten women who have been employed during the menopause have left work due to menopause symptoms.** Mapped on to the UK population that would represent an estimated 333,000 women leaving their jobs due to the menopause. 14% of women had reduced their hours at work, 14% had gone part-time, and 8% had not applied for promotion. " Menopause and the Workplace | April 2022 | www.fawcettsociety.org.uk	Thank you for your comment. NICE takes reports of the significant impact of menopause seriously. Experience of menopause at work and what women would want to know about this would fall into the category of the topic of information and support needs which included qualitative analysis of women's experience of the information they received. This was not a topic which was in the scope for the 2024 guideline update. The NICE surveillance team regularly checks for evidence for topics in guidelines to be considered for future updates.
Neuro-Informed Ltd	Guideline	General		2 / 3 people with Alzheimer's disease are female. Historically the reason given for this was that women lived longer. Recent neuroscience research has found that brain	Thank you for your comment. The review question investigated the impact of taking HRT or not taking HRT on dementia (including Alzheimer disease). The observational evidence showed no significant

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				changes associated with Alzheimer's can be seen two decades before symptoms are noticed and are associated with menopausal stage. In a systematic review and meta-analysis, encompassing over 6 million women, findings suggest that women who took hormones in mid-life to treat their menopause symptoms were less likely to develop dementia than those who hadn't taken estrogen.	differences in dementia risk when comparing oestrogen-only HRT with no HRT use. The evidence from the RCT also showed no significant differences in incidence of dementia, between those who are taking or have taken oestrogen-only HRT and those taking placebo. The committee therefore concluded that dementia is unlikely to increase with oestrogen-only HRT. Whether brain changes associated with Alzheimer's that can be seen two decades before symptoms are noticed are associated with the menopause is a different question that was not in the scope of the 2024 guideline and the committee could therefore not comment on this.
Newson Health Limited	Guideline	General	General	**Newson Health Limited stakeholder response to the NICE Menopause: diagnosis and management draft guideline consultation** **About Newson Health Group Limited** Newson Health Menopause and Wellbeing Centre was established in 2018 by Dr Louise Newson and Dr Rebecca Lewis in response to difficulties many women face in obtaining perimenopause and menopause treatment. Our clinicians provide individualised consultations, with a holistic approach to perimenopause and menopause. Treatment options, both HRT and non-hormonal treatments, are discussed which are relevant to each patient, their symptoms and also their future health. We operate nine clinics across the UK, offering both face to face and virtual appointments to around 4,000 women from all socioeconomic backgrounds each month. Newson Health's mission to improve the future health of women around the world. We reinvest	Thank you for your comment. Thank you for the information about Newson Health Group Limited. The committee acknowledged that the media has particularly focused on CBT when consultation on the guideline started. The recommendation related to CBT was revised to emphasise that CBT is an option (1) in addition to HRT (2) for people for whom HRT is contraindicated or (3) for people who prefer not to take HRT. The guideline recommends offering HRT for some symptoms, for example vasomotor symptoms. This has not changed since the 2015 guideline. One of the reasons the 2015 guideline required updating was the pharmacovigilance risk assessments by the MHRA and the EMA, concerning the impact of HRT on the risk of breast cancer. NICE is required to consider the impact of regulatory guidance from MHRA in its guidance and as such the additional information on breast cancer does change the balance of risks and benefits from that in the

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				significant portions of our profits from our clinics to fund research in hormone health and provide free menopause resources, including our free balance app and balance menopause website, which have been used by millions of people worldwide. We are also proud of our CPD-accredited Confidence in the Menopause online education programme, which has been accessed more than 32,000 times since its launch in 2021. **Our response to the NICE: Menopause diagnosis and treatment draft guideline** Too many women are currently being disserved by having to give up their work because of untreated symptoms, by being misdiagnosed with psychiatric disorders, and by not being listened to. So as an organisation which cares for thousands of women, and educates and empowers millions through our resources, we were dismayed to read the draft update to the 2015 NICE Menopause: diagnosis and management guideline. At best the draft guideline is a missed opportunity; at worst it represents a retrograde step for the health of millions of women, as well as healthcare professionals globally who depend on national guidelines like these to inform treatment and care. We felt compelled as organisation to respond and have set out our responses below. Our response also includes a summary of feedback of 665 women and healthcare professionals who submitted their views, personal stories and professional assessments of the draft guideline.	original 2015 guideline. There were other outcomes where the systematically reviewed evidence also showed an increased risk and the committee agreed that people should be made aware of these. However, this has to be seen in the context of absolute numbers and based on the numbers in the appendix of the consultation version of the guideline (with tables of absolute numbers) a discussion aid document has been developed which includes data visualisation as well as a verbal description of what the numbers mean. Descriptions of the underlying concepts and calculation are also provided. This includes estimates and that there are uncertainties around them. This discussion aid has undergone user-testing and was refined based on user feedback. In relation to symptoms and experiences of the menopause, NICE takes the reports of the debilitating symptoms, the considerable concern they cause, and the impact menopause has seriously. Whilst an update of the list of symptoms and experiences (including cognitive symptoms) was outside the scope of the 2024 guideline update and therefore no evidence review was conducted. The topic of symptoms and experience of the menopause has been logged with NICE surveillance team which checks regularly for new evidence for topics within guidelines to see where further work is needed. Thank you for the thematic analysis of the 665 responses that you received. Theme 1 CBT as primary treatment: CBT is intended to be an option rather than a primary

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				We urge you to consider our response and the hundreds of people who took the time to share their views as part of our response. We hope that you can rethink the current draft as it stands to ensure women have access to unbiased, evidence-based, individualised care for perimenopause and menopause they both need and deserve. **We urge a rethink of the recommendation that cognitive behavioural therapy (CBT) should be considered alongside or as an alternative to HRT** CBT might have a place when taking a holistic approach to managing some (but not all) symptoms of the perimenopause and menopause, but it is not relevant to most menopausal symptoms and won't treat the underlying hormone deficiency. In addition, recommending CBT at a time when there are already lengthy waiting lists for NHS talking therapy services is both shortsighted and risks further delaying women's access to appropriate treatment for management of the perimenopause and menopause. CBT will not address the health risks of the menopause either which needs to be highlighted. **The guideline needs to greater reflect the benefits of hormone therapy (HRT) as *the* first line treatment to improve symptoms** HRT is inexpensive, effective, reduces morbidity and improves life quality and life expectancy. Yet the current draft neglects most of these benefits.	treatment. The revision mentioned at the beginning of this response make this explicit. The wording related to CBT has also been changed from a 'treatment' to 'management' option. Theme 2 Advocacy of HRT: The guideline contains a strong recommendation related to offering HRT for vasomotor symptoms which has not been changed. How effective it is in the treatment of the vast range of symptoms that were mentioned by the respondents is unclear because neither the section on symptoms nor the effectiveness of HRT to treat all of them was part of the 2024 guideline update and the committee could therefore not comment on this. The topic of symptoms of menopause has been logged with the NICE surveillance team for future consideration. Theme 3: Criticism of the guideline's understanding of menopause, and frustration with limited recognition of menopausal symptoms: As highlighted above NICE takes the reports of the debilitating symptoms, the considerable concern they cause, and the impact menopause has seriously. Whilst an update of the list of symptoms and experiences (including cognitive symptoms) was outside the scope of the 2024 guideline update and therefore no evidence review was conducted. The topic of symptoms and experience of the menopause has been logged with NICE surveillance team which checks regularly for new evidence for topics within guidelines to see where further work is needed. Theme 4: Concerns about access to treatment: Access to HRT was not part of the scope of the

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				Only 14 per cent of menopausal women in the UK are currently prescribed HRT and in areas of deprivation it is much lower. In our clinical experience, we hear from women daily who are often told that they do not need HRT, or their symptoms are not related to their hormones. This amounts to medical gaslighting. It is our belief that publishing the draft in its current form will only serve to reduce the already patchy access to HRT even further. **The guideline needs to better reflect the long-term benefits of HRT** In addition to the numerous and often distressing symptoms, we must address the long-term health risks of hormone deficiency. There is good quality, established evidence about the protective effects of HRT in relation to osteoporosis, heart disease, clinical depression and colon cancer, and there is emerging evidence around dementia risk also being reduced. These are ignored in this draft document. **The perceived risks of breast cancer stated in the draft guideline are not based on good quality evidence** Breast cancer is mentioned 150 times in the draft, yet discussion about the potential risks of HRT focuses principally on older types of HRT. This too is a disservice to the thousands of women who could be helped by more modern forms of HRT, including body-identical and transdermal preparations. Much of the evidence used to discuss HRT risks regarding breast cancer are not relevant and depend on data	guideline. The committee acknowledges that this is an issue and that there are potential equality issues associated with this. However, the committee could not comment on this. Theme 5: The need for personalised care: People need to be heard and treated with dignity and respect, for example by taking their individual risk factors or triggers into account. Further detail on treating people as individuals and communicating with people is covered in the NICE guideline on patient experience in adult NHS services as well as in the NICE guideline on shared decision-making so this information is not repeated in all other NICE guidelines (they are cross referred to in recommendations 1.1.1 and 1.1.2). There is an emphasis throughout the guideline on tailoring information to the individual and information and support (see sections 1.1 and 1.2 of the guideline), for example it is emphasised that healthcare professionals should tailor their approach to the person at all times when identifying, discussing, investigating and managing menopause, and adapt the approach if symptoms change over time. It is also highlighted that information about benefits and risks needs to be individualised to the person's age, individual circumstances and potential risk factors. Theme 6: The importance of the patient voice: From the quotes within this theme, it seems that this is referring to the CBT recommendation. The related recommendation has been changed to explain that this is an option rather than a first line treatment. The guideline committee included 3 experts by experience who had input into the

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				from the discredited Million Women Study and also from WHI which did not have breast cancer as its primary end point. Oestrogen only HRT lowers future risk of breast cancer and also oestrogen only and combination HRT reduce the risk of dying from breast cancer but this is not highlighted in this draft guideline. **The guideline needs to reflect the full spectrum of perimenopause and menopause symptoms and associated long-term health risks** Menopause is described by NICE as a 'normal life transition'. To that, we have to ask: What is normal about having an increased risk of common diseases including cardiovascular disease, type 2 diabetes, osteoporosis, clinical depression and dementia: diseases behind more than 60 per cent of mortality in England? It is not normal, and it is not inevitable. **Public views which form part of our response** We are not alone in our disappointment at the numerous gaps and missed opportunities the draft guideline represents. As a stakeholder, we invited our patients, members of the public and fellow healthcare professionals to submit their comments to form part of our response to the consultation. The response to this callout was overwhelming, with a total of 665 responses received. We received comments from women currently experiencing the perimenopause and menopause, as well numerous responses from healthcare professionals, including GPs, nurses	wording of the pre-consultation document as well as the changes made post consultation. Theme 7: Importance of holistic and comprehensive care: The recommendation about discussions related to CBT have been amended to highlight that the healthcare professional should explain what CBT is (including menopause-specific CBT) and it has been added that the person's preferences and needs have to be taken into account in these discussions. Theme 8: Inclusion of testosterone in treatment: At the time when the scope of the 2024 guideline update was agreed, there was no substantive new evidence that would change the recommendation related to testosterone. However, NICE recognises the importance of this issue and has worked with the NIHR to prioritise funding for research on the matter. Theme 9: Need for better communication and support from healthcare professionals: NICE has developed 'foundational' guidelines, such as the NICE guideline on patient experience in adult NHS services as well as in the NICE guideline on shared decision-making which provide guidance about communication and support that should be provided to people with any condition accessing NHS services. These recommendations are overarching and therefore do not have to be repeated in every other NICE product. We note from the associated direct quotes that there also appear to be training issues related to this. Professional training is outside the remit of NICE since this is the responsibility of the related

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				and pharmacists. We also received several responses from counsellors, psychotherapists and psychiatrists specifically on the draft guideline recommendation that CBT be considered alongside or as an alternative to HRT. We have analysed these responses thematically and have identified nine recurring themes. These themes are listed below in order of frequency, from most to least common, along with representative quotes to illustrate views for each theme. **Theme 1: Criticism of cognitive behavioural therapy (CBT) as a primary treatment in the draft guideline** The most common theme in the responses is criticism of the emphasis on cognitive behavioural therapy (CBT) as a primary treatment for menopausal symptoms. Respondents argue that CBT is not a suitable replacement for hormone replacement therapy (HRT) and that it should be offered as a complementary treatment, not a primary one. They express concern that the focus on CBT may lead to the misconception that menopause is a mental health issue, rather than a physiological one. Representative quotes: *1. 'I am deeply concerned about the emphasis placed upon CBT in the upcoming guidelines.'* *2. 'As a psychotherapist who uses CBT techniques in my private practice I can honestly say I'm incensed: I was so incredibly unwell mentally that I was almost suicidal due to menopause symptoms. NO amount of using*	professional bodies. There are also laws and professional standards that healthcare professionals have to abide by. A list of these is highlighted in the following link at the beginning of the guideline - Making decisions using NICE guidelines.

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				CBT techniques helped me. It wasn't until I was prescribed the suitable HRT regime that I regained my quality of life.' *3. 'As a perimenopausal woman of 52, I felt patronised and insulted by the recommendation for the use of CBT to treat the menopause. How can CBT replace the hormones that my body is no longer able to produce and has caused my symptoms? I had crippling anxiety which only HRT solved.'* **Theme 2: Advocacy for HRT** Many respondents advocate for HRT as a primary treatment for menopausal symptoms. They argue that HRT is safe and effective, and that it should be offered to all women experiencing menopause. They express frustration with the perceived lack of access to HRT and the impact this has on women's mental health. Representative quotes: *1. 'I am a chartered Physiotherapist and a lecturer (so very familiar with academic research) and yet there was nothing I could do to alleviate the menopause symptoms until I started HRT.'* *2. 'Providing CBT is illogical as the symptoms are due to a lack of hormones. I am actually begging you to please treat women with the respect we deserve & allow us to live our lives with the hormones that we need.'* *3. 'As a GP of 25 years, I've made more difference to the quality of my patients lives and that of their families, by prescribing HRT, than any other medical intervention.*	

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				We continue to underestimate the benefits of HRT both short and long term at our peril. *I have seen lives, devastated by the impact of osteoporosis, which has resulted directly from hormonal deficiencies, which were entirely preventable.* *The new NICE guidance is not only hugely disappointing and short sighted to those of us who have been trying to promote good care for women in both the perimenopause and menopause but I genuinely believe could be hugely harmful in the long run.* *To underestimate the benefits of HRT to both the individuals involved, and those around them is such a backward step which will sadly cost both lives and money which both our healthcare and our economy desperately need.'* **Theme 3: Criticism of the guideline's understanding of menopause, and frustration with limited recognition of menopausal symptoms** Several respondents criticise the guidelines for not fully understanding or addressing the range of menopausal symptoms. They argue that the guidelines should include a broader list of symptoms to better reflect the experiences of women going through menopause and recognise the significant impact of menopause on women's lives. Representative quotes: *1. 'The proposed Guidelines use a far too narrow list of menopausal symptoms.'* *2. 'No mention of brain fog, low energy, mood swings, gastro-intestinal changes, weight changes and more as experienced by women.'*	

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				3. 'What about mentioning the lack of energy/loss of interest in daily activities/loss of self-worth and confidence/feelings of madness/feelings of rage (especially at people belittling menopausal symptoms)/hormonal acne/allergies/brain fog/mood swings and all the other symptoms that are listed in the balance app?' *4. 'I have spent 3 years with poor sleep, weight gain, but mainly Genitourinary Syndrome of Menopause. When I read the recommendation, I actually laughed; it is part of the ongoing structural patriarchy that us women are so sick to death of, bored of, exhausted by. If menopause symptoms affected men in the gravity they impact women there is absolutely no chance that any report would come out advising CBT as a possible option.'* **Theme 4: Concerns about access to treatment** Some respondents express concerns about access to treatment, particularly HRT. They argue that there are barriers to accessing appropriate support and help for menopause symptoms, and that these barriers need to be addressed. Representative quotes: *1. 'I know many women who have struggled to access appropriate support and help for menopause symptoms.'* *2. 'I'm on HRT. For 2.5 years I've suffered from multiple perimenopause symptoms and after listening to you helped me to make my case to my GP for HRT. They tried to push me down the anti-depressant route as a starting point, but*	

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				I was having none of that. One of the dominant symptoms aside from lack of libido, which affected my relationship, was horrendous brain fog... I tried to push for testosterone, but GP wouldn't prescribe it...' *3. 'I'm suffering severe mental health problems due to menopause. My antidepressant dose has been doubled and I have been started on pregabalin. A decision has not been made on HRT yet... but I would like HRT to help with my mental health and give me long term health protection.'* **Theme 5: The need for personalised care** Respondents highlight the need for personalised care in the management of menopause. They argue that treatment should be tailored to the individual's circumstances and needs, rather than a one-size-fits-all approach. Representative quotes: *1. 'It is important that healthcare practitioners take a personalised approach when discussing treatments, using evidence-based information tailored to individuals' circumstances.'* *2. 'As a therapist, I want to say that the suggestion people might benefit from CBT tells me that this is still considered something that can be resolved by the way you think about it... There are much better ways to work with symptoms in terms of listening to oneself and the body, accepting one's feelings about the changes that are occurring and having compassion for oneself. However, none of this can compensate for the impact changing hormones has on fluctuating mood, physical sensations, and issues such as bleeding for*	

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				months at a time, cold sores, fluctuating exhaustion, lack of sex drive, dizziness, palpitations, food intolerance, bloating, brain fog and many other things…how dare they.' *3. 'I believe that whilst CBT has its place it does not and will not help all of the symptoms. HRT should be used alongside it... Women have a right to have their reducing hormones replaced for quality of life.'* **Theme 6: The importance of the patient voice** Respondents emphasise the importance of the patient voice in shaping guidelines and treatment options. They argue that the experiences and perspectives of women going through menopause should be central to the development of guidelines and treatment approaches. Representative quotes: *1. 'I can imagine a scenario where women are refused HRT pending CBT, and the waiting lists in my area are over two years for mental health services. Essentially, I see recommending CBT as another way for NHS professionals to gaslight women into not getting the care they need.'* *2. 'It's medical negligence that 50% of the population are not supported or prepared for quite seismic changes to a human being... I have had to fight every step of the way to get my hormones replaced and it is only now, 5 years post menopause am I stable.'* *3. 'Cognitive therapy cannot be a first line 'treatment' for a disorder of the endocrine system... I lost 3 years of my life to the suffering*	

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				of peri menopause, being a health professional myself I was at least lucky enough to have an understanding of health and lifestyle choices to support myself, and afforded private health care, others are not so fortunate sadly. Health Inequality at its finest!' **Theme 7: Importance of holistic and comprehensive care** Respondents emphasize the need for a holistic and comprehensive approach to menopause care. They argue that healthcare professionals should consider all aspects of a woman's life, including physical, emotional, and social factors, when providing treatment and support. Representative quotes: *1. 'If CBT is going to be offered it should not be capped in duration, and therapists should have a broad, holistic and menopause educated approach.'* *2. 'Feedback on recommendation that CBT be offered as an alternative or complimentary treatment for menopause symptoms: this is a retrograde step that implies that some of the symptoms of the menopause and perimenopause are not a consequence of the reduction in hormones but instead a psychological reaction to the menopause experience... CBT cannot be considered an alternative to HRT but may offer some help to those who cannot take it or do not want it.'* *3. 'I completely agree with Newson Health's stance on managing menopause. I believe the proposed NICE guidelines are a step backwards for women's health. CBT may have a place when taking a holistic approach to*	

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				managing the perimenopause, but it won't improve every menopause symptom and won't treat the underlying hormone deficiency.' **Theme 8: Inclusion of testosterone in treatment** Some respondents highlight the importance of considering testosterone as part of menopause treatment. They share their experiences with testosterone therapy and its positive impact on their symptoms. Representative quotes: *1. 'My GP finally prescribed testosterone, but wanted me to say it was for a low sex drive (which it wasn't in fact, there was, and is, nothing wrong with my sex drive!) then she could prescribe it.'* *2. 'I now take oestrogen, progesterone and testosterone. To say it was transformative is no exaggeration. The debilitating hot flushes tolerated for over 15 years stopped... I cannot get an NHS prescription for Testosterone. I have appealed 3 times, sent NICE guidelines, but my GP will not prescribe it without a consultant approving it.'* *3. 'Finally access to testosterone including more research on testosterone levels to baseline women before perimenopause so it's better understood. My Dr is still waiting for the local guidelines to change as she's unable to prescribe.'* **Theme 9: Need for better communication and support from healthcare professionals** Respondents call for better communication and support from healthcare professionals when it	

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				comes to menopause treatment. They share their experiences of feeling dismissed or misunderstood by their healthcare providers. Representative quotes: *1. 'It angers me that CBT is being recommended as an alternative treatment to HRT. I gave up on accessing healthcare support for my symptoms of perimenopause via the NHS as my GP was ill-educated, over-stretched and hell-bent on fobbing me off. Firstly I was refused any symptom-based treatment, referred for blood tests that I waited months for and then nobody followed up with me whatsoever. My symptoms were so bad that during that time I accessed support and care privately... My worry is that by including CBT as an alternative recommendation to HRT this is going to be seized by doctors as a method refuse women HRT when they really need it.'* *2. 'It is only in recent times that women have felt able to feel liberated enough to talk about the menopause openly and to share their experiences. This in turn has led to a greater understanding of the signs and symptoms and a realisation that there is treatment that can significantly impact the health and wellbeing of those suffering from perimenopausal/ menopausal signs and symptoms.'* *3. 'Talking therapies cannot help with physical aches and pains, loss of libido, mental sharpness, mood swings and cannot replace lost hormones. They help with managing situations and responses. Maybe talking therapy would help women deal with the enormous frustration many feel whilst trying to access HRT.'*	

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				Conclusion Women deserve to be educated and involved at every step of their healthcare consultation to make an informed decision on the right treatment or combination of treatments for them. And while we have seen a rise in recent years in women accessing HRT, a postcode lottery still exists, particularly for those from lower socio-economic backgrounds. The menopause is sorely under-researched and under-funded, and this must change. In the meantime, women deserve to have a choice, and those who want to take HRT should be able to have it prescribed. Healthcare professionals too deserve to be able to access balanced, evidence-based and comprehensive guidance which they can use to best help their patients. Half of the UK population will experience the perimenopause and menopause during their lifetimes, and an updated guideline update presents a golden opportunity to improve the lives of menopausal women. We urge you to consider our response, and the views of the hundreds of people who contributed to it and rethink the current draft.	
Newson Health Limited	Guideline	General	General	**[This text was identified as confidential and has been removed]**	Thank you for your comment. Please refer to your organisation's other comment, and the detailed response we have provided.
NHS England	Guideline	General		The additional detail and clarity is welcome since uncertainties around this topic that can use a considerable amount of primary care consultation time.	Thank you for your comment in support of this.

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NHS England	Guideline	general	general	Research on autistic people's experiences of menopause is very limited. There have been some qualitative studies (see link below) of autistic women's experiences of menopause where they mention exacerbation of some existing difficulties and, in some cases, some new issues. 'When my autism broke': A qualitative study spotlighting autistic voices on menopause - Rachel L Moseley, Tanya Druce, Julie M Turner-Cobb, 2020 (sagepub.com) This paper also highlights that autistic women experience higher menopausal complaints and were associated with higher levels of depression and autistic traits: https://journals.sagepub.com/doi/full/10.1177/13623613211059721 Public Health England found that women with a learning disability had similar experiences of menopausal symptoms to other women but that they had poorer understanding of menopause and menstruation. Level of knowledge about the menopause has been found to be generally low in women with a learning disability. There is a need for better understanding by healthcare professionals of how to support autistic women and those with a learning disability with menopausal symptoms. Health_inequalities_menopause.pdf	Thank you for your comment. The impact and experience of menopause and the support needs was a topic that was referred to by many stakeholders and NICE takes reports of the impact on neurodivergent people seriously. Prevalence of early menopause was also not part of the 2024 guideline update. The committee could therefore not comment on these topics. However, the committee asked the NICE surveillance team to log prevalence of menopause (including in different populations) as a topic to look for evidence. This could then be considered for future updates. The cited references have also been passed on to the NICE surveillance team so that they can be considered for future updates.

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				Women with Down syndrome tend to go through menopause at a slightly younger age. The median age of menopause in women with Down syndrome was reported to be 46 (Seltzer et al., 2001). The median age of menopause in white women without Down syndrome from industrialized countries was reported to be between the ages of 50-52. Menopause in Women with Down Syndrome | Adult Down Syndrome Center (advocatehealth.com)	
NHS England	Guideline	general	general	We strongly suggest the document makes reference to making reasonable adjustments to care for disabled people. This is a legal requirement as stated in the Equality Act 2010. Adjustments aim to remove barriers, do things in a different way, or to provide something additional to enable a disabled person to receive the assessment and treatment they need. Possible examples include; allocating a clinician by gender, taking blood samples by thumb prick rather than needle, providing a quiet space to see the patient away from excess noise and activity. We recommend including reference to the Reasonable Adjustment Digital Flag (RADF) and the Information Standard Notice which mandates all providers and commissioners of health services and publicly funded social care to identify, record, flag, share, meet and review reasonable adjustments for disabled people who need them	Thank you for your comment. Making reasonable adjustments as required by the Equality Act is a statutory requirement and so this requirement would not need to be repeated in each individual NICE guideline.

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				DAPB4019: Reasonable Adjustment Digital Flag - NHS Digital	
NHS England	Guideline	general	general	We recommend including a reference to the importance of communication: Using simple, clear language, avoiding medical terms and 'jargon' wherever possible. Some people may be non-verbal and unable to describe verbally how they feel. Pictures may be a useful way of communicating with some people, but not all. Ask the person, and/ or their family or carers, what their communication preferences are and whether this information is in a communication or health and care passport	Thank you for your comment. T, Information needs to be accessible and adapted to each individual, making sure that the person is heard and being treated with dignity and respect (which would include for example giving information in the most suitable format to tailor to the individual). Further detail on treating people as individuals is covered in the NICE guideline on patient experience in adult NHS services as well as in the NICE guideline on shared decision-making so this information is not repeated in all other NICE guidelines (which is the reason why they are cross referred to in recommendations 1.1.1 and 1.1.2). There is an emphasis throughout the guideline on tailoring information to the individual, for example it is emphasised that information about benefits and risks needs to be individualised to the person's age, individual circumstances and potential risk factors. There are also recommendations that highlight that a family member or carer can be involved. Making reasonable adjustments as required by the Equality Act 2010 is a statutory requirement and so this would not need to be repeated in each individual NICE guideline. The Equalities Impact Assessment has been reviewed and we have included further points in the section on disabilities to emphasise the person-centred approach that the committee has taken which they felt would positively impact these groups.
NHS England	Guideline	general	general	Please note recent LeDeR research: Master LeDeR 2023 (2022 report) (kcl.ac.uk)	Thank you for highlighting this. The committee noted that the annual LeDeR report relates to

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					deaths of people with a learning disability and autism in general. However, it does not refer to menopause. The report therefore does not specifically apply to this guideline.
NHS England	Guideline	General	General		There is no comment. So, we cannot respond to this.
NHS England	Guideline	023 - 034		The level of detail in these tables is extremely helpful for professionals and the public when considering risk.	Thank you for your comment in support of this.
NHS England	Guideline	008	009	When referring to 'a healthcare professional with expertise in menopause', it must say that the menopause specialist needs to liaise with the team treating the breast cancer for a discussion of risk versus benefit. Many only consider HRT which is mainly contraindicated.	Thank you for your comment. This recommendation does not specifically relate to HRT, but talks about all treatment options available for symptoms associated with the menopause. The 'healthcare professional with expertise in menopause' has been defined in the 'terms used in the guideline' section (which is hyperlinked) as someone 'who can advise and support colleagues in managing complex menopause-related needs and risk factors affecting decision making, including: complex medical problems that potentially affect use of treatments for menopause symptoms and menopause symptoms for those at elevated risk of breast or ovarian cancer or with a personal history of hormone dependent cancer, in collaboration with oncologists'. It therefore states that there is a need to liaise with oncology where appropriate.
NHS England	Guideline	017	014	Wonder whether there should be something in this sentence about communication with their oncologist given that vaginal oestrogen preparations are accessible (although unlikely to be directly supplied to this group of course) over the counter which can lower the public perception of risk. Also to flag the importance of sharing the information across healthcare	Thank you for your comment. The committee reflected on this and thought adding communication with the oncologist to this recommendation would make it sound more concerning than intended. However, they specifically recommended discussions with the oncologist specialist for people who have adjuvant aromatase inhibitor treatment.

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				environments. The sentence could read ….”cancer, troublesome genitourinary menopause symptoms that have continued despite trying non-hormonal treatments and following consideration of discussion with their oncology specialist.”	
NHS England	Guideline	019	016	This statement is a helpful reminder since the recent publicity around HRT seems to have prompted a greater appetite and a lower wariness of risk for HRT. The dose required to relieve symptoms (and also the dose requirement for premature ovarian insufficiency) is likely to fall with time, wonder if there should be something about review of dose on p21 line 1?	Thank you for your comment. The committee recommended the lowest effective dosage which would be reviewed in 3 months to assess efficacy and tolerability and annually thereafter (as highlighted in a different recommendation on reviewing treatments). All dosages would be within licensed ranges and a statement has now been added to emphasise this. The reviews would assess effectiveness and tolerability and dosages could be adjusted accordingly. The committee did not want to be prescriptive about decreasing dosage over time to provide flexibility related to clinical judgement.
NHS Somerset Integrated Care Board (ICB)	Guideline	General	General	Whilst there is a place for CBT, we believe there has been overemphasis on the use of CBT in managing menopause. 42 mentions throughout document.	Thank you for your comment. The wording of the recommendation has been revised to make it explicit that this is an option which could be in addition to HRT, for people in whom HRT is contraindicated or for those who prefer not to take HRT.
NHS Somerset Integrated Care Board (ICB)	Guideline	General	General	Pleased to see inclusion of trans and non-binary people within the guidance.	Thank you for your comment in support of this.
NHS Somerset Integrated Care Board (ICB)	Guideline	General	General	Develop a patient decision aid on the risk and benefits of HRT.	Thank you for your comment. Based on the numbers in the appendix of the consultation a discussion aid document has been developed which includes data visualisation as well as a verbal description of what the numbers mean. Descriptions of the underlying concepts and calculation are also provided. This discussion aid

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					has undergone user-testing and was refined based on user feedback.
NHS Somerset Integrated Care Board (ICB)	Guideline	General	General	There is not a significant emphasis on the benefits of HRT in the document.	Thank you for your comment. Recommendations related to offer HRT for vasomotor symptoms and the recommendation to consider it for depressive symptoms have not changed in the 2024 guideline update. Neither has the information on osteoporosis which shows a decrease of incidence of fragility fractures with HRT. One of the reasons the 2015 guideline required updating was the pharmacovigilance risk assessments by the MHRA and the EMA, concerning the impact of HRT on the risk of breast cancer. NICE is required to consider the impact of regulatory guidance from MHRA in its guidance and as such the additional information on breast cancer does change the balance of risks and benefits from that in the original 2015 guideline. The guideline adopts a person-centred approach emphasising that the information about benefits and risks of HRT should be tailored to the person's age, individual circumstances and potential risk factors - see the 'discussing management options' section.
NHS Somerset Integrated Care Board (ICB)	Guideline	General	General	No guidance re recurrent UTIs. Needs to be mentioned and signpost to page 15 of NG112 patient decision aid re Genitourinary symptoms. NG112 Patient decision aid on reducing the chance of recurrent urinary tract infection (UTI) in postmenopausal women (nice.org.uk)	Thank you for your comment. A link to the patient decision aid on reducing the chance of recurrent urinary tract infection (UTI) in postmenopausal women in the NICE guideline on urinary tract infection (recurrent) has been added.
NHS Somerset Integrated Care Board (ICB)	Guideline	General	General	More guidance required on treatment pathways, particularly transdermal, oral or topical and the dosing and suitability for clinicians choosing treatment options with their patient.	Thank you for your comment. Tables 1 and 2 include information on the impact of route of administration and different treatment regimens (such as continuous or sequential combined HRT). The committee reflected on the presentation of

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					risks and concluded that there could be more information and visualisation of the data in the appendix of the consultation version. Details have been added to facilitate discussions between the person and the healthcare professional. Furthermore, the absolute numbers in the appendix were reviewed and used to produce a discussion aid document with visualisation of the data and verbal description aimed to facilitate shared decision-making. This discussion aid has undergone user-testing and was refined based on user feedback.
NHS Somerset Integrated Care Board (ICB)	Guideline	General	General	Advice/signposting needed for where non-specialists need to look for guidance regarding HRT.	Thank you for your comment. Tables 1 and 2 include information on the impact of route of administration and different treatment regimens (such as continuous or sequential combined HRT). The committee reflected on the presentation of risks and concluded that there could be more information and visualisation of the data in the appendix of the consultation version. Details have been added to facilitate discussions between the person and the healthcare professional. The absolute numbers in the appendix were reviewed and used to produce a discussion aid document with visualisation of the data and verbal description aimed to facilitate shared decision-making. This discussion aid has undergone user-testing and was refined based on user feedback.
NHS Somerset Integrated Care Board (ICB)	Guideline	023 - 034	General	What guidance should we be following nationally re the risks and benefits of HRT? The tables included in the draft are incomplete, without comparisons between oral and transdermal for some risks	Thank you for your comment. Where there is evidence and a difference between transdermal and oral HRT this is covered in 'Does the way combined / oestrogen-only HRT is taken affect these risks' column. Where this is not included due to insufficient or lack of data, a research

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					recommendation has been made. This is then described in the related rationale section.
NHS Somerset Integrated Care Board (ICB)	Guideline	023 - 034	General	Does not appear to be differentiation around risks and benefits between oral, transdermal and topical HRT.	Thank you for your comment. Where there is evidence and a difference between transdermal and oral HRT this is covered in 'Does the way combined / oestrogen-only HRT is taken affect these risks' column. Where this is not included to insufficient or lack of data, a research recommendation has been made. This is then described in the related rationale section.
NHS Somerset Integrated Care Board (ICB)	Guideline	023 - 034	General	Risk and benefits of HRT do not include ovarian insufficiency.	Thank you for your comment. Ovarian insufficiency is covered in section 1.7 on 'Diagnosing and managing premature ovarian insufficiency'.
NHS Somerset Integrated Care Board (ICB)	Guideline	023 - 034	General	Lack of guidance on choice of HRT i.e. continuous or combined.	Thank you for your comment. Where there is evidence and a difference between continuous and sequential combined HRT this is covered in 'Does the way combined / oestrogen-only HRT is taken affect these risks' column.
NHS Somerset Integrated Care Board (ICB)	Guideline	078 - 079	General	What should the GP do if patient reports vaginal bleeding? a. Vulval cancer pathway b. Endometrial cancer pathway c. Lichen sclerosis	Thank you for your comment. This is in reference to the update table. The related comment to vaginal bleeding was removed from the body of the text and consequently the update table.
NHS Somerset Integrated Care Board (ICB)	Guideline	019	006	More guidance required around the use and benefits of testosterone for other symptoms other than just for altered sexual function.	Thank you for your comment. At the time when the scope of the 2024 guideline update was agreed, there was no substantive new evidence that would change the recommendation related to testosterone. It was therefore not included in the update and the committee could not comment on this. However, NICE recognises the importance of this issue and has worked with the NIHR to prioritise funding for research on the matter.

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NHS Somerset Integrated Care Board (ICB)	Guideline	058	014 - 015	There is no need for consideration of progesterone for people without a uterus as it is only currently used to protect the endometrium this may change as further research progresses into the wider role of progesterone.	Thank you for your comment. As pointed out progesterone is currently not given to people who do not have a uterus which is stated in the guideline. NICE surveillance regularly checks for evidence on topics in guidelines and if further research progresses which may change this conclusion this can be considered for an update in future.
NHS Somerset Integrated Care Board (ICB)	Guideline	096	Appendix A	More information required on table on page 96 – Appendix A re osteoporosis. There is a link to resource but the source is not clear.	Thank you for your comment. Parts of the osteoporosis tables were incorrect in the 2015 guideline and have been updated to rectify this. It still shows that HRT improves fracture risk, but the RCT and observational data now align. The error related to the source of the data has now been clarified and corrected.
Pelvic Obstetric and Gynaecological Physiotherapy (POGP)	Guideline	General	General	potential improvement of joint pain Resource https://movingmedicine.ac.uk/consultation-guides/condition/adult/menopause/ A small number of randomised controlled trials and some cross-sectional studies showed that increased levels of physical activity led to reduced levels of joint pain. The form of physical activity in the randomised controlled trials varied between daily stretching, gym-based exercises and aerobic exercise but all showed significant improvement in symptoms (1,2,3). This was in both menopausal and peri-menopausal women. In the cross-sectional studies those undertaking at least the recommended amount of physical activity as per their countries national guidelines reported much less joint pain symptoms than those who didn't.Quality of Evidence: Grade B – there is some evidence from RCTs that joint	Thank you for your comment. The effects of physical activity in the management of symptoms associated with the menopause was not in the scope of the 2024 guideline update. Evidence for this topic was therefore not searched for, reviewed or discussed with the committee. The committee could therefore not comment on this. The references listed have been checked and none of them meet the criteria set out in the protocols for the evidence reviews that were updated.

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				pain is reduced with increased levels of physical activity, particularly if the national guidelines are met. Strength of Recommendation: Grade 2 – limited number of good-quality RCTs. Conclusion: Studies have shown that increased physical activity levels can lead to reduced joint pain in peri and post-menopausal women. Daily stretching and moderate aerobic exercise have shown encouraging signs of improvement in symptoms in RCTs, but further trials are needed to determine the optimal dose, frequency and type of exercise to control symptoms most effectively References: 1. Kai, Y., Nagamatsu, T., Kitabatake, Y. and Sensui, H. (2016) 'Effects of stretching on menopausal and depressive symptoms in middle-aged women: a randomized controlled trial', 1(8), pp. 827-32. 2. Courneya, K. S., McNeil, J., O'Reilly, R., Morielli, A. R. and Friedenreich, C. M. 'Dose-Response Effects of Aerobic Exercise on Quality of Life in Postmenopausal Women: results from the Breast Cancer and Exercise Trial in Alberta (BETA)'. 3. Javadivala, Z., Allahverdipour, H., Jafarabadi, M. A. and Emami, A. (2020) 'An	

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				Interventional strategy of physical activity promotion for reduction of menopause symptoms', *Health Promotion Perspectives,* 10(4), pp. 383-392. 4. Kim, M. J., Cho, J., Ahn, Y., Yim, G. and Park, H. Y. (2014) 'Association between physical activity and menopausal symptoms in perimenopausal women', *Bmc Womens Health,* 14 5. Lum, K. J. and Simpson, E. E. A. (2021) 'The impact of physical activity on psychological well-being in women aged 45-55 years during the Covid pandemic: A mixed-methods investigation', *Maturitas,* 153, pp. 19-25. 6. Tan, M. N., Kartal, M. and Guldal, D. 'The effect of physical activity and body mass index on menopausal symptoms in Turkish women: a cross-sectional study in primary care'. 7. Mansikkamäki, K., Raitanen, J., Malila, N., Sarkeala, T., Männistö, S., Fredman, J., Heinävaara, S. and Luoto, R., 2014. *Physical activity and menopause-related quality of life – A population-based cross-sectional study*. 8. Dabrowska-Galas, M., Dabrowska, J., Ptaszkowski, K. and Plinta, R. (2019) 'High Physical	

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				Activity Level May Reduce Menopausal Symptoms', *Me*	
Pelvic Obstetric and Gynaecological Physiotherapy (POGP)	Guideline	general	general	Considering the evidence for physical activity in terms of symptom management as well as health outcomes-in particular Higher intensity & multidirectional impact and strength training, there appears to be a lack of evidence in the guidelines. • The efficacy of strength exercises for reducing the symptoms of menopause, a systematic review Ana María Capel-Alcaraz et al. J Clin Med. 2023. The search was 2015/2022 and 12 articles selected. The results showed improvements in the strength of the legs and pelvic floor, physical activity, bone density, metabolic and hormonal changes, heart rate and blood pressure and a change in hot flashes. Conclusions: There is evidence that strength exercises can be beneficial for improving strength, physical activity, bone density and hormonal and metabolic levels. In terms of the appropriate type of strength training, the evidence is still unclear given that the same benefits are achieved by various types of exercises. 1. 2.Comparative efficacy different resistance training protocols on bone mineral density in postmenopausal women: A systematic review and network meta-analysis	Thank you for your comment. The effects of physical activity in the management of symptoms associated with the menopause was not in the scope of the 2024 guideline update. Evidence for this topic was therefore not searched for, reviewed or discussed with the committee. The committee could therefore not comment on this. The references listed have been checked and none of them meet the criteria set out in the protocols for the evidence reviews that were updated.

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				SYSTEMATIC REVIEW article Front. Physiol., 07 February 2023 Sec. Skeletal Physiology Volume 14 - 2023 | https://doi.org/10.3389/fphys.2023.1105303 Objective: To systematically review the effects of different resistance training (RT) protocols on bone mineral density (BMD) in postmenopausal women. Methods: Randomized controlled trials (RCTs) on the resistance training in improving bone mineral density for postmenopausal women were searched in databases including ProQuest, PubMed, Cochrane Library, Embase, and Web of Science. The retrieval time range was from the establishment of the database to May 2022. The included literature was independently screened and relevant data was extracted by two reviewers. The systematic review followed the Joanna Briggs Institute (JBI) methodology for reviews of quantitative evidence. Quality of risk was assessed using the Physical Therapy Evidence Database (PEDro) scale, risk of bias was assessedusing the Cochrane RoB2 tool and a network Meta-analysis was performed on the data using Stata 16.0. Conclusion: Current evidence shows that moderate intensity resistance training for 3 days/week can be preferred clinically to improve bone mineral density in postmenopausal women, and it is recommended that the duration of the same training should not exceed 1 year.	

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				Nevertheless, more high-quality studies are needed to verify the above conclusion 1. Does Menopausal Hormone Therapy, Exercise, or Both Improve Pain and Function in Postmenopausal Women With Greater Trochanteric Pain Syndrome? A 2 × 2 Factorial Randomized Clinical Trial Cowan, Rachael Mary, et al. "Does menopausal hormone therapy, exercise, or both improve pain and function in postmenopausal women with greater trochanteric pain syndrome? A 2× 2 factorial randomized clinical trial." *The American journal of sports medicine* 50.2 (2022): 515-525. Postmenopausal women (Menopausal Hormone Therapy) (N = 132; n = 12, lost to follow-up) with GTPS were randomized into MHT and placebo transdermal cream groups combined with tendon-specific or sham exercise. All groups received education about avoiding gluteal tendon compression and load management throughout 12 weeks of intervention. The primary outcome was the Victorian Institute of Sport Assessment for gluteal tendinopathy (VISA-G), and secondary outcomes were measured at baseline and at 12 and 52 weeks. The Global Rating of Change was assessed at 12 and 52 weeks. A linear mixed-effects model was used to assess differences. Body mass index (BMI) was included as a covariate.	

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				MHT or placebo combined with tendon-specific or sham exercise plus education reduced pain and increased function for this population. For women with a BMI <25, MHT with any exercise plus education was better than placebo. A targeted exercise or sham exercise strategy is effective when prescribed with education about avoiding gluteal tendon compression and load management.	
Pelvic Obstetric and Gynaecological Physiotherapy (POGP)	Guideline	014		1.4.16 Consider Physical activity for troublesome vasomotor symptoms associated with the menopause, as well as CBT- there is some evidence for treatment of vaso-motor symptoms-Moving Medicine produced a menopause resource- Quality of Evidence: Grade A – a systematic review, literature review and several RCTs have reviewed the effect of physical activity on vasomotor symptoms. Resource https://movingmedicine.ac.uk/consultation-guides/condition/adult/menopause/ A systematic review and literature review both concluded that there was little improvement in vasomotor symptoms with a variety of different forms of physical activity (1,2). No form of physical activity, particularly aerobic or resistance exercise, showed led to a consistent improvement in vasomotor symptoms. However, the three more recent randomised controlled trials of various forms of physical activity including walking, stretching and gym-based exercises showed significant improvements in vasomotor symptoms Conclusion:	Thank you for your comment. The effectiveness of physical activity on symptoms associated with the menopause was not in the scope of the 2024 guideline update. Evidence for this topic was not searched for, reviewed or discussed with the committee. The committee could therefore not comment on this. The references listed have been checked, and none of them meet the criteria set out in the protocols for the evidence reviews that were updated.

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				Conclusion: So far, there is no conclusive evidence to suggest that physical activity reduces vasomotor symptoms. This is based on a systematic review and several RCTs which showed inconsistent effect of physical activity on vasomotor symptoms. However, specific forms of physical activity at particular times of day have not been researched fully as it is likely that evening, high- intensity physical activity could worsen VMS. References: 1. Pettee Gabriel, K., Mason, J. and Sternfeld, B., 2015. Recent evidence exploring the associations between physical activity and menopausal symptoms in midlife women: perceived risks and possible health benefits. *Women's Midlife Health*, 1(1). 2. Shorey, S., Ang, L. and Lau, Y. (2020) 'Efficacy of mind–body therapies and exercise-based interventions on menopausal-related outcomes among Asian perimenopause women: A systematic review, meta-analysis, and synthesis without a meta- analysis', *Journal of Advanced Nursing,* 76(5), pp. 1098-1110. 3. Kai, Y., Nagamatsu, T., Kitabatake, Y. and Sensui, H. (2016) 'Effects of stretching on menopausal and depressive symptoms in middle-aged women: a randomized controlled trial', 1(8), pp. 827-32.	

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				4. Javadivala, Z., Allahverdipour, H., Jafarabadi, M. A. and Emami, A. (2020) 'An Interventional strategy of physical activity promotion for reduction of menopause symptoms', *Health Promotion Perspectives,* 10(4), pp. 383-392. 5. Hu, L., Zhu, L., Lyu, J. Y., Zhu, W. J., Xu, Y. P. and Yang, L. (2017) 'Benefits of Walking on Menopausal Symptoms and Mental Health Outcomes among Chinese Postmenopausal Women', *International Journal of Gerontology,* 11(3), pp. 166-170. 6. Bailey, T. G., Cable, N. T., Aziz, N., Atkinson, G., Cuthbertson, D. J., Low, D. A. and Jones, H. (2016) 'Exercise training reduces the acute physiological severity of post-menopausal hot flushes', *The Journal of Physiology,* 594(3), pp. 657-667. References: 7. leh, S., Fatolahi, H. and Azarbayjani, M. A. (2020) 'Effect of eight weeks of low, moderate, and high-intensity TRX training on hot flashes, mood, fat percentage, and muscular endurance in postmenopausal women', *Apunts-Medicina De L Esport,* 55(207), pp. 97-103. 8. Asghari, M., Mirghafourvand, M., Mohammad-Alizadeh-Charandabi, S., Malakouti, J. and Nedjat, S. (2017) 'Effect of aerobic exercise and nutrition educationon quality of life and early menopause symptoms:A randomized	

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				controlled trial', *Women & Health,* 57(2), pp. 173-188. 9. Dabrowska-Galas, M., Dabrowska, J., Ptaszkowski, K. and Plinta, R. (2019) 'High Physical Activity Level May Reduce Menopausal Symptoms', *Medicina-Lithuania,* 55(8). 10. Daley, A., Stokes-Lampard, H., Thomas, A. and MacArthur, C. 'Exercise for vasomotor menopausal symptoms'. El Hajj, A., Wardy, N., Haidar, S., Bourgi, D., El Haddad, M., El Chammas, D., El Osta, N., Khabbaz, L. R. and Papazian, T. (2020) 'Menopausal symptoms, physical activity level and quality of life of women living in the Mediterranean region', *Plos One,* 15(3).	
Pelvic Obstetric and Gynaecological Physiotherapy (POGP)	Guideline	015		1.4.19 Uro-genital atrophy: Offer Pelvic floor muscle training & Physical activity advice Pelvic floor muscle training to be considered a valid option for treating uro-genital atrophy Mercier J, Morin M, Zaki D, Reichetzer B, Lemieux MC, Khalifé S, Dumoulin C. Pelvic floor muscle training as a treatment for genitourinary syndrome of menopause: A single-arm feasibility study. *Maturitas.* 2019;125:57-62. https://pubmed.ncbi.nlm.nih.gov/31133219/ https://www.imsociety.org/2021/03/15/pelvic-floor-muscle-training-as-a-treatment-for-genitourinary-syndrome-of-menopause/ Pelvic Floor Muscle Exercises as a Treatment for Urinary Incontinence in Postmenopausal	Thank you for your comment. The effectiveness of pelvic floor muscle training was not in the scope of the 2024 guideline update (and the cited references were therefore not included because they did not match any inclusion criteria). Evidence for this topic was therefore not searched for and not reviewed and discussed with the committee. The committee could therefore not comment on this.

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				Women: A Systematic Review of Randomized Controlled Trials López-Pérez, M.P.; Afanador-Restrepo, D.F.; Rivas-Campo, Y.; Hita-Contreras, F.; Carcelén-Fraile, M.d.C.; Castellote-Caballero, Y.; Rodríguez-López, C.; Aibar-Almazán, A. Pelvic Floor Muscle Exercises as a Treatment for Urinary Incontinence in Postmenopausal Women: A Systematic Review of Randomized Controlled Trials. *Healthcare* 2023, *11*, 216. https://doi.org/10.3390/healthcare11020216 Abstract Women frequently suffer from urinary incontinence due to atrophic changes in the urogenital tract. Recommended conservative treatment includes evaluation of pelvic-floor strength and the functional use of pelvic-floor-muscle (PFM) training. Following the PRISMA 2020 guidelines, a search was conducted in the electronic databases PubMed, Web of Science, and Scopus for articles with at least one group performing PFM exercises in post-menopausal women with urinary incontinence. Eight articles were included, and each study had at least one group of PFM exercise-based intervention alone or combined. The volume or duration, frequency, and number of sessions were heterogeneous. All the studies reported significant differences in favor of PFM exercise in strength, quality of life, and/or severity of urinary incontinence. PFM exercise is a highly recommended intervention to treat urinary incontinence in postmenopausal women.	

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				However, more research is needed to establish specific factors such as dose–response relationships and to standardize methods for measuring effects. 1. Malinauskas, Ana Paula, et al. "Efficacy of pelvic floor physiotherapy intervention for stress urinary incontinence in postmenopausal women: Systematic review." *Archives of Gynecology and Obstetrics* 308.1 (2023): 13-24. ***Conclusion*** There is not a literature consensus about the most effective pelvic floor physiotherapy intervention applied to stress urinary incontinence in postmenopausal women. It seems appropriate to state that further randomized controlled clinical trials should be done, due to the limited number of studies and heterogeneity of physiotherapeutic interventions applied to date. Evidence Physical activity and pelvic floor muscle training to be included: Moving medicine resource https://movingmedicine.ac.uk/consultation-guides/condition/adult/menopause/ Improves sexual function, urogenital symptoms and vaginal dryness Evidence Summary There is strong evidence that undertaking physical activity and pelvic floor exercise training improves sexual function and urogenital symptoms for women going through the menopause. A systematic review showed that	

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				sexual function was positively correlated to regular physical activity, sexual satisfaction was greater amongst women doing regular physical activity and a strong association between high levels of physical activity and better sexual functioning. The interventions which were included were aerobic exercise, resistance training as well as pelvic floor exercise training. Another systematic review showed a significant improvement in vaginal dryness symptoms in menopausal women. There are scant few other reviews or trials reviewing this symptom and the dose, frequency and timing of exercise has not yet been established. Conclusion: Physical activity including pelvic floor exercise training has been consistently shown to im- prove sexual function, sexual satisfaction as well as reduce urogenital symptoms. There is good preliminary evidence that shows physical activity improves vaginal dryness but further studies are required. Quality of Evidence: B - Moderate quality of evidence from RCT's and systematic reviews Strength of Recommendation: Strong - There are consistent results from the evidence and there were no harmful outcomes from the studies. References: 1. Asghari M, Mirghafourvand M, Mohammad-Alizadeh-Charandabi S, Malakouti J, Nedjat S. Ef- fect of aerobic exercise and nutrition education on quality of life and early menopause symp- toms:A randomized controlled trial. Women & Health. 2017;57(2):173-88.	

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				training for prolapse and incontinence symptoms. Strength of Recommendation: Grade 1 Conclusion: Menopausal women would be best served undertaking regular pelvic floor muscle training to manage any continence symptoms they suffer from. Pelvic floor muscle training would require patient education to ensure they are performing them correctly. There is little evidence that higher levels of physical activity help manage continence or prolapse symptoms so more definite randomised-controlled trials are needed. References: 1. Carcelén-Fraile, M. D. C., Aibar-Almazán, A., Martínez-Amat, A., Cruz-Díaz, D., Díaz-Mohedo, E., Redecillas-Peiró, M. T. and Hita-Contreras, F. (2020) 'Effects of Physical Exercise on Sexual Function and Quality of Sexual Life Related to Menopausal Symptoms in Peri- and Postmenopausal Women: A Systematic Review', *Int J Environ Res Public Health,* 17(8). 2. Pettee Gabriel, K., Mason, J. and Sternfeld, B., 2015. Recent evidence exploring the associations between physical activity and menopausal symptoms in midlife women: perceived risks and possible health benefits. *Women's Midlife Health*, 1(1). 3. Javadivala, Z., Allahverdipour, H., Jafarabadi, M. A. and Emami, A. (2020) 'An Interventional strategy of physical	

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Pelvic Obstetric and Gynaecological Physiotherapy (POGP)	Guideline	018		1.4.34 Consider higher levels of physical activity to alleviate mild depressive symptoms with onset in association with other menopause symptoms Resource https://movingmedicine.ac.uk/consultation-guides/condition/adult/menopause/ Anxiety and depression are common presentations in women going through the menopause. There is a large amount of strong evidence from RCTs, systematic reviews and meta-analysis that show increased levels of physical activity reduced low mood and	Thank you for your comment. The effectiveness of physical activity on depressive symptoms related to the menopause was not in the scope of the 2024 guideline update. This means that a search was not conducted, and an evidence review related to this was not discussed. The committee could therefore not comment on this. The references listed have been checked and none of them meet the criteria set out in the protocols for the evidence reviews that were updated.

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				depressive symptoms, as well as improved anxiety and quality of life. Low, moderate, and high intensity physical activities were included, as well as resistance exercises and mind body disciplines such as yoga and pilates. Overall, the menopause quality of life (MENQOL) scores improved with higher levels of physical activity. From the qualitative data this may be due to overall improved mood, mental wellness and an overall reduced perception of the impact of menopausal symptoms. It was also shown that social and supervised activities had greater adherence rates long term. Quality of Evidence: A - Strong evidence from multiple RCTs, systematic review and meta-analysis. Strength of Recommendation: 1 - Strong recommendation, clinical and patient consensus is that physical activity improves depression and anxiety symptoms as well as reduces the overall impact of menopausal symptoms as measured by the MENQOL score. Conclusion: Strong recommendations can be applied to most patients in most circumstances and should be followed unless there are compelling reasons to do otherwise. References 1. Carcelén-Fraile MDC, Aibar-Almazán A, Martínez-Amat A, Cruz-Díaz D, Díaz-Mohedo E, Redecillas-Peiró MT, et al. Effects of Physical Exercise on Sexual Function and Quality of Sexual Life Related to Menopausal Symptoms in Peri- and Postmenopausal	

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Pelvic Obstetric and Gynaecological Physiotherapy (POGP)	Guideline	019		2 1.4.37 Consider increasing physical activity for difficulties with sleep associated with the menopause Resource https://movingmedicine.ac.uk/consultation-guides/condition/adult/menopause/ Symptom: Sleep quality is positively correlated to level of physical activity in menopausal women. Evidence Summary: The evidence from both a systematic review and a literature review suggests a moderate improvement in sleep quality when undertaking increased levels of physical activity (1,2). The systematic review by Rubio-Arias et al examined 5 randomised-controlled trials with a 12–16- week course of physical activity and found menopausal women had improved sleep quality but no change in insomnia symptoms (1).	Thank you for your comment. Physical exercise as an intervention for outcomes associated with the menopause was not in the scope of the 2024 guideline update. Evidence for this topic was not searched for, reviewed or discussed with the committee. The committee could therefore not comment on this. The references you have listed have been checked and none of them meet the criteria set out in the protocols for the evidence reviews that were updated.

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				There have been multiple further randomised control trials and cross-sectional studies which further support the use of physical activity to improve sleep quality in both menopausal and peri-menopausal women (3,4,5,6,7,8,9) . Of note, the options for the types of physical activity that may improve sleep quality include yoga undertake two-three times a week, walking or stretching (3,5,6). Encouragingly, just 10 minutes daily of stretching led to a significant decrease in insomnia in a trial for peri and post- menopausal women (3). This is thus an option for those women who are particularly time pressured or have not previously undertaken much physical activity. Quality of Evidence: Grade A – a good quality systematic review and several RCTs support the evidence that increased levels of physical activity led to less sleep problems and possibly reduced insomnia symptoms. Strength of Recommendation: Grade 1 – Strong – systematic review and good amount of RCTs support the recommendation. Conclusion: Regular physical activity in menopausal and peri-menopausal women has been shown to improve sleep quality in these patients. There is more inconsistent evidence that physical activity helps with insomnia however. References: 1. Rubio-Arias, J. A., Marin-Cascales, E., Ramos-Campo, D. J., Hernandez, A. V. and Perez- Lopez, F. R. (2017) 'Effect of exercise on sleep quality and insomnia in middle-aged women: A systematic	

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RCGP Special Interest Group in Learning Disability and Neurodiversity	Guideline	General	General	General Comment 1 This draft guideline correctly discusses the health implications of the menopause to members of several minorities but we feel that, in the interests of health equality, it should also refer to another minority – those with learning disability (at least 2.5% of the population). This minority are subject to early menopause and their presentation can be atypical and their	Thank you for your comment. The committee made a recommendation related to time of menopause and potential differences by ethnic background based on their knowledge and experience, but it was not a specific research question that was part of the scope of the 2024 guideline update. They reflected on this and decided based on consensus to add that people with lifelong medical conditions may also experience menopause at a younger age to this

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				counselling requires reasonable adjustment suitable to their needs. Schupf, N., Zigman, W., Kapell, D., Lee, J. H., Kline, J., & Levin, B. (1997). Early menopause in women with Down's syndrome. *Journal of Intellectual Disability Research, 41*(3), 264–267. https://doi.org/10.1111/j.1365-2788.1997.tb00706.x Seltzer, G., Schupf, N., & Wu, H. (2001). A prospective study of menopause in women with Down's syndrome. *Journal of Intellectual Disability Research,* 45 (pt. 1), 1–7. http://doi.org/10.1046/j.1365-2788.2001.00286.x. PMID: 11168771. Willis, D. S. (2008). A decade on: What have we learnt about supporting women with intellectual disabilities through the menopause? *Journal of Intellectual Disabilities, 12*(1), 9–23. https://doi.org/10.1177/1744629507086604 Willis, D. S., Wishart, J. G., & Muir, W. J. (2010). Carer knowledge and experiences with menopause in women with intellectual disabilities. *Journal of Policy and Practice in Intellectual Disabilities, 7*(1), 42–48. *https://doi.org/10.1111/j.1741-1130.2010.00246.x* Martin, D. M., Cassidy, G., Ahmad, F., & Martin, M. S. (2001). Women with learning disabilities and the menopause. *Journal of Learning Disabilities, 5*(2), 121–132. https://doi.org/10.1177/146900470100500204 McCarthy, M. (2002a). Going through the menopause: Perceptions and experiences of women with intellectual disability. *Journal of*	recommendation. However, the committee has also logged prevalence of menopause (including in different populations) with the NICE surveillance team so that this could be considered for future updates. The impact and experience of menopause and the support needs was a topic that was referred to by many stakeholders and NICE takes reports of the impact on people with learning disabilities seriously. Since this was not part of the 2024 update, the committee could not comment on this. However, the cited references have been passed on to the NICE surveillance team so that they can be considered for future updates.

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				Winterhalder R 2022 Bone health, intellectual disability and epilepsy: An observational community-based study Acta Endo Scandc 145(6): 753–761. Burke É, Carroll R, O'Dwyer M, et al. Quantitative examination of the bone health status of older adults with intellectual and developmental disability in Ireland: a cross-sectional nationwide study. BMJ Open 2019;9:e026939. doi:10.1136/ bmjopen-2018-026939	
RCGP Special Interest Group in Learning Disability and Neurodiversity	Guideline	General	General	**General Comment 2** This draft guideline correctly discusses the health implications of the menopause to members of several minorities but we feel that, in the interests of health equality, it should also refer to another minority – those with neurodiversity. This minority are subject to atypical presentation of the menopause and their counselling requires reasonable adjustment suitable to their needs. El Baou et al (2023) Effectiveness of primary care psychological therapy services for treating depression and anxiety in autistic adults in England: a retrospective, matched, observational cohort study of national health-care records Lancet Psychiatry 10,12, 944-954 Moseley, R. L., Druce, T., & Turner-Cobb, J. M. (2020). 'When my autism broke': A qualitative study spotlighting autistic voices on menopause. Autism, 24(6), 1423–1437. https://doi.org/10.1177/1362361319901184 Moseley, R. L., Druce, T., & Turner, C. J. M. (2021). Autism research is 'all about the blokes and the kids': Autistic women breaking the	Thank you for your comment. The committee made a recommendation related to time of menopause and potential differences by ethnic background based on their knowledge and experience, but it was not a specific research question that was part of the scope of the 2024 guideline update. They reflected on the recommendation related to earlier age of menopause and decided based on consensus to add that people with lifelong medical conditions may also experience menopause at a younger age. However, the committee has also logged prevalence of menopause (including the key references cited) with the NICE surveillance team so that this could be considered for future updates. The impact and experience of menopause and the support needs was a topic that was referred to by many stakeholders and NICE takes reports of the impact on neurodivergent people seriously. Since this was not part of the 2024 guideline update, the committee could not comment on this. However, the cited references have been passed on to the NICE surveillance team so that they can be considered for future updates.

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				silence on menopause. *British Journal of Health Psychology*, *26*(3), 709–726. https://doi.org/10.1111/bjhp.12477 Karavidas, M., & de Visser, R. O. (2022). "It's Not Just in My Head, and It's Not Just Irrelevant": Autistic Negotiations of Menopausal Transitions. *Journal of Autism & Developmental Disorders*, *52*(3), 1143–1155. https://doi.org/10.1007/s10803-021-05010-y Groenman, A. P., Torenvliet, C., Radhoe, T. A., van Rentergem, J. A. A., & Geurts, H. M. (2022). Menstruation and menopause in autistic adults: Periods of importance? *Autism: The International Journal of Research & Practice*, *26*(6), 1563–1572. https://doi.org/10.1177/13623613211059721 Spain D, Happe 2019 How to Optimise Cognitive Behaviour Therapy (CBT)for People with Autism Spectrum Disorders (ASD): A Delphi Study. Debbie Spain1 · Francesca Happé1 Journal of Rational-Emotive & Cognitive-Behavior Therapy (2020) 38:184–208 https://doi.org/10.1007/s10942-019-00335-1 Owens A P MATHIAS C IODICE C 2021 Autonomic Dysfunction in Autism Spectrum Disorder Front *Integr Neurosci.* 15: 787037. Published online 2021 Dec 30. doi: 10.3389/fnint.2021.787037 PMCID: PMC8756818PMID: 35035353	
RCGP Special Interest Group in Learning Disability and Neurodiversity	Guideline	006	021	1.2.2 Add In patients with LD the menopause may present with changes of behaviour and require careful assessment particularly in non-verbal patients In patients with neurodiversity, the menopause may be the time in their lives when the	Thank you for your comment. It is agreed that people should be assessed in an individualized manner, ensuring they are heard and treated with dignity and respect, including providing information in the most suitable format. Further detail on treating people as individuals is covered in the the NICE guideline on patient

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				difficulties of being neurodiverse manifest themselves or are exacerbated	experience in adult NHS services as well as in the NICE guideline on shared decision-making so this information is not repeated in all other NICE guidelines (they are cross referred to in recommendations 1.1.1 and 1.1.2). There is an emphasis throughout the guideline on tailoring information to the individual, for example it is emphasised that information about benefits and risks needs to be individualised to the person's age, individual circumstances and potential risk factors. There are also recommendations that highlight that a family member or carer can be involved. Making reasonable adjustments as required by the Equality Act 2010 is a statutory requirement and so this would not need to be repeated in each individual NICE guideline. This would include adjustments for people with learning disabilities as well as neurodivergent people. The Equalities Impact Assessment has been reviewed and further points included in the section on disabilities to emphasise the person-centred approach that the committee has taken which they felt would positively impact these groups.
RCGP Special Interest Group in Learning Disability and Neurodiversity	Guideline	008	008	1.2.8 Add Information available should include literature etc suitable for people with learning disability and neurodiversity including EasyRead literature.egLearning Disabilities booklet (balance-menopause.com)	Thank you for your comment. It is agreed that information needs to be accessible and adapted to each individual, ensuring they are heard and treated with dignity and respect. This includes providing information in the most suitable format tailored to the individual. Further detail on treating people as individuals is covered in the NICE guideline on patient experience in adult NHS services as well as in the NICE guideline on shared decision-making so this information is not repeated in all other NICE guidelines (which is the reason why they are cross referred to in recommendations 1.1.1 and 1.1.2).

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					There is an emphasis throughout the guideline on tailoring information to the individual, for example it is emphasised that information about benefits and risks needs to be individualised to the person's age, individual circumstances and potential risk factors. There are also recommendations that highlight that a family member or carer can be involved. Making reasonable adjustments as required by the Equality Act 2010 is a statutory requirement and so this would not need to be repeated in each individual NICE guideline. This would include adjustments for people with learning disabilities as well as neurodivergent people. The Equalities Impact Assessment has been reviewed and further points have been included in the section on disabilities to emphasise the person-centred approach that the committee has taken which they felt would positively impact these groups. The NICE guideline on learning disabilities and behaviour that challenges: service design and delivery as well as the NICE guideline on autism spectrum disorder in adults: diagnosis and management contain sections on 'enabling person-centred care and support' and 'identifying the correct interventions and monitoring their use' respectively which outline the ways to get people with learning disabilities and neurodivergent people involved in decision making that is tailored to their needs. These apply to all other NICE guidance and so this would not need to be repeated in each individual NICE guideline.
RCGP Special Interest Group in Learning Disability and Neurodiversity	Guideline	008	010 and after	1.2.9 Add People with LD require special consideration as:	Thank you for your comment. It is agreed that consultations and discussions need to be accessible and tailored to each individual, ensuring they are heard and treated with dignity

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				- their menopause can occur prematurely - Consultation and discussion with them and their supportive friend will require additional time and reasonable adjustment in terms of timing and location of consultation. People with neurodiversity require special consideration in their discussions about the menopause tailored to their neurocognitive profile	and respect. This includes providing information in the most suitable format for the individual. Further detail on treating people as individuals is covered in the the NICE guideline on patient experience in adult NHS services as well as in the NICE guideline on shared decision-making so this information is not repeated in all other NICE guidelines (which is the reason why they are cross referred to in recommendations 1.1.1 and 1.1.2). There is an emphasis throughout the guideline on tailoring information to the individual, for example it is emphasised that information about benefits and risks needs to be individualised to the person's age, individual circumstances and potential risk factors. There are also recommendations that highlight that a family member or carer can be involved. Making reasonable adjustments as required by the Equality Act 2010 is a statutory requirement and so this would not need to be repeated in each individual NICE guideline. This would include adjustments for people with learning disabilities as well as neurodivergent people. The Equalities Impact Assessment has been reviewed and further points have been included in the section on disabilities to emphasise the person-centred approach that the committee has taken which they felt would positively impact these groups. The NICE guideline on learning disabilities and behaviour that challenges: service design and delivery as well as the NICE guideline on autism spectrum disorder in adults: diagnosis and management contain sections on 'enabling person-centred care and support' and 'identifying the correct interventions and monitoring their use' respectively which outline the ways to get people

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					with learning disabilities and neurodivergent people involved in decision making that is tailored to their needs. These apply to all other NICE guidance and so this would not need to be repeated in each individual NICE guideline.
RCGP Special Interest Group in Learning Disability and Neurodiversity	Guideline	008	026	1.3.3 Add Learning disability is associated with having menopause at an earlier age	Thank you for your comment. The committee made this recommendation related to time of menopause and potential differences by ethnic background based on their knowledge and experience. It was not a specific research question that was part of the scope of the 2024 guideline update. They reflected on this and decided based on consensus to add that people with lifelong medical conditions may also experience menopause at a younger age to this recommendation. The Equalities Impact Assessment has been reviewed and further points have been included in the section on disabilities to emphasise the person-centred approach that the committee has taken which they felt would positively impact these groups.However, the committee has also logged prevalence of menopause (including in different populations, for example people with disabilities) with the NICE surveillance team so that this could be considered for future updates.
RCGP Special Interest Group in Learning Disability and Neurodiversity	Guideline	009	012	1.3.5 Add Patients with LD can benefit, after consent or best of interests assessment of undergoing FSH measurement together with prolactin measurement if they have amenorrhoea. They are at higher risk both of early menopause and Hyperprolactinaemia which can be due to concurrent treatment with neuroleptic or tricyclic	Thank you for your comment. The identification of menopause, including FSH measurement, was not in the scope of the 2024 guideline update. Therefore, no searches were carried out or systematic reviews conducted. The committee could therefore not comment on this. However, this has been logged with the NICE surveillance team for consideration for future updates.

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				medications. Both measurements need repeating in 4-6 weeks with reasonable adjustment on both occasions to result in least distress at the time of the phlebotomy.	
RCGP Special Interest Group in Learning Disability and Neurodiversity	Guideline	009	015	1.3.5 Add • people with neurodiversity who: -May present for the first time with distress due to neurodiversity at the time of the menopause -Are at greater risk of developing depression at the time of the menopause with risk of suicidal intent	Thank you for your comment. This wording related to psychological support is part of the recommendation that precedes it which refers to FSH measurement in 2 specific age groups and the text is cross referring to the relevant sections for these age groups. It is therefore not a wider statement on groups that may need psychological support. The text has been revised to make it clearer that it all belongs to the same recommendation. The general topic of neurodiversity and menopause has been logged with the NICE surveillance team for consideration in future updates.
RCGP Special Interest Group in Learning Disability and Neurodiversity	Guideline	011	009	1.4.4 Extend Individual face- to- **face which, in the care of patients with LD or neurodiversity may require the presence of a supportive friend – a family member, a carer or friend.**	Thank you for your comment. It is agreed that information must be accessible and tailored to each individual, ensuring they are heard and treated with dignity and respect. This includes providing information in the most suitable format for the individual. Further detail on treating people as individuals is covered in the NICE guideline on patient experience in adult NHS services as well as in the NICE guideline on shared decision-making so this information is not repeated in all other NICE guidelines (which is the reason why they are cross referred to in recommendations 1.1.1 and 1.1.2). There is an emphasis throughout the guideline on tailoring information to the individual, for example it is emphasised that information about benefits and risks needs to be individualised to the person's age, individual circumstances and

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					potential risk factors. There are also recommendation that highlight that a family member or carer can be involved. Making reasonable adjustments as required by the Equality Act 2010 is a statutory requirement and so this would not need to be repeated in each individual NICE guideline. This would include adjustments for people with learning disabilities as well as neurodivergent people. The Equalities Impact Assessment has been reviewed and further points have been included in the section on disabilities to emphasise the person-centred approach that the committee has taken which they felt would positively impact these groups. The NICE guideline on learning disabilities and behaviour that challenges: service design and delivery as well as the NICE guideline on autism spectrum disorder in adults: diagnosis and management contain sections on 'enabling person-centred care and support' and 'identifying the correct interventions and monitoring their use' respectively which outline the ways to get people with learning disabilities and neurodivergent people involved in decision making that is tailored to their needs. These apply to all other NICE guidance and so this would not need to be repeated in each individual NICE guideline.
RCGP Special Interest Group in Learning Disability and Neurodiversity	Guideline	014	006	1.4.16 Add Patients with neurodiversity have variable response to CBT which may, on balance, cause more harm and their vasomotor symptoms are likely to be more severe due to the risk of autonomic instability including "POTs" which has an increased prevalence in people with neurodiversity.	Thank you for your comment. The committee decided that this would be a matter of making adjustments to CBT to tailor it to the individual. Making reasonable adjustments as required by the Equality Act 2010 is a statutory requirement and so this would not need to be repeated in each individual NICE guideline.

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RCGP Special Interest Group in Learning Disability and Neurodiversity	Guideline	015	007	1.4.19 Add Patients known to be menopausal with LD presenting with recurrent LUTS may benefit from vaginal oestrogen preparations	Thank you for your comment. This recommendation is for all people with genitourinary symptoms associated with the menopause. If recurrent LUTS is the main symptom the person with learning difficulties is presenting with, NICE has produced elsewhere a patient decision aid about reducing the chance of recurrent urinary tract infection (UTI) in postmenopausal women (which is relevant to all women with recurrent UTI) which a healthcare professional can use in a shared decision making process adapted to the person's needs. A cross reference to this patient decision aid has been added.
RCGP Special Interest Group in Learning Disability and Neurodiversity	Guideline	018	010	1.4.34 Extend Consider HRT to alleviate mild depressive symptoms with onset in association with other menopause symptoms **particularly in people with LD or neurodiversity who may present with atypical symptoms of both menopause and depression.**	Thank you for your comment. It is agreed that all assessments (including atypical presentations) and management plans need to be tailored to each individual, ensuring they are heard and treated with dignity and respect. Further detail on treating people as individuals is covered in the NICE guideline on patient experience in adult NHS services as well as in the NICE guideline on shared decision-making so this information is not repeated in all other NICE guidelines (which is the reason why they are cross referred to in recommendations 1.1.1 and 1.1.2). There is an emphasis throughout the guideline on tailoring information to the individual, for example it is emphasised that information about benefits and risks needs to be individualised to the person's age, individual circumstances and potential risk factors. There are also recommendation that highlight that a family member or carer can be involved. Making reasonable adjustments as required by the Equality Act 2010 is a statutory requirement and

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					so this would not need to be repeated in each individual NICE guideline. This would include adjustments for people with learning disabilities as well as neurodivergent people. The Equalities Impact Assessment has been reviewed and now includes further points in the section on disabilities to emphasise the person-centred approach that the committee has taken which they agreed would positively impact these groups. The NICE guideline on learning disabilities and behaviour that challenges: service design and delivery as well as the NICE guideline on autism spectrum disorder in adults: diagnosis and management contain sections on 'enabling person-centred care and support' and 'identifying the correct interventions and monitoring their use' respectively which outline the ways to get people with learning disabilities and neurodivergent people involved in decision making that is tailored to their needs. These apply to all NICE guidance and so this would not need to be repeated in each individual NICE guideline.
RCGP Special Interest Group in Learning Disability and Neurodiversity	Guideline	018	011	1.4.35 Extend Consider CBT for depressive symptoms associated with the menopause, **being aware of the unpredictable response of patients with neurodiversity to CBT.**	Thank you for your comment. In the section on CBT in the 'discussing treatment options' 2 revisions were made (1) it should be 'explained what CBT is (including menopause-specific CBT)' and (2) that 'the person's preferences and needs' should be taken into account. The committee decided that they could not be more specific than this and that it would also be a matter of making adjustments to CBT to tailor it to the individual. Making reasonable adjustments as required by the Equality Act 2010 is a statutory requirement and so this would not need to be repeated in each individual NICE guideline.

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RCGP Special Interest Group in Learning Disability and Neurodiversity	Guideline	018	017	1.4.36 Add Consider a new diagnosis of autism presenting or associated with depression and associated with a higher risk of suicide. Consider that patients with LD can present with a new onset of behaviour problems due to menopause or depression or the two combined.	Thank you for your comment. It is agreed that all assessments of depressive symptoms (including atypical presentations) need to be tailored to each individual, ensuring they are heard and treated with dignity and respect. Further detail on treating people as individuals is covered in the NICE guideline on patient experience in adult NHS services as well as in the NICE guideline on shared decision-making so this information is not repeated in all other NICE guidelines (which is the reason why they are cross referred to in recommendations 1.1.1 and 1.1.2). A definition of depressive symptoms has been added to the guideline which also links to the criteria for depression in the NICE guideline on depression in adults (which includes symptoms such as recurrent thoughts of death or suicidal ideation or evidence of attempted suicide). The assessment of depression in neurodivergent adults is outside the scope of the guideline. There is an emphasis throughout the guideline to tailor information to the individual, for example it is emphasised that information about benefits and risks needs to be individualised to the person's age, individual circumstances and potential risk factors. There are also recommendation that highlight that a family member or carer can be involved. Making reasonable adjustments as required by the Equality Act 2010 is a statutory requirement and so this would not need to be repeated in each individual NICE guideline. This would include adjustments for people with learning disabilities as well as neurodivergent people. The Equalities Impact Assessment has been reviewed and now includes further points in the section on disabilities to emphasise the person-centred

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					approach that the committee has taken which they agreed would positively impact these groups. The NICE guideline on learning disabilities and behaviour that challenges: service design and delivery as well as the NICE guideline on autism spectrum disorder in adults: diagnosis and management contain sections on 'enabling person-centred care and support' and 'identifying the correct interventions and monitoring their use' respectively which outline the ways to get people with learning disabilities and neurodivergent people involved in decision making that is tailored to their needs. These apply to all NICE guidance and so this would not need to be repeated in each individual NICE guideline.
RCGP Special Interest Group in Learning Disability and Neurodiversity	Guideline	019	003	1.4.37 Extend Consider CBT for difficulties with sleep associated with the menopause **being aware of patients with neurodiversity having a variable response to CBT.**	Thank you for your comment. The committee decided that this would be a matter of making adjustments to CBT to tailor it to the individual. Making reasonable adjustments as required by the Equality Act 2010 is a statutory requirement and so this would not need to be repeated in each individual NICE guideline.
RCGP Special Interest Group in Learning Disability and Neurodiversity	Guideline	020	003	1.5.3 Add details of the increased risk of endometrial hyperoestrinism and carcinoma in patients with LD and the need for increased vigilance because of this increased risk.	Thank you for your comment. The relationship between learning disabilities and risk of endometrial hyperthyroidism and carcinoma is outside the scope of the 2024 guideline update. The committee could therefore not comment on this.
RCGP Special Interest Group in Learning Disability and Neurodiversity	Guideline	021	015	1.5.11 Extend If needed refer them to specialist psychology services p**articularly if they are known or have recently been found to be affected by neurodiversity.**	Thank you for your comment. The impact of menopause on people in general as well as impact on specific populations was outside the scope of the 2024 guideline update. The recommendation referred to was based on the topic of the effects of either taking or not taking HRT on specific health outcomes in early menopause aged 40 to 44. This

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					sparked a discussion in the committee about the support that people may need, and the recommendation was based on consensus. Due to the specific nature of this recommendation and where it originated from, the committee could not make general comments about psychological impact in other groups (such as neurodivergent people).
RCGP Special Interest Group in Learning Disability and Neurodiversity	Guideline	026		Table In section on osteoporosis mention that any adult patient with LD is at increased risk of osteoporosis which can be exacerbated by the menopause	Thank you for your comment. The relationship between learning disabilities and the risk of osteoporosis is outside the scope of the guideline. The committee could therefore not comment on this.
Reed Wellbeing Ltd	Evidence Review A	013	024 - 039	The recommendation to use CBT for menopausal symptoms (e.g. vasomotor symptoms) was based upon data/evidence that was confirmed within the consultation to be of low to moderate quality. Having additional *options* available to patients, such as CBT, could be of benefit, however without strong evidence at present, providing CBT as a clear adjunct, distinct to HRT, may result in better outcomes.	Thank you for your comment. The recommendation has been revised to explain that CBT is recommended 'as an option: in addition to HRT, for people for whom HRT is contraindicated or for people who prefer not to take HRT'. This wording clarifies the relationship between this recommendation and the recommendation related to HRT.
Reed Wellbeing Ltd	Evidence review A	021	003	The guidance suggests there could be an option for self-led/self-help CBT. However, this may be challenging in practice when considerations have not been made with regards to the potential fluctuating motivation of this demographic. Measures may need to be put in place to support these individuals with continuing self-led CBT if they are struggling with motivation.	Thank you for your comment. The guideline recommends a person-centred approach to shared decision making. This means that the information and plan is tailored to the individual and the CBT related discussions have been revised to take account of the person's preferences and needs. If motivation may be an issue, then alternative options to self-led CBT can be explored.
Reed Wellbeing Ltd	Evidence review A	021	021	It is suggested that access to facilitated CBT would be down to availability, which is not equitable. Whilst the guidelines acknowledge	Thank you for your comment. The committee acknowledged in the impact section of the guideline that there are long waiting times for CBT.

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				that CBT could be an option rather than routine treatment, it does not sound like it will be an option for all, based on the availability of talking therapy services in their area. Alternative options need to be made clear.	They also noted that people currently trained in providing this kind of therapy may not be familiar with menopause-specific CBT and training on this may incur costs and increase waiting times in the short term. However, online and group CBT may be easier and less costly to adapt to menopause-specific CBT. There are also resources available to train people in providing menopause-specific CBT (and could also inform the adaptation of online CBT), which could facilitate implementation. Your comment will be considered by NICE where relevant support activity is being planned. With regards to alternative options the recommendation has been revised to ensure clarity about CBT 'as an option: in addition to other treatment (including HRT), for people for whom other treatments are contraindicated or for people who prefer not to take other treatments'.
Reed Wellbeing Ltd	Guideline	044	005 - 006	The barriers and facilitators associated with making CBT successful do not appear to have been considered. CBT requires a time investment that would need to be made clear, to manage expectations of the outcomes associated with CBT. It is not outlined how practitioners will be expected to navigate these conversations.	Thank you for your comment. The committee agrees that motivation and expectations are important factors when choosing any option in order to assess likelihood of a person's adherence to a treatment regime. Therefore, the first recommendation of the guideline emphasises a person centred approach by tailoring it 'to the person at all times when identifying, discussing, investigating and managing menopause, and adapt the approach if symptoms change over time'.
Reed Wellbeing Ltd	Guideline	049	017	Suggest including who cannot to sentence 'options for those who do not wish to use pharmacological treatments'. If included this could read as 'options for those who cannot or do not wish to use pharmacological treatments'.	Thank you for your comment. This was revised accordingly.

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Rethink Menopause	Evidence Review A	General	General	The quality of evidence for CBT is rated as moderate 7 times and low or very low 28 times. Was this deemed to be robust enough data for these recommendations?	Thank you for your comment. The committee reflected on the wording of the recommendations related to CBT and revised them to ensure clarity about this 'as an option: in addition to other treatments (including HRT), for people for whom other treatments are contraindicated or for people who prefer not to take HRT'. This makes it clear that CBT is not seen as a first line treatment but as an option where this is a preferred choice. Although the majority of the evidence base ranged from low to very low quality, the committee acknowledged the benefits of CBT seen in the outcome's vasomotor symptoms, depressive symptoms and sleep. The wording used reflect the strength of the recommendation. In 'strong' recommendations for actions that should (or should not) be offered, directive language such as 'offer' is used, as it is used for the use of HRT for vasomotor symptoms. In keeping with the principles of shared decision making, people may choose whether or not to accept what they are offered or advised. If there is a closer balance between benefits and harms as in CBT (for instance when evidence is rated lower), the word 'consider' is used to reflect that the recommendation is 'weak' (see Developing NICE guidelines: the manual).
Rethink Menopause	Guideline	General	General	We are concerned that "referral to a healthcare professional with expertise in menopause" is recommended frequently, and does not include those working to a more advanced level in primary care who are not formally recognised as BMS specialists. This will further increase the demand on secondary care services with associated cost implications, and the impact of	Thank you for your comment. The definition of 'healthcare professional with expertise in menopause' is not mandating that these professionals are in tertiary centres. They have been defined as professionals with specialist knowledge, skills and training (for example as recognised by the British Menopause Society, the Faculty of Sexual and Reproductive Healthcare or the Royal College of Obstetricians and

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				symptoms on people whilst awaiting specialist review.	Gynaecologists) who can advise and support colleagues in managing complex menopause-related needs and risk factors affecting decision-making....'. Therefore, this could also be GPs with a special interest in menopause who have undertaken further training. This broader definition would mean a wider pool of such professionals with a positive impact on waiting times.
Rethink Menopause	Guideline	008	006	Please be explicit by what is meant by a high risk of breast cancer here	Thank you for your comment. This is a recommendation that was not updated apart from the removal of one of the bullet points related to SSRIs which was likely to cause confusion (because these were otherwise not recommended elsewhere). It is likely that high risk refers to people at a higher risk of breast cancer compared to the general population. This was not defined in the 2015 guideline most likely because a higher risk can be due to many different factors. As this was not discussed as part of the 2024 update, the committee could not provide a definition for this.
Rethink Menopause	Guideline	008	024 - 026	We find this to be a helpful inclusion. It would also be useful to highlight that menopause is often experienced at an earlier age by those with learning disabilities.	Thank you for your comment. The committee made this recommendation related to time of menopause and potential differences by ethnic background based on their knowledge and experience. Prevalence of early menopause (including in different subgroups of people, for example with learning disabilities) was neither part of the original guideline nor part of the scope of the 2024 update. The committee agreed that knowledge of this could impact practice and have logged this with the NICE surveillance team so that relevant information can be identified which could inform future updates.

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Rethink Menopause	Guideline	015	028	We are concerned this may imply vaginal moisturisers and lubricants should not be used with vaginal oestrogen.	Thank you for your comment. This recommendation was specifically related to people in whom vaginal oestrogen preparations are contraindicated or for people who would prefer not to use vaginal oestrogen. However, on reflection it was recognised that the order of recommendations could have led to confusion. The recommendation stating that vaginal oestrogen and non-hormonal moisturisers or lubricants can be used alone or in combination has therefore been moved up to a position before this recommendation to clarify this point.
Rethink Menopause	Guideline	017	001	We are concerned this will contribute to increased concern, especially in primary care, about the use of local oestrogen for those with a personal history of breast cancer taking tamoxifen treatment, and not aromatase inhibitors.	Thank you for your comment. The recommendation related to uncertainty about efficacy of vaginal oestrogen in the context of a history of breast cancer (including the reference to other cancer therapies) has been removed.
Rethink Menopause	Guideline	018	010	We find this to be a confusing statement. Is the recommendation that HRT can benefit mild depressive symptoms in women with menopause symptoms or just that it can be used in women with menopause symptoms who also "happen" to have mild depressive symptoms?	Thank you for your comment. This recommendation is worded in this way because the committee did not want to specify the relationship between the 2 types of symptoms and whether or how they are linked. The 2024 guideline update did not look for evidence around this potential relationship, but the wording of this recommendation was used to imply that they may be linked by virtue of the fact that their onset was simultaneous.
Rethink Menopause	Guideline	022	018	This links to a past guideline. The lifestyle advice is generic, not specific to those experiencing menopause and does not include any reference to stress management or sleep.	Thank you for your comment. The link has been updated so that it directs readers to the current version of the guideline. In the context of the recommendation the committee decided that the cross reference makes sense because they recommended against HRT to be used for primary or secondary prevention of cardiovascular

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					disease. Therefore, general advice is applicable since the cross-referred guideline includes information on prevention.
Rethink Menopause	Guideline	022	022	The lifestyle advice is generic, not specific to those experiencing menopause and does not include any reference to stress management or sleep.	Thank you for your comment. In the context of the recommendation the committee decided that the cross reference to the dementia guideline is appropriate because they recommended against HRT to be used for the purpose of dementia prevention. Therefore, general advice is applicable since the cross-referred guideline includes information on prevention.
Rethink Menopause	Guideline	023	Table 1 column 5	Please provide further explanation on this as many clinicians have been prescribing on the basis that these are both preferred options for mitigating breast cancer risk.	Thank you for your comment. The committee considered that the sample sizes for some of the progestogens in the evidence were small, and they could not confidently make conclusions based on this evidence. They agreed that there was insufficient evidence to support any differences in the risk of breast cancer with difference progestogens, and making a recommendation on limited evidence would cause more harm. The committee agreed that more evidence was required to make any robust recommendations about the risks of different progestogens, and agreed to make a research recommendation to support further work in the area. The committee's discussion of the evidence section in Evidence Report D has been updated to provide more detail regarding different preparations of combined HRT.
Rethink Menopause	Guideline	023	Table 1 column 4	Combined HRT preparations containing transdermal oestrogen increase the risk of breast cancer less than combined HRT preparations containing oral oestradiol. This could imply oral preparations with conjugated oestrogens do not confer the same risks?	Thank you for your comment. The statement has been removed and a research recommendation was added aimed to clarify matters related to different routes of administration.

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Rethink Menopause	Guideline	024	Table 1 column 4	It is noted that "Sequential combined HRT may slightly increase the risk of endometrial cancer, and that risk may be greater with: • longer duration of use and • fewer days of progestogen per cycle • increased dosage of oestrogen. [2023]" Additional guidance regarding using more progestogen for those at higher risk eg BMI over 30 and for those using a higher dose of oestrogen may be a useful addition to include, especially for colleagues in primary care.	Thank you for your comment. The committee decided not to add dosage of progestogen as an extra bullet because 'fewer days of progestogen per cycle' is linked both to dosage of progestogen and type of progestogen. The evidence was also insufficient to base a recommendation on. There was evidence related to BMI but not to both BMI and different dosages of progestogen together. The committee therefore decided that they could not comment on this.
Royal College of General Practitioners	General	General	General	It is important not to discourage the use of HRT when it can be beneficial and to view CBT as an additional option, not the primary recommendation for GPs when consulting with women about the menopause. Additionally, it is important to discuss the risks as well as the benefits of treatment options to provide a balanced understanding, allowing for informed decisions to be made based on individual needs.	Thank you for your comment. The scope of the 2024 guideline update did not include the effectiveness of HRT for symptoms associated with menopause. Existing recommendations on the use of HRT for the treatment and management of menopausal symptoms remain unchanged. The scope of this guideline update was to explore CBT as an option for the treatment or management of symptoms associated with menopause. The committee did not intend to discourage the use of HRT or recommend that CBT is a primary recommendation in all women, however, the aim was to provide additional treatment options in those for whom HRT is contraindicated, or for those women who do not wish to take HRT. The committee reflected on the wording of the recommendations related to CBT and revised them to ensure clarity about this' as an option: in addition to other treatments (including HRT), for people for whom other treatments are contraindicated or for people who prefer not to take HRT'. This makes it clear that CBT is not seen as a first-line treatment but as an option where this is a preferred choice. In addition, the scope of the guideline update looked at a number

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					of outcomes which are considered negative outcomes such as breast cancer and ovarian cancer and are therefore seen as risks, if the use of HRT increases the incidence of these outcomes. The committee recognise that there may be other health outcomes for which HRT might have a positive effect however they are unable to comment on any outcomes that were not part of the scope for this particular update.
Royal College of General Practitioners	General	General	General	We appreciate the overall direction of this guideline, but we have concerns about the exclusion of learning disabilities and neurodiversity and have therefore included comments related to these areas, alongside a few additional comments to be considered (highlighted).	Thank you for your comment. People with learning disabilities and neurodiversity are not excluded from this guideline. ~The team agrees that people need to be heard and treated with dignity and respect, for example by being communicated with, and their symptoms managed in a person-centred way. Further detail on treating people as individuals is covered in the NICE guideline on patient experience in adult NHS services as well as in the NICE guideline on shared decision-making so this information is not repeated in all other NICE guidelines (they are cross referred to in recommendations 1.1.1 and 1.1.2). There is an emphasis throughout the guideline on tailoring information to the individual, for example it is emphasised that information about benefits and risks needs to be individualised to the person's age, individual circumstances and potential risk factors. There is also a recommendation that highlights that a family member or carer can be involved. Making reasonable adjustments as required by the Equality Act 2010 is a statutory requirement and so this would not need to be repeated in each individual NICE guideline. This would include adjustments for people with learning disabilities as well as neurodivergent people. The Equalities Impact Assessment has been reviewed

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					and further points have been included in the section on disabilities to emphasise the person-centred approach that the committee has taken which they felt would positively impact these groups. The NICE guideline on learning disabilities and behaviour that challenges: service design and delivery as well as the NICE guideline on autism spectrum disorder in adults: diagnosis and management contain sections on 'enabling person-centred care and support' and' identifying the correct interventions and monitoring their use' respectively which outline the ways to get people with learning disabilities and neurodivergent people involved in decision making that is tailored to their needs. These apply to all other NICE guidance so this would not need to be repeated in each individual NICE guideline.
Royal College of General Practitioners	Guideline	General	General	This draft guideline correctly discusses the health implications of the menopause to members of several minorities but we feel that, in the interests of health equality, it should also refer to another minority – those with learning disability (at least 2.5% of the population). This minority are subject to early menopause and their presentation can be atypical and their counselling requires reasonable adjustment suitable to their needs. Relevant references: Schupf, N., Zigman, W., Kapell, D., Lee, J. H., Kline, J., & Levin, B. (1997). Early menopause in women with Down's syndrome. *Journal of Intellectual Disability Research, 41*(3), 264–267. https://doi.org/10.1111/j.1365-2788.1997.tb00706.x	Thank you for your comment. People with learning disabilities are not excluded from this guideline. The committee agrees that people need to be heard and treated with dignity and respect, for example by taking their individual risk factors or triggers into account. Further details on treating people as individuals is covered in the NICE guideline on patient experience in adult NHS services as well as in the NICE guideline on shared decision-making so this information is not repeated in all other NICE guidelines (they are cross referred to in recommendations 1.1.1 and 1.1.2). Due to this and other stakeholder comments, the recommendation relating to experiencing menopause at an earlier age has been updated to say that people with lifelong medical conditions may also experience menopause at an earlier age. Another recommendation related to discussions about CBT

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				Seltzer, G., Schupf, N., & Wu, H. (2001). A prospective study of menopause in women with Down's syndrome. *Journal of Intellectual Disability Research,* 45 (pt. 1), 1–7. http://doi.org/10.1046/j.1365-2788.2001.00286.x. PMID: 11168771. Willis, D. S. (2008). A decade on: What have we learnt about supporting women with intellectual disabilities through the menopause? *Journal of Intellectual Disabilities, 12*(1), 9–23. https://doi.org/10.1177/1744629507086604 Willis, D. S., Wishart, J. G., & Muir, W. J. (2010). Carer knowledge and experiences with menopause in women with intellectual disabilities. *Journal of Policy and Practice in Intellectual Disabilities, 7*(1), 42–48. *https://doi.org/10.1111/j.1741-1130.2010.00246.x* Martin, D. M., Cassidy, G., Ahmad, F., & Martin, M. S. (2001). Women with learning disabilities and the menopause. *Journal of Learning Disabilities, 5*(2), 121–132. https://doi.org/10.1177/146900470100500204 McCarthy, M. (2002a). Going through the menopause: Perceptions and experiences of women with intellectual disability. *Journal of Intellectual and Developmental Disability, 27*(4), 281–295. *https://doi.org/10.1080/13668250210000558 17* McCarthy, M. (2002b). The Menopause and Women with Learning Disabilities. Updates, *The Foundation for People with Learning Disabilities. Mental Health Update*	has also been revised to include that peoples' preferences and needs should be taken into account. There is an emphasis throughout the guideline on tailoring information to the individual, for example it is emphasised that information about benefits and risks needs to be individualised to the person's age, individual circumstances and potential risk factors. There are also recommendations that highlight that a family member or carer can be involved. Making reasonable adjustments as required by the Equality Act 2010 is a statutory requirement and so this would not need to be repeated in each individual NICE guideline. This would include adjustments for people with disabilities such as people with epilepsy. The Equalities Impact Assessment has been reviewed and further points have been included in the section on disabilities to emphasise the person-centred approach that the committee has taken which they felt would positively impact these groups. The committee has also asked the NICE surveillance team to log prevalence of menopause (including in different populations) as a topic to look for evidence. This could then be considered for future updates. The impact and experience of menopause and the support needs was a topic that was referred to by many stakeholders and NICE takes reports of the impact on people with learning disabilities seriously. Since this was not part of the 2024 guideline update, the committee could not comment on this. However, the cited references have been passed on to the NICE

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				3(14). https://www.learningdisabilities.org.uk/learning-disabilities/publications/menopause-and-women-learning-disabilities McCarthy, M. (2002c). Responses to women with learning disabilities as they go through the menopause. Tizard Learning Disability Review, 7(1), 4–12. McCarthy, M., & Millard, L. (2003). Discussing the menopause with women with learning disabilities. British Journal of Learning Disabilities, 31(1), 9–17. https://doi.org/10.1046/j.1468-3156.2003.00182.x De Almeida, E. W., & Greguol, M. (2015). Healthcare for Women with Disabilities in the Climacteric and Menopause. Sexuality and Disability, 33(2), 279–298. https://doi.org/10.1007/s11195-014-9390-4 Chou, Y.-C., Lu, Z.-Y. J., & Pu, C.-Y. (2013). Menopause experiences and attitudes in women with intellectual disability and in their family carers. Journal of Intellectual & Developmental Disability Frighi, Vet al; 2022 Incidence of fractures in people with intellectual disabilities over the life course: a retrospective matched cohort study eClinical Medicine, Volume 52, October 2022, Winterhalder R 2022 Bone health, intellectual disability and epilepsy: An observational community-based study Acta Endo Scandc 145(6): 753–761. Burke É, Carroll R, O'Dwyer M, et al. Quantitative examination of the bone health status of older adults with intellectual and developmental disability in Ireland: a cross-sectional nationwide study. BMJ	surveillance team so that they can be considered for future updates.

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				Open 2019;9:e026939. doi:10.1136/ bmjopen-2018-026939	
Royal College of General Practitioners	Guideline	General	General	This draft guideline correctly discusses the health implications of the menopause to members of several minorities but we feel that, in the interests of health equality, it should also refer to another minority – those with neurodiversity. This minority are subject to atypical presentation of the menopause and their counselling requires reasonable adjustment suitable to their needs. Relevant references: El Baou et al (2023) Effectiveness of primary care psychological therapy services for treating depression and anxiety in autistic adults in England: a retrospective, matched, observational cohort study of national health-care records Lancet Psychiatry 10,12, 944-954 Moseley, R. L., Druce, T., & Turner-Cobb, J. M. (2020). 'When my autism broke': A qualitative study spotlighting autistic voices on menopause. Autism, 24(6), 1423–1437. https://doi.org/10.1177/1362361319901184 Moseley, R. L., Druce, T., & Turner, C. J. M. (2021). Autism research is 'all about the blokes and the kids': Autistic women breaking the silence on menopause. British Journal of Health Psychology, 26(3), 709–726. https://doi.org/10.1111/bjhp.12477	Thank you for your comment. The committee made a recommendation related to time of menopause and potential differences by ethnic background based on their knowledge and experience, but it was not a specific research question that was part of the scope of the update. However, the committee asked the NICE surveillance team to log prevalence of menopause (including in different populations) as a topic to look for evidence. This could then be considered for future updates. The impact and experience of menopause and the support needs was a topic that was referred to by many stakeholders and NICE takes reports of the impact on neurodivergent people seriously. Since this was not part of the 2024 guideline update, the committee could not comment on this. However, the cited references have been passed on to the NICE surveillance team so that they can be considered for future updates.

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				Karavidas, M., & de Visser, R. O. (2022). "It's Not Just in My Head, and It's Not Just Irrelevant": Autistic Negotiations of Menopausal Transitions. Journal of Autism & Developmental Disorders, 52(3), 1143–1155. https://doi.org/10.1007/s10803-021-05010-y Groenman, A. P., Torenvliet, C., Radhoe, T. A., van Rentergem, J. A. A., & Geurts, H. M. (2022). Menstruation and menopause in autistic adults: Periods of importance? Autism: The International Journal of Research & Practice, 26(6), 1563–1572. https://doi.org/10.1177/13623613211059721 Spain D, Happe 2019 How to Optimise Cognitive Behaviour Therapy (CBT)for People with Autism Spectrum Disorders (ASD): A Delphi Study. Debbie Spain1 · Francesca Happé1 Journal of Rational-Emotive & Cognitive-Behavior Therapy (2020) 38:184–208 https://doi.org/10.1007/s10942-019-00335-1 Owens A P MATHIAS C IODICE C 2021 Autonomic Dysfunction in Autism Spectrum Disorder Front Integr Neurosci. 15: 787037. Published online 2021 Dec 30. doi: 10.3389/fnint.2021.787037 PMCID: PMC8756818PMID: 35035353	
Royal College of General Practitioners	Guideline	006	021	Rec 1.2.2 This recommendation should include the following: In patients with LD the menopause may present with changes of behaviour and require careful assessment particularly in non-verbal patients. In patients with neurodiversity, the menopause may be the time in their lives when the difficulties of being	Thank you for your comment. Identifying or diagnosing the menopause and the symptoms of the menopause were not in the scope of the 2024 guideline update. This means that evidence for these topics was not searched for or systematically reviewed. The committee could therefore not comment on whether there may be

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				neurodiverse manifest themselves or are exacerbated.	differences in how menopause impacts people with learning difficulties or neurodivergent people. This has been logged with the NICE surveillance team to be considered for future updates.
Royal College of General Practitioners	Guideline	008	008	Rec 1.2.9 It is important that the Information available should include literature etc suitable for people with learning disability and neurodiversity including Easy read literature.eg Learning Disabilities booklet	Thank you for your comment. It is agreed that information must be accessible and tailored to each individual, ensuring they are heard and treated with dignity and respect. This includes providing information in the most suitable format for the individual. Further detail on treating people as individuals is covered in the NICE guideline on patient experience in adult NHS services and the NICE guideline on shared decision-making so this information is not repeated in all other NICE guidelines (which is the reason why they are cross referred to in recommendations 1.1.1 and 1.1.2). There is an emphasis throughout the guideline on tailoring information to the individual, for example it is emphasised that information about benefits and risks needs to be individualised to the person's age, individual circumstances and potential risk factors. There are also recommendations that highlight that a family member or carer can be involved. Making reasonable adjustments as required by the Equality Act 2010 is a statutory requirement and so this would not need to be repeated in each individual NICE guideline. This would include adjustments for people with learning disabilities as well as neurodivergent people. The Equalities Impact Assessment has been reviewed and further points have been included in the section on disabilities to emphasise the person-centred approach that the committee has taken which they felt would positively impact these groups. The

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					NICE guideline on learning disabilities and behaviour that challenges: service design and delivery as well as the NICE guideline on autism spectrum disorder in adults: diagnosis and management contain sections on 'enabling person-centred care and support' and 'identifying the correct interventions and monitoring their use' respectively which outline the ways to get people with learning disabilities and neurodivergent people involved in decision making that is tailored to their needs. These apply to all other NICE guidance and so this would not need to be repeated in each individual NICE guideline.
Royal College of General Practitioners	Guideline	008	010	Rec 1.2.9 This recommendation should include the following: People with LD require special consideration as: - their menopause can occur prematurely. - Consultation and discussion with them and their supportive friend will require additional time and reasonable adjustment in terms of timing and location of consultation. People with neurodiversity require special consideration in their discussions about the menopause tailored to their neurocognitive profile	Thank you for your comment. The committee made this recommendation related to time of menopause and potential differences by ethnic background based on their knowledge and experience. Prevalence of early menopause (including in different subgroups of people, for example with learning disabilities) was neither part of the original guideline nor part of the scope of the 2024 update. The committee agreed that knowledge of this could impact practice and have logged this with the NICE surveillance team so that relevant information can be identified which could inform future updates.
Royal College of General Practitioners	Guideline	008	024	Rec 1.3.3 This recommendation does not read very well. People with ethnic minority background could also have a white background therefore, rewording it to say "...people with predominantly white ethnicity." may read better. Additionally, it is important to	Thank you for your comment. The recommendation has been reworded and the comparison to people from white ethnicity was removed. Given this and other stakeholder comments related to people with learning disabilities, it has also been added that people with some lifelong conditions may also experience

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				include that Learning disability is associated with having menopause at an earlier age.	menopause at a younger age. The topic of prevalence of early menopause in different groups was not part of the current scope and the recommendation was based on consensus. However, the topic has been logged with the NICE surveillance team so that this can be considered for future updates so that specific recommendations can be made.
Royal College of General Practitioners	Guideline	009	012	Rec 1.3.5 It is important to include: Patients with LD can benefit, after consent or best of interests assessment of undergoing FSH measurement together with prolactin measurement if they have amenorrhoea. They are at higher risk both of early menopause and Hyperprolactinaemia which can be due to concurrent treatment with neuroleptic or tricyclic medications. Both measurements need repeating in 4-6 weeks with reasonable adjustment on both occasions to result in least distress at the time of the phlebotomy.	Thank you for your comment. The identification of menopause, including FSH measurement, was not in the scope of the 2024 guideline update. Therefore, no searches were carried out or systematic reviews conducted. The committee could therefore not comment on this.
Royal College of General Practitioners	Guideline	009	015	Rec 1.3.5 The following information regarding individuals with neurodiversity should be added: - May present for the first time with distress due to neurodiversity at the time of the menopause - Are at greater risk of developing depression at the time of the menopause with risk of suicidal intent	Thank you for your comment. This wording related to psychological support is part of the recommendation that precedes it which refers to FSH measurement in 2 specific age groups and the text is cross referring to the relevant sections for these age groups. It is therefore not a wider statement on groups that my need psychological support. The text has been revised to make it clearer that it all belongs to the same recommendation.
Royal College of General Practitioners	Guideline	010	022	Rec 1.4.2 We suggest tailoring the information to a person's health literacy level too.	Thank you for your comment. It is agreed that people need to be assessed individually, ensuring they are heard and treated with dignity and respect. This includes providing information in a

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					way that is appropriate to the person's health literacy level. Further detail on treating people as individuals is covered in the NICE guideline on patient experience in adult NHS services as well as in the NICE guideline on shared decision-making so this information is not repeated in all other NICE guidelines (they are cross referred to in recommendations 1.1.1 and 1.1.2). There is an emphasis throughout the guideline to tailor information to the individual, for example it is emphasised that information about benefits and risks needs to be individualised to the person's age, individual circumstances and potential risk factors. There are also recommendation that highlight that a family member or carer can be involved. Making reasonable adjustments as required by the Equality Act 2010 is a statutory requirement and so this would not need to be repeated in each individual NICE guideline.
Royal College of General Practitioners	Guideline	010	026	Rec 1 .4.3 We believe that this recommendation should also include some information on how long it may take for medication to take effect, when to re-consult if symptoms are not improving, adjusting doses or medication depending on response, the method of application e.g. oral, transdermal etc and how to apply/take medication e.g. ensuring transdermal is on clean, dry skin, don't put near breasts etc	Thank you for your comment. This has been rephrased to read 'discuss the possible duration of treatment at the outset', followed by 'rediscuss the benefits and risks of continuing treatment at every review'. Therefore, it is a general discussion about the potential duration which would then be revisited at review which would usually include symptoms in comparison to baseline and optimising treatment if needed. This also now includes a cross reference to the reviewing treatment section (and a link to the relevant section on reviews has been added).
Royal College of General Practitioners	Guideline	011	009	Rec 1.4.4 It is important to extend Individual face- to- face to include that in the care of patients with LD or neurodiversity, individuals	Thank you for your comment. It is agreed that information needs to be accessible and adapted to each individual, ensuring they are heard and

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				may require the presence of a supportive friend – a family member, a carer or friend.	treated with dignity and respect. This includes providing information in the most suitable format for the individual. Further detail on treating people as individuals is covered in the NICE guideline on patient experience in adult NHS services as well as in the NICE guideline on shared decision-making so this information is not repeated in all other NICE guidelines (which is the reason why they are cross referred to in recommendations 1.1.1 and 1.1.2). There is an emphasis throughout the guideline on tailoring information to the individual, for example it is emphasised that information about benefits and risks needs to be individualised to the person's age, individual circumstances and potential risk factors. There are also recommendation that highlight that a family member or carer can be involved. Making reasonable adjustments as required by the Equality Act 2010 is a statutory requirement and so this would not need to be repeated in each individual NICE guideline. This would include adjustments for people with learning disabilities as well as neurodivergent people. The Equalities Impact Assessment has been reviewed and further points have been included in the section on disabilities to emphasise the person-centred approach that the committee has taken which they felt would positively impact these groups. The NICE guideline on learning disabilities and behaviour that challenges: service design and delivery as well as the NICE guideline on autism spectrum disorder in adults: diagnosis and management contain sections on 'enabling person-centred care and support' and 'identifying the correct interventions and monitoring their use'

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					respectively which outline the ways to get people with learning disabilities and neurodivergent people involved in decision making that is tailored to their needs. These apply to all other NICE guidance and so this would not need to be repeated in each individual NICE guideline.
Royal College of General Practitioners	Guideline	014	006	Rec 1.4.16 It is important to add that patients with neurodiversity have variable response to CBT which may, on balance, cause more harm and their vasomotor symptoms are likely to be more severe due to the risk of autonomic instability including "POTs" which has an increased prevalence in people with neurodiversity.	Thank you for your comment. The committee decided that this would be a matter of making adjustments to CBT to tailor it to the individual. Making reasonable adjustments as required by the Equality Act 2010 is a statutory requirement and so this would not need to be repeated in each individual NICE guideline.
Royal College of General Practitioners	Guideline	015	007	Rec 1.4.19 We believe that it is important to include that patients known to be menopausal with LD presenting with recurrent LUTS may benefit from vaginal oestrogen preparations	Thank you for your comment. This recommendation is for all people with genitourinary symptoms associated with the menopause. If recurrent LUTS is the main symptom the person with learning difficulties is presenting with, NICE has produced elsewhere a patient decision aid about reducing the chance of recurrent urinary tract infection (UTI) in postmenopausal women (which is relevant to all women with recurrent UTI) which a healthcare professional can use in a shared decision making process adapted to the person's needs. A cross reference to this patient decision aid has now been added.
Royal College of General Practitioners	Guideline	017	010	Rec 1.4.29 It will be beneficial to provide specific information about how the hormone receptor status of the person would have an impact on safety.	Thank you for your comment. The committee reflected on the wording of all bullet points (including the one related to hormone receptor status) and made changes to clarify how they impact safety. Further information has also been added to the rationale to explain this further.

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Royal College of General Practitioners	Guideline	018	007	Rec 1.4.33 We recommend removing "unless part of a randomised controlled trial."	Thank you for your comment. There were some promising results for laser treatment, but the evidence was insufficient to make a recommendation and the committee thought that there was a potential for adverse effects. However, given some trials showing this to be effective the committee made a research recommendation related to this. Therefore, the wording 'unless part of a randomised controlled trial' cannot be removed because it would not allow this research to be carried out.
Royal College of General Practitioners	Guideline	018	010	Rec 1.4.34 We are concerned that this recommendation does not consider moderate or severe depressive symptoms. Additionally, we think it is important to extend the recommendation to include the following: Consider HRT to alleviate mild depressive symptoms with onset in association with other menopause symptoms **particularly in people with LD or neurodiversity who may present with atypical symptoms of both menopause and depression.**	Thank you for your comment. It is agreed that all assessments of depressive symptoms (including atypical presentations) need to be tailored to each individual, ensuring they are heard and treated with dignity and respect. Further detail on treating people as individuals is covered in the NICE guideline on patient experience in adult NHS services as well as in the NICE guideline on shared decision-making so this information is not repeated in all other NICE guidelines (which is the reason why they are cross referred to in recommendations 1.1.1 and 1.1.2). A definition of depressive symptoms has been added to the guideline which also links to the criteria for depression in the NICE guideline on depression in adults (which includes symptoms such as recurrent thoughts of death or suicidal ideation or evidence of attempted suicide). This definition delineates depressive symptoms from diagnosed depression which is not covered in this guideline. The assessment of depression in people with learning disabilities and neurodivergent adults is outside the scope of the guideline. There is an emphasis throughout the guideline to tailor information to the individual, for

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					example it is emphasised that information about benefits and risks needs to be individualised to the person's age, individual circumstances and potential risk factors. There are also recommendations that highlight that a family member or carer can be involved. Making reasonable adjustments as required by the Equality Act 2010 is a statutory requirement and so this would not need to be repeated in each individual NICE guideline. This would include adjustments for people with learning disabilities as well as neurodivergent people. The Equalities Impact Assessment has been reviewed and now includes further points in the section on disabilities to emphasise the person-centred approach that the committee has taken which they agreed would positively impact these groups. The NICE guideline on learning disabilities and behaviour that challenges: service design and delivery as well as the NICE guideline on autism spectrum disorder in adults: diagnosis and management contain sections on 'enabling person-centred care and support' and 'identifying the correct interventions and monitoring their use' respectively which outline the ways to get people with learning disabilities and neurodivergent people involved in decision making that is tailored to their needs. These apply to all NICE guidance and so this would not need to be repeated in each individual NICE guideline.
Royal College of General Practitioners	Guideline	018	011	Rec 1.4.35 We believe that this recommendation should be extended to include: Consider CBT for depressive symptoms associated with the menopause, **being aware of the unpredictable response of patients with neurodiversity to CBT.**	Thank you for your comment. The committee decided that this would be a matter of making adjustments to CBT to tailor it to the individual. Making reasonable adjustments as required by the Equality Act 2010 is a statutory requirement and

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					so this would not need to be repeated in each individual NICE guideline.
Royal College of General Practitioners	Guideline	018	017	Rec 1.4.36 We believe that the following information should be added to this recommendation: Consider a new diagnosis of autism presenting or associated with depression and associated with a higher risk of suicide. Consider that patients with LD can present with a new onset of behaviour problems due to menopause or depression or the two combined.	Thank you for your comment. Reported symptoms associated with the menopause and the impact that they could have on people with learning difficulties and people with neurodiversity was not a review question that was in the scope of the 2024 guideline update. However, the guideline emphasises in the guideline a person-centred approach to the management of symptoms associated with the menopause by tailoring information and management to the person's age, individual circumstances and potential risk factors. Given that no evidence was systematically reviewed for this matter, the committee could not make specific recommendations related to this.
Royal College of General Practitioners	Guideline	019	003	Rec 1.4.37 This recommendation should be extended to include: Consider CBT for difficulties with sleep associated with the menopause **being aware of patients with neurodiversity having a variable response to CBT.**	Thank you for your comment. The committee decided that this would be a matter of making adjustments to CBT to tailor it to the individual. Making reasonable adjustments as required by the Equality Act 2010 is a statutory requirement and so this would not need to be repeated in each individual NICE guideline.
Royal College of General Practitioners	Guideline	020	003	Rec 1.5.3 It is important to add details of the increased risk of endometrial hyperoestrinism and carcinoma in patients with LD and the need for increased vigilance because of this increased risk.	Thank you for your comment. The relationship between learning disabilities and risk of endometrial hyperoestrinism and carcinoma is outside the scope of the guideline. The committee could therefore not comment on this.
Royal College of General Practitioners	Guideline	021	015	Rec 1.5.11 It is important to extend this recommendation to the following: if needed refer them to specialist psychology services p**articularly if they are known or have recently been found to be affected by neurodiversity.**	Thank you for your comment. The impact of menopause on people in general as well as impact on specific populations was outside the scope of the current guideline. The recommendation referred to was based on the topic of the effects of either taking or not taking HRT on specific health outcomes in early menopause aged 40 to 44. This

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					sparked a discussion in the committee about the support that people may need, and the recommendation was based on consensus. Due to the specific nature of this recommendation and where it originated from, the committee could not make general comments about psychological impact in other groups (such as neurodivergent people).
Royal College of General Practitioners	Guideline	026	Table	In the section on osteoporosis, it is important to mention that any adult patient with LD is at increased risk of osteoporosis which can be exacerbated by the menopause.	Thank you for your comment. The relationship between learning disabilities and risk of osteoporosis is outside the scope of the guideline. The committee could therefore not comment on this.
Royal College of General Practitioners	Guideline	044	011	We are concerned that "and will standardise it." is unclear. It will be beneficial to specify what will be standardised.	Thank you for your comment. This has been rephrased to emphasise that this section would raise awareness about what to discuss.
Royal College of Nursing	Guideline	006	021	Examples of menopause symptoms should include brain fog as it is one of the most common and distressing symptoms.	Thank you for your comment. NICE takes the reports of distressing symptoms associated with menopause seriously. Whilst an update of the list of symptoms and experiences (including in their work environment) was outside the current scope of the 2024 guideline update and therefore, no evidence review was conducted, the NICE surveillance team regularly checks for new evidence for topics within guidelines to see where further work is needed.
Royal College of Nursing	Guideline	007	006	Options for treatment should include lifestyle medication to reflect the evidence that weight management and exercise improves symptom control.	Thank you for your comment. The impact of lifestyle modification was not in the scope of the 2024 guideline update. Evidence for this topic was therefore not searched for and not reviewed and discussed with the committee. The committee could therefore not comment on this. However, in the 'information and support' section of the guideline it is recommended that healthcare professionals should provide information on

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					'interventions, or changes the person can make to support their health and wellbeing'.
Royal College of Nursing	Guideline	009	016	This is contrary to FSRH guidance which says you can test FSH levels on high dose progesterone https://www.fsrh.org/documents/fsrh-guidance-contraception-for-women-aged-over-40-years-2017/	Thank you for your comment. Identifying perimenopause and menopause was not in the scope of the 2024 guideline update. Evidence for this topic was not searched for and not reviewed and discussed with the committee (and the cited reference did therefore not meet inclusion criteria). The committee could therefore not comment on this.
Royal College of Nursing	Guideline	011	007	*When discussing CBT for troublesome menopause symptoms* - needs to be clarified that this does not work on joint pain, vaginal dryness, so needs to be clear what CBT will help with as stated in line 15 on page 12. It is worth mentioning that it is also very difficult to access this on the NHS.	Thank you for your comment. This is referring to the section on discussing treatment options and all options should be discussed. The related recommendations are then in the context of the relevant symptom management (for example it is not mentioned in the section on genitourinary symptoms). Taking into account current pressures on access to services, your comment will be considered by NICE where relevant support activity is being planned.
Royal College of Nursing	Guideline	015	016	*Vaginal Bleeding should be reported to* **healthcare professionals** - Not GP as currently stated This is a multi-professional guidance and should recognise that menopause care is delivered by a wide range of healthcare professionals.	Thank you for your comment. The comment related to vaginal bleeding has been removed because the committee agreed with other stakeholders that this would usually be unrelated to vaginal oestrogen.
Royal College of Nursing	Guideline	019	002	HRT, exercise, and sleep station have all shown to be effective options and are easier to access than CBT, so should be included as treatment options for poor sleep.	Thank you for your comment. Apart from CBT other management options for sleep problems associated with the menopause were not in the scope of the 2024 guideline update. However, the committee acknowledged that there are other options that may be used (including HRT). They have therefore reworded the recommendation to reflect this. It now states that CBT could be used as an option (1) in addition to other treatments

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					(including HRT), or (2) for people for whom other treatments are contraindicated or (3) for people who prefer not to have other treatments. Given the constraints of the scope they could not be more specific than this. A recommendation that information should be shared about 'interventions, or changes the person can make, to support their health and wellbeing' is included in the section on 'information and support'. Information about exercise would fall into the remit of these conversations.
Royal College of Nursing	Guideline	019	006	It is a significantly missed opportunity not to talk about testosterone and when and who to use on This does not give enough clarity about how to initiate or monitor this and what advice to give. It should also discuss role management of women having premature ovary insufficiency (POI) or surgical menopause.	Thank you for your comment. At the time when the scope of the 2024 guideline update was agreed, there was no substantive new evidence that would change the recommendation related to testosterone. It was therefore not included in the update and the committee could not comment on this. However, NICE recognises the importance of this issue and has worked with the NIHR to prioritise funding for research on the matter.
Royal College of Nursing	Guideline	019	015	Should specify not in subtotal or after complex endometriosis surgery - The guidance would have benefitted from covering trial of progesterone in subtotal hysterectomy and endometriosis to be useful in practice.	Thank you for your comment. The committee discussed that choice between oestrogen-only and combined HRT may be different for people with a sub-total hysterectomy. They decided that they could not be prescriptive about the type of HRT to be used for people who have had a sub-total hysterectomy because their condition is clinically complex and they had not reviewed evidence about the effect of HRT on risk of endometrial cancer for this group. They acknowledged that people who were going to have, or had had, a sub-total hysterectomy would be under the care of a specialist who could discuss HRT options tailored to their needs (or a relevant specialist within the MDT). Due to a lack of evidence, no

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					specific recommendation was made for sub-total hysterectomy; however, the term "total" was added before "hysterectomy" in guidance regarding the offer of oestrogen-only HRT to those who have had a hysterectomy. This addition alerts healthcare professionals to consider other factors for patients with a sub-total hysterectomy. The committee also noted that some people have a hysterectomy for a condition that may be affected by HRT, such as endometriosis. The committee did not review evidence related to such conditions. They recognised that the decision about the type of HRT that best balances benefits and risks for the person may be affected by that condition (for example endometriosis) or having had a subtotal hysterectomy. For this reason, they added a recommendation highlighting that advice from a healthcare professional with specialist knowledge of that condition may be needed when making this choice. Due to this stakeholder comment and other related comments, this topic has been logged with NICE surveillance so that it can be considered for a possible update to either the Menopause or the Endometriosis guideline in future.
Royal College of Nursing	Guideline	021	013	There is currently limited or no access to psychological services. How is this to be implemented?	Thank you for your comment. As stated in the rationale, the committee agreed that it is common practice to provide psychological support to people. While a potential referral will have a resource impact, the committee agreed that specialist psychological services will lead to improvements in quality of life and reduce future

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					contacts with health services. Your comment will be considered by NICE where relevant support activity is being planned.
Royal College of Nursing	Guideline	023		Table 1 In the tables on cancer, it states: *Combined HRT preparations containing transdermal oestrogen increase the risk of breast cancer less than combined HRT preparations containing oral oestradiol. [2023]* In the tables of evidence, we could not see robust evidence to back up the above statement. The guideline needs to be clear that the statement is correct that there is evidence that oral oestrogen has increased risk of breast cancer and that the evidence is strong for all types of oral and not just CCE, as this could potentially have a major impact on women.	Thank you for your comment. The committee considered the evidence for oral and transdermal routes of administration of the oestrogen component of HRT. Since some of the evidence showed a significant difference between the subgroups of oral and transdermal routes of administration in the combined HRT comparison, they had made a recommendation to inform people that the increase was smaller with transdermal than oral. This now also includes a study by Vinogradova (2020) which include data on transdermal versus oral HRT but did not provide greater clarity on this matter. The committee considered this and the Brusseler 2018 evidence and discussed that since the same difference was not observed in the oestrogen-only comparison, the argument was less robust than previously discussed. Upon reflection the committee agreed to remove this recommendation and the rationale section revised accordingly as well and a detailed discussion of the evidence and their decision was updated and can be found in the committee discussion of the evidence section of Evidence Review D. The committee also decided that more evidence is needed to clarify this and prioritised this for a research recommendation.
Royal College of Nursing	Guideline	046	018	There is limited resources for CBT, how is this to be implemented?	Thank you for your comment. Your comment will be considered by NICE where relevant support activity is being planned.
Royal College of Nursing	Guideline	078		Table 3	Thank you for your comment. The committee could understand why this could be interpreted as being

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				In table 1.4.10 - the proposed changes are not related to the original statement which was saying that women who could not take systemic HRT could have vaginal oestrogen, this meaning is now lost and will lead to women not being able to have vaginal HRT.	unrelated to the original statement. This is due to the difference in what the 2015 guideline and the 2024 guideline update considered as first line treatment for people where vaginal oestrogen is contraindicated (such as in people with a history of breast cancer). In 2015 the statement referred to the contraindication for systemic HRT and it went to a potential first line treatment of vaginal oestrogen after seeking advice from a healthcare professional with expertise in menopause. In the 2024 update the committee were more cautious and started with a strong recommendation for non-hormonal moisturisers and lubricants and only consider vaginal oestrogen if symptoms have continued despite trying non-hormonal treatments. In the final guideline and in the web version these tables are removed and then sit in a different place because without context it can sometimes lead to misunderstandings. We will make sure that we then put both the stronger recommendation for non-hormonal treatments and the new recommendation related to vaginal oestrogen together so that this relationship between the 2015 and 2024 recommendations is clearer.
Royal College of Obstetricians & Gynaecologists	Evidence Review A	103	003	Hummel 2017: This study includes women diagnosed with sexual dysfunction following breast cancer treatment; CBT for sexual dysfunction is very different from CBT for VMS or CBT for depressive symptoms or sleep experienced during menopause. Sexual dysfunction in this population may not be associated with induced menopause. We suggest that this study is not included together with others as the populations are likely to be different as are the CBT treatments used.	Thank you for your comment. The protocol developed for this review does not specify the types of CBT or the specific symptoms of menopause for inclusion. On this basis, Hummel 2017 meets the requirement of the protocol. The guideline committee expressed an interest in the population of this trial as people with a personal history of breast cancer was a predefined protocol strata for this review.

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Royal College of Obstetricians & Gynaecologists	Evidence Review B2	010	020	This section only states potential harm. Many women with breast cancer seriously struggle and deserve choice of options based on committee experience perhaps.	Thank you for your comment. The aim of this review is to analyse what the impact of vaginal oestrogen is on incidence (recurrence) of breast cancer for people with a personal history of breast cancer. Therefore, the discussion is focused on the evaluation of this potential risk. Given the data that was consistent with a potential increase or decrease in risk of breast cancer recurrence, the committee decided that non-hormonal options would be the first line and vaginal oestrogen second line option for managing genitourinary symptoms. Therefore, vaginal oestrogen, as well as a potential change to adjuvant breast cancer treatment are several options that are discussed. The committee made changes to the order of recommendations so that considerations of adjuvant treatments are being made early in shared decision making and revised the recommendation related to safety considerations for clarity. This would give this section a more logical flow and greater clarity about safety. The rationale of the guideline and the committee discussion section of the evidence were revised accordingly. A visual summary was produced for the management of genitourinary symptoms to clarify treatment options and facilitate decision making.
Royal College of Obstetricians & Gynaecologists	Guideline	General	General	We welcome the update on this important guidance. It's good to see inclusiveness in the guideline with the terminology "women, trans-men and non-binary people registered female at birth". However, we would suggest explaining this term in the introduction and then adhere to using the word "people" /generic terminology for	Thank you for your comment. The guideline's introduction states that the guideline covers women, trans men and non-binary people registered female at birth. For accuracy, some of the recommendations need to list all groups. Elsewhere, the term 'people' is used to be inclusive and concise. This is used where we speak about people for whom it has already been

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				rest of the document except where data/info is referring specifically to this group.	identified that their symptoms are associated with the menopause.
Royal College of Obstetricians & Gynaecologists	Guideline	General	General	We suggest avoiding subjective terms like "bothersome" and troublesome" menopause symptoms and recommend use of more objective language like mid/moderate/severe symptoms to describe. Language in the guidance is over-complicated/lacks clarity/does not make an easy read!	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline. The word 'bothersome' was used in one specific context where a particular measurement scale was used to ask how 'bothered' they were by their symptoms. This was therefore retained it to be consistent with the study's results.
Royal College of Obstetricians & Gynaecologists	Guideline	General	General	While it is good to see the option of offering CBT for treatment of menopausal symptoms, we are concerned about the limited access to CBT in the NHS and lack of good quality evidence on symptom control to be recommending this as first line option for moderate/severe symptoms. Absence of risks does not equate to being an effective treatment option and CBT alone will risk causing harm to many women who should have taken HRT instead for the various health benefits it offers. This is especially true for those who would have benefitted from HRT usage during the transition period.	Thank you for your comment. The CBT recommendations were based on RCT evidence some of which was high quality. However, the committee reflected on the wording of the recommendations and updated it to make it explicit that this was not recommended as a first line treatment. It is now stated that it is an option (1) in addition to other treatments (including HRT) (2) for people in whom other treatments are contraindicated or (3) for people who prefer not to have other treatments. In relation to access to CBT. Your comment will be considered by NICE where relevant support activity is being planned.
Royal College of Obstetricians & Gynaecologists	Guideline	General	General	Despite availability of evidence and data, the guideline makes some recommendations purely based on committee opinion, which can potentially impacts NICE's credibility.	Thank you for your comment. Recommendations were based on evidence reviews which followed rigorous NICE methods and processes, with details outlined in a supplement available on the website (supplement 1 - methods), consistent with the NICE guideline manual. Evidence was systematically reviewed and discussed with a committee consisting of experts and lay people. NICE also commissioned an independent review of the breast cancer and cardiovascular evidence

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					reviews and these checks support the conclusions reached by the committee (with changes made post consultation).
Royal College of Obstetricians & Gynaecologists	Guideline	General	General	Use of observational data to support some recommendations when RCT data is available is difficult to justify/accept in a NICE guidance.	Thank you for your comment. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). However, they highlighted that RCT, and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. The wording has been adjusted in some instances where there were discrepancies between RCT and observational data (for example impact of oestrogen-only HRT on breast cancer). These and other evidence reviews have been revised to implement these changes accordingly.
Royal College of Obstetricians & Gynaecologists	Guideline	General	General	On many occasions, the guideline states "women should be made aware of these risks". Whilst it is important to discuss the benefits and the risks of any proposed treatment including HRT, the current wording of the guideline neither supports the woman nor the clinician with shared decision-making as it highlights the risks without stating the full benefits. It promotes indecision and likely to adversely impact women's health in the long-run. We support the use of statement (P 43 line 5, committee discussion) "using an individualised	Thank you for your comment. Recommendations related to offer HRT for vasomotor symptoms and the recommendation to consider it for depressive symptoms have not changed in the 2024 guideline update. Neither has the information on osteoporosis which shows a decrease of incidence of fragility fractures with HRT. One of the reasons the 2015 guideline required updating was the pharmacovigilance risk assessments by the MHRA and the EMA, concerning the impact of HRT on the risk of breast cancer. NICE is required to consider the impact of regulatory guidance from

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				approach with discussions about benefits and risks of treatment options and tailoring information to individual circumstances and potential risk factors" for all relevant recs.	MHRA in its guidance and as such the additional information on breast cancer does change the balance of risks and benefits from that in the original 2015 guideline. The guideline adopts a person-centred approach emphasising that the information about benefits and risks of HRT should be tailored to the person's age, individual circumstances and potential risk factors - see the 'discussing management options' section. Based on the numbers in the appendix of the consultation version of the guideline (with tables of absolute numbers) a discussion aid document has been developed which includes data visualisation as well as a verbal description of what the numbers mean. Descriptions of the underlying concepts and calculation are also provided. This includes estimates and explains that there are uncertainties around these. This discussion aid has undergone user-testing and was refined based on user feedback.
Royal College of Obstetricians & Gynaecologists	Guideline	General	General	Tables 1& 2, I think there needs to be more clarity as to exactly what they are suggesting? Why isn't HRT mentioned to help sleep, only CBT (1.4.37) ? Overall, it is a very lengthy and unwieldy guideline – Some concerns that many GPs would not read it.	Thank you for your comment. For the draft guideline, the committee opted for a verbal format complemented by tables, providing estimates of absolute numbers from a single source rather than from two different study types. This differs from the approach used in the published version of NG23. This decision was made to facilitate conversations between clinicians and individuals, enabling shared decision-making regarding menopause management. The appendix has been used to produce a discussion aid document including visualisation of the data. This provides details about the type of evidence data originated from, how to interpret the numbers and information about explaining that there is uncertainty around estimates. It also links to the relevant evidence

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					reviews which contain details of the estimates from different study types as well as the confidence intervals. This discussion aid has undergone user-testing and was refined based on user feedback.
Royal College of Obstetricians & Gynaecologists	Guideline	General		**Would it be challenging to implement of any of the draft recommendations?** Yes, offering CBT as first line option in the current NHS is very challenging due to limited resources. There is limited access to CBT and from practical experience, women do not adhere with online CBT sessions and are left to cope with severe symptoms impacting their life and career as they struggle to get back to seen HCP's for advice after being referred for CBT and discharged form services. **Would implementation of any of the draft recommendations have significant cost implications?** Yes, based on over-emphasis on the potential risks without lack of good evidence on the same, there will be less doctors prescribing HRT and less women using it, leading us back to the era where women have struggled with short-medium term symptoms impacting life and career and losing long term health benefits—bone and cardiovascular leading to loss of QALYs.	Thank you for your comment. The CBT recommendations were based on RCT evidence some of which was high quality. However, the committee reflected on the wording of the recommendations and updated it to make it explicit that this was not recommended as a first line treatment. It is now stated that it is an option (1) in addition to other treatments (including HRT) (2) for people in whom other treatments are contraindicated or (3) for people who prefer not to have other treatments. In relation to access to CBT. Your comment will be considered by NICE where relevant support activity is being planned. The committee reviewed the tone of the guideline and made some adjustments to the wording. However, the 2024 guideline update mainly revolved around risks and therefore these are mentioned. The absolute numbers in the appendix were reviewed and used to produce a discussion aid document with visualisation of the data and verbal description so that people can use them to think about the size of these risk in the context of their own individual risk factors. This will aid shared decision-making, has undergone user-testing and was refined based on user feedback.
Royal College of Obstetricians & Gynaecologists	Guideline	Research recommendations	038 - 042	We welcome the research recommendation (8) on safety and effectiveness of alternatives to HRT in women with breast cancer which is very much needed. It is topical with the imminent	Thank you for your comment in support of this.

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				product licensing of a neurokinin 3 receptor antagonist.	
Royal College of Obstetricians & Gynaecologists	Guideline	Research recommendations	038 - 042	The 'key recommendations' include three on vaginal treatments; (3) and (4) could be combined into one recommendation with two bullets. Research rec (8) should be given higher prioritisation as a key recommendation.	Thank you for your comment. All research recommendations in the key research recommendation section are prioritised and the numbering only reflects the order of presentation.
Royal College of Obstetricians & Gynaecologists	Guideline	010	027	1.4.3 It is practically impossible to discuss the duration of HRT at the outset and will vary from person to person depending upon individual circumstances. Better to say, review the indication for HRT at each annual visit.	Thank you for your comment. This has been rephrased to read 'discuss the possible duration of treatment at the outset', followed by 'rediscuss the benefits and risks or continuing treatment at every review'.
Royal College of Obstetricians & Gynaecologists	Guideline	010		1.4.4 The word "prolonged" is inappropriate and unclear! Suggest amendment to provide clarity.	Thank you for your comment. This has been rephrased and the word 'prolonged' has been removed. It has been reworded to read 'discuss the possible duration of treatment at the outset', followed by 'rediscuss the benefits and risks or continuing treatment at every review'.
Royal College of Obstetricians & Gynaecologists	Guideline	011	007 - 014	1.4.4 CBT is not always easy to access, is under-resourced and not a cheap option with lack of evidence around long-term sustained benefits on symptom control. Needs more evidence before recommending as a first line option.	Thank you for your comment. Taking into account current pressures on services, your comment will be considered by NICE where relevant support activity is being planned. In NICE style the wording of the recommendation reflects the level of evidence. Where there is some uncertainty around the evidence the word 'consider' is used to reflect this. The committee reflected on the wording of the recommendations related to CBT and updated it to make it explicit that this was not recommended as a first line treatment. It is now stated that it can be considered as an option (1) in addition to other treatments (including HRT) (2) for people in whom other treatments are contraindicated or (3) for people who prefer not to have other treatments. The committee recommended an approach that is

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					tailored to the individual considering benefits and risks of each treatment in a shared decision making process.
Royal College of Obstetricians & Gynaecologists	Guideline	012	015	1.4.9 This recommendation is not consistent with the text on p47, lines 4-8 which states "not all the evidence on vasomotor symptoms showed that CBT was beneficial. Most of the benefits were seen in reducing how much women were bothered by the symptoms….CBT should be an option rather than a routine treatment for all." The recommendation should be adjusted to reflect that.	Thank you for your comment. The wording has been revised to ensure clarity about CBT 'as an option: in addition to HRT, for people for whom HRT is contraindicated or for people who prefer not to take HRT'.
Royal College of Obstetricians & Gynaecologists	Guideline	012	021	1.4.10 This needs to be a clearer recommendation for allowing the use of HRT in women with type 2 Diabetes. A stronger recommendation that there is no reason why women with Diabetes cannot have HRT if indicated and co-morbidities considered would be welcome. Women with type 2 diabetes mellitus are a group for whom there is a dearth of data on menopause treatment outcomes, in particular risks and benefits of HRT.	Thank you for your comment. Whilst there are some new recommendations in this section, the general topic of comorbidities (including issues relating to type 2 diabetes mellitus) was not in the scope of the 2024 guideline update. Evidence for this topic was not searched for and not reviewed and discussed with the committee. The committee could therefore not comment on this. However, due to this and other feedback some cited references have been passed on to the NICE surveillance team which regularly checks evidence for guideline topics to see whether further updates are needed.
Royal College of Obstetricians & Gynaecologists	Guideline	013	005	1.4.12 We request an update because referral to a haematologist will not change management when there is good quality observational data indicating transdermal HRT does not affect risk of VTE. Referral prolongs the agony wasting NHS resources. Advice from a menopause specialist should suffice.	Thank you for your comment. The impact of HRT on risk of VTE was not in the scope of the 2024 guideline update. Evidence for this topic was therefore not searched for, reviewed or discussed with the committee. The committee could therefore not comment on this. Some stakeholders have provided a list of related references and this has been passed on to the NICE surveillance team to consider for a future update.

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				Define family history.	
Royal College of Obstetricians & Gynaecologists	Guideline	014	005	1.4.16 Consider CBT for troublesome vasomotor symptoms; Avoid troublesome! No good evidence to support this statement. 1.4.16 Within the committee's discussion and interpretation of the evidence for CBT for vasomotor symptoms "they agreed that CBT should not be offered routinely" due to the limited, variable and low quality evidence, but rather "considered as a treatment option." The guidelines should clarify that "CBT should not be offered routinely".	Thank you for your comment. The evidence showed significant improvements for some symptoms. However, to improve clarity the wording of the recommendation has been revised to make it explicit that CBT is an option which could be in addition to HRT, for people in whom HRT is contraindicated or for those who prefer not to take HRT.
Royal College of Obstetricians & Gynaecologists	Guideline	015	014	1.4.20 The statement "some oestrogen is absorbed but, compared with systemic HRT, the amount is small " is confusing and alarming. The amount of oestrogen absorbed with the widely used ultra-low doses of vaginal estrogen is not clinically significant. The MHRA approved vaginal oestrogen in the reduced dosage of 10mcg for over-the-counter use. We recommend re-phrasing to: "the amount absorbed is not clinically significant effect and has no stimulatory effect on the endometrium"	Thank you for your comment. This bullet point was reworded to say that vaginal oestrogen is absorbed locally - a minimal amount is absorbed into the bloodstream (when compared with systemic HRT), but this is unlikely to have a significant effect throughout the body. It is then described in the rationale section that 'the committee agreed to highlight this because it means that there is no need to combine low-dose vaginal oestrogens with systemic progestogen treatment to protect the person against endometrial hyperplasia and cancer'.
Royal College of Obstetricians & Gynaecologists	Guideline	016	008	In the grey box, there is a typo with the repeated phrase 'with no history of breast cancer'	Thank you for your comment. The duplicate text has been removed.
Royal College of Obstetricians & Gynaecologists	Guideline	018		Are there no other psychological symptoms related to the menopause to include in this section? Anxiety as common as depression and	Thank you for your comment. The evidence for CBT in the management of anxiety associated with the menopause did not show overall effectiveness and was not considered by the

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				it may give the impression that CBT should only be considered for depressive symptoms?	committee to be convincing enough to feature in a recommendation. It is possible that anxiety could co-occur with depressive symptoms in the menopause. If this was the case, then CBT for depressive symptoms may also impact on the co-occurring anxiety but the evidence was not there to be specific about this.
Royal College of Obstetricians & Gynaecologists	Guideline	019	013 - 015	1.5.1 There is no mention of women who have had a subtotal hysterectomy or hysterectomy for severe endometriosis when progestogens would usually be prescribed with oestrogen.	Thank you for your comment. The committee discussed that choice between oestrogen-only and combined HRT may be different for people with a sub-total hysterectomy. They decided that they could not be prescriptive about the type of HRT to be used for people who have had a sub-total hysterectomy because their condition is clinically complex, and they had not reviewed evidence about the effect of HRT on risk of endometrial cancer for this group. They acknowledged that people who were going to have, or had had, a sub-total hysterectomy would be under the care of a specialist who could discuss HRT options tailored to their needs (or a relevant specialist within the MDT). Due to a lack of evidence, no specific recommendation was made for sub-total hysterectomy; however, the term "total" was added before "hysterectomy" in guidance regarding the offer of oestrogen-only HRT to those who have had a hysterectomy. This addition alerts healthcare professionals to consider other factors for patients with a sub-total hysterectomy. The committee also noted that some people have a hysterectomy for a condition that may be affected by HRT, such as endometriosis. The

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					committee did not review evidence related to such conditions. They recognised that the decision about the type of HRT that best balances benefits and risks for the person may be affected by that condition (for example endometriosis) or having had a subtotal hysterectomy. For this reason, they added a recommendation highlighting that advice from a healthcare professional with specialist knowledge of that condition may be needed when making this choice. Due to this stakeholder comment and other related comments, this topic has been logged with NICE surveillance so that it can be considered for a possible update to either the Menopause or the Endometriosis guideline in future.
Royal College of Obstetricians & Gynaecologists	Guideline	035	010	1.6.4 People in early menopause. "Taking HRT increases the risk of breast cancer." This statement is not supported by the data in this age group. The way this is presented in isolation and without added context is misleading and will cause considerable confusion and alarm and this could cause long term harm to many.	Thank you for your comment. The section on early menopause has been revised and only the message to explain to people experiencing early menopause that, for them, the benefits and risks of either taking or not taking HRT are likely to lie between those for people with premature ovarian insufficiency and those for people aged 45 or over has been retained from the consultation version. In accordance with the systematic review protocol only evidence on breast cancer was identified but it was decided that this highlighted that further research is necessary to clarify the benefits and risks. The committee also noted that the focus of this topic was too narrow to cover early menopause adequately and suggested several topics that based on stakeholder feedback which were logged with the NICE surveillance team for future consideration in an update. This also

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					includes the topic of the impact of early menopause itself on various health outcomes and what the best options are to manage potential negative impact. However, this was not part of the 2024 guideline update and so the committee could not comment on this.
Royal College of Obstetricians & Gynaecologists	Guideline	066	055	"oestrogen-only HRT very slightly increases the risk of ovarian cancer after 5 years of use and this risk increases with duration of use" The Table shows no increase in risk at 5 years and a slight increase at 10. It cannot be extrapolated that the risk goes up at 5 years, it should say 10.	Thank you for your comment. For oestrogen-only HRT a significant risk increase was identified from the evidence (5 to 9 years of use) - see evidence review F (figure 21). The tables of absolute numbers were checked, and this amounted to an increase of 1 in 1000 women which whilst significant is small.
Royal College of Obstetricians & Gynaecologists	Guideline	067	013 - 021	Long term FU from the WHI RCT showed that there was a reduced risk of coronary heart disease for women starting oestrogen only HRT aged 50 to 59. Manson et al 2013 showed significant reduction in coronary heart disease including MI OR 0.67 95% CI 0.46-0.98 with oestrogen only HRT in women aged 50-59. This was presented in the NICE analysis yet is not reflected in the recommendations. Patients need to know that if they start HRT at the time of the menopause, this is likely to be associated with CVD benefit: window of opportunity especially for those with early menopause.	Thank you for your comment. The result mentioned in your comment refers to a result in Evidence Review C for the comparison oestrogen-only versus placebo, outcome coronary heart disease (including MI) in current and past users (unknown recency) with 5-9 years duration of HRT use at 13 years cumulative follow-up, for the age at first use 50-59, which is part of a subgroup analysis that also includes results for age at first use 60-69 and 70-79. The data shows that there is a statistically significant difference in the individual subgroup 50-59 (RR 0.67 (0.46 to 0.98)), but no statistically significant differences for 60-69 (RR 1.01 (0.83 to 1.22) or 70-79 (RR 0.98 (0.79 to 1.23)). However, it is misleading to conclude that there is a difference in effect in different subgroups, because the test for subgroup differences was not statistically significant p=0.17 (please see forest plot figure 77 in Appendix E of Evidence Review C). Therefore, it is misleading to conclude that the reduced effect shown is specific to the age group 50-59. This methodology is in line

					with the NICE methods and processes and the Cochrane Handbook. As a result, the committee are unable to make a recommendation highlighting any reduced risk in coronary heart disease based on this result. This is further discussed in the committee's discussion of the evidence section in Evidence Review C which has been updated. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). With regards to the conclusion related to coronary heart disease the independent review concluded 'If considering each forest plot individually, there were subgroups where evidence suggests that HRT appears to be associated with cardiovascular benefits, which have been noted in the stakeholder comments. However, we agree with the committee's interpretation of the evidence, based on the limited power in these analyses to detect subgroup differences, and lack of interpretable trends of effects.' To address the issue of 'limited power' highlighted in this independent review a research recommendation was made to increase the evidence base. However, they highlighted that RCT, and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. These and other evidence reviews have been revised to implement these changes accordingly.

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Royal College of Obstetricians & Gynaecologists	Guideline	095	Appendix A - Table 12	Dementia: It is exceptional to start HRT for the first time at the age of 65 or above. Including these figures here may come across as the risk of dementia with HRT use for all users. The vast majority of users would have started before 65 and these figures would therefore not apply to them. Hence, not sure of the purpose of this table.	Thank you for your comment. This statement is underpinned by RCT data of women who initiated HRT use after the age of 65. This study showed an increased risk and therefore the committee decided that it was important to highlight this. Data for ages younger than 65 were inconclusive because there were studies that were inconsistent with each other (one showing and increased risk and the other showing no difference). The committee therefore decided not to comment on dementia risk for people initiating HRT use before the age of 65 because no clear conclusions could be reached.
Royal College of Podiatry	Guideline	General	General	The guideline recommends consideration of referral to CBT, as a low-risk intervention, as an alternative to HRT, for those who do not wish to take HRT, for whom HRT is contraindicated, for those with troublesome vasomotor symptoms, sleep difficulties, and symptoms associated with the menopause in trans men and non-binary people registered female at birth. The evidence around the effectiveness of CBT in managing menopausal symptoms is low to moderate, but the potential impact in the event of a surge in service demand could make implementation challenging. However, a preference for CBT over HRT may generate an unrealistic demand for psychological services. We would welcome examples of good practice for healthcare professionals, including podiatrists, for appropriate referral pathways to psychology therapy services. We would also welcome increased training in CBT for all healthcare professionals.	Thank you for your comment. The committee reflected on the wording of the recommendation to make the points cited by the stakeholder explicit, it now states that CBT is an option (1) in addition to other treatments (including HRT) (2) for people in whom other treatments are contraindicated or (3) for people who prefer not to have other treatments. Making this optional is in line with the quality of the evidence. The committee acknowledged in the impact section of the guideline that there are long waiting times for CBT. They also noted that people currently trained in providing this kind of therapy may not be familiar with menopause-specific CBT and training on this may incur costs and increase waiting times in the short term. However, online and group CBT may be easier and less costly to adapt to menopause-specific CBT. There are also resources available to train people in providing menopause-specific CBT (and could also inform the adaptation of online CBT), which could facilitate implementation. Your comment will be considered by NICE where relevant support activity is being planned.

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Royal College of Podiatry	Guideline	general	General	The guideline identifies low levels of evidence for the needs of people from Black and ethnic minority groups, who may be susceptible to early menopause. As a professional group podiatrists take an active role in delivering public health messages, they are therefore, well placed for shared involvement in the provision of educational support in the community, to mitigate inconsistencies in equality of opportunity for access to advice for HRT and associated service provision**.** Targeted education support in the community will be needed to mitigate inconsistencies in the equality of opportunity for access to advice and service provision.	Thank you for your comment. The committee felt that it was important to raise awareness that early menopause may be more prevalent in people from some ethnic backgrounds. NICE is planning implementation support to disseminate the guideline's information. Your comment will be considered by NICE where relevant support activity is being planned.
Royal College of Podiatry	Guideline	007 26 Table 1	001	The draft guideline has not updated research on the role of HRT and relief from musculoskeletal symptoms, such as joint or muscle pain. The incidence of musculoskeletal pain is particularly high in menopausal aged women raising the possibility these symptoms relate to changes in hormone levels. Podiatrists are well placed to identify, protect, and facilitate shared care aimed at improving women's lower limb musculoskeletal health caused by life-course factors, such as hormone changes. We would therefore welcome the inclusion of two reviews from 2018 and 2023 in the draft guidelines, which indicate (limited) evidence that HRT may help musculoskeletal symptoms at population level. *Watt F. E. (2018). Musculoskeletal pain and menopause. Post reproductive health, 24(1), 34–43.*	Thank you for your comment. Prevention or treatment of musculoskeletal symptoms was not in the scope of the 2024 guideline update (and the cited references therefore did not meet any protocol criteria). Evidence for this topic was therefore not searched for and not reviewed and discussed with the committee. The committee could therefore not comment on this.

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				Gulati, M., Dursun, E., Vincent, K., & Watt, F. E. (2023). The influence of sex hormones on musculoskeletal pain and osteoarthritis. Lancet Rheumatology, 5(4), e225–e238. In addition, Table 1 shows no updated research on the role of HRT on muscle mass, strength, or osteoporosis. The Royal Osteoporosis Society advocates the provision of HRT to prevent osteoporosis in the years around the menopause, particularly in the case of early menopause. We would also welcome signposting in the draft guidelines to organisations such as *the Royal Osteoporosis Society*.	
Royal College of Podiatry	Guideline	010	008, 009, 010	*Rec 1.4.1* This recommendation will be a challenging change in healthcare practice with the need to update understanding of evidence in key areas, such as cardiovascular disease, breast cancer, venous thromboembolism, and stroke risk. Podiatrists take an active role in delivering public health messages, for example, they specialise in early detection and management of limb and life-threatening chronic conditions through early detection of vascular and neurological disease in the foot and lower limb. They also promote healthy active lifestyles, protecting, and improving health through having healthy conversations with service users. Therefore, we would welcome national signposting of all healthcare staff, to organisations such as the *British Menopause Society and the International Menopause Society* for further development and or training.	Thank you for your comment. The committee noted that recommendation 1.4.1 would reinforce rather than change healthcare practice because it is usually expected that the healthcare professionals would provide information about treatment options and the related benefits and risks associated with them. The relevant key information is then provided in tables 1 and 2. The committee reflected on the presentation of information and used the appendix to produce a discussion aid document that includes visual presentation aimed to facilitate the shared decision making process between the person and the healthcare professional. This discussion aid has undergone user-testing and was refined based on user feedback. The committee agreed that continuing professional development is important for all healthcare

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					professionals and could include training related to menopause.
Royal College of Podiatry	Guideline	013	010, 011,012	*Rec 1.4.13* To implement this may require podiatrists to re-evaluate existing local cardiovascular and cardiac rehabilitation services with the potential for service redesign focusing on early detection, prevention, and management. In addition, Healthcare professionals would need further training and development to have meaningful discussions on menopause and HRT to facilitate local shared care referral pathways. The podiatry profession is ideally placed and has experience in implementing service redesigns to improve health outcomes for people with a history of peripheral arterial disease. *Matthews, S., Smith, P., Chadwick, P., Smyth V., (2016). Implementing a community-based structured exercise programme for patients with peripheral arterial disease in conjunction with an existing cardiac rehabilitation service results in better outcomes. The British Journal of Diabetes*.	Thank you for your comment. Organisation of services was outside the scope of the 2024 guideline update. Your comment will be considered by NICE where relevant support activity is being planned.
Royal College of Podiatry	Guideline	021	016 - 020	*Rec 1.6.2* For healthcare professionals already working with people at risk of cardiovascular disease, this will require some change in healthcare practice with the need to update understanding of evidence in this area. Therefore, we would welcome signposting of healthcare professionals, including podiatrists, to organisations such as the *British Menopause Society and the International Menopause Society* for further development and or training.	Thank you for your comment. Making recommendations related to continuous professional development is outside the scope of the 2024 guideline update. This is within the remit of the relevant professional bodies.

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Royal College of Podiatry	Guideline & EVIDENCE REVIEW g	021 006	021 - 023 010 - 011	*Rec 1.6.3* To clarify the use of HRT in dementia prevention and overcome limited evidence in this area, we suggest the development of an algorithm for NG23, or to offer existing resources/examples of good practice. This would support healthcare professionals, including podiatrists, in navigating discussions with people and their families. We would welcome a clear set of key messages from the guideline, for the public, to reduce current confusion about the associated risks and benefits of HRT.	Thank you for your comment. The committee decided to adopt a person-centred approach to HRT whereby the person is given the information and can then make an informed choice about whether or not to take it. This would not be achieved by an algorithm which suggests a specific choice to start with. However, the committee reflected on the tables in the appendix and decided to develop a discussion aid document which includes data visualisation to facilitate shared decision making between the person and the healthcare professional when making treatment choices. This discussion aid has undergone user-testing and was refined based on user feedback. The key message of the previous guideline to offer HRT for vasomotor symptoms has not otherwise been changed.
Royal Pharmaceutical Society	Guideline	General	General	We welcome the updating of the 2015 guidance. Individualising care for people experiencing menopausal symptoms and explaining all available treatment options is essential and we are pleased to see this emphasised in the guidelines. The guidance demonstrates a growing recognition of the complexities and unique challenges faced by women during menopause. The inclusion of comprehensive, evidence-based recommendations in this guideline reflects a commendable effort to improve the quality of care for women experiencing menopausal symptoms	Thank you for your comment in support of this.

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Royal Pharmaceutical Society	Guideline	General	General	More emphasis on CBT to help alleviate some menopausal symptoms is well placed.	Thank you for your comment in support of this.
Royal Pharmaceutical Society	Guideline	General	General	It is good to see genitourinary symptoms mentioned alongside a variety of treatment options.	Thank you for your comment in support of this.
Royal Pharmaceutical Society	Guideline	General	General	Further areas for research have been identified and we agree with these priority areas.	Thank you for your comment in support of this.
Royal Pharmaceutical Society	Guideline	General	General	More support is needed to ensure all healthcare professionals have a general understanding of the menopause.	Thank you.
Royal Pharmaceutical Society	Guideline	General	General	We welcome the tables: Combined HRT: effect on health outcomes and Oestrogen-only HRT: effect on health outcomes. They will be very useful in practice	Thank you for your comment in support of this.
Royal Pharmaceutical Society	Guideline	007	012 - 014	It would be helpful to have the NHSE endorsed Selfcare Forum Menopause PIL cross referenced here for health professionals to use in consultations. It would be good if this PIL was available in different languages to ensure inclusivity.	Thank you for your comment. This section of the guideline was not updated. This means that the only changes were related to wording to bring it in line with the current NICE style. We could therefore not add a link to the PIL to this section because it would have needed to go through all relevant processes to ensure consistency with the current content.
Royal Pharmaceutical Society	Guideline	011	007 - 013	We note that there are already long waiting lists and capacity issues with CBT services for patients with mental health or malignancy indications. We would welcome NICE NG23 updated guidance indication that menopausal anxiety and depression needs are a priority indication. Considering the evidence base	Thank you for your comment. The committee acknowledged in the impact section of the guideline that there are long waiting times for CBT. They also noted that people currently trained in providing this kind of therapy may not be familiar with menopause-specific CBT and training on this may incur costs and increase waiting times in the

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				review for CBT as outlined within the consultation document, the focus should include patient profiles such as clinical depression and menopausal anxiety and depression; cancer and menopause anxiety and depression.	short term. However, online and group CBT may be easier and less costly to adapt to menopause-specific CBT. There are also resources available to train people in providing menopause-specific CBT (and could also inform the adaptation of online CBT), which could facilitate implementation. Your comment will be considered by NICE where relevant support activity is being planned. The symptoms for which CBT can be considered is captured in section 1.5 (evidence showed it to be effective in the management of vasomotor symptoms, depressive symptoms and sleep problems) and wording has been revised to ensure clarity about CBT 'as an option: in addition to other treatments (including HRT), for people for whom other treatments are contraindicated or for people who prefer not to take HRT'. This clarifies that this is an option rather than a routine treatment which would also impact on waiting times. The committee did not agree that menopausal anxiety and depression should be the focus for CBT and decided that vasomotor and sleep problems should equally be considered because the evidence was of equal strength if not stronger than for depressive symptoms. If there are significant depressive symptoms and depression is suspected or a threshold for a diagnosis is met, then the NICE guideline on depression in adults applies to which a cross reference is made. To delineate depressive symptoms from clinical depression a definition has been added.
Royal Pharmaceutical Society	Guideline	012	011 - 014	There is a need for NICE guidance on HRT dosing regimens that maybe required for treatment of menopause symptoms in Trans Men and Non-binary people registered female	Thank you for your comment. The effectiveness of HRT treatment was not part of the 2024 guideline update and in topics that were part of the scope of the update. No evidence was identified that

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				at birth. The updated guidance when published in 2024 will raise expectations in this group for HRT treatment. Experience within clinics indicate that even if these patients are off GAT they feel that they need higher HRT dosing. We welcome the recommendation for research in these patient groups; however, guidance on prescribing should be considered now.	specifically related to people who had taken gender affirming hormone therapy in the past and are experiencing symptoms associated with the menopause. Without the evidence the committee could not comment on dosages.
Royal Pharmaceutical Society	Guideline	013	001 - 012	We would suggest a change in the sentence as follows - ...initiated on recommendation by a health professional with expertise in menopause. There are already capacity issues as specialists are dealing with COVID backlogs. The expectation that the first prescription is issued by the menopause specialist will have ramifications on capacity and affect patient care adversely due to long waiting times. We suggest that initiation is not limited to a menopause specialist.	Thank you for your comment. The definition of 'healthcare professional with expertise in menopause' is not mandating that these professionals are in tertiary centres. They have been defined as professionals with specialist knowledge, skills and training (for example as recognised by the British Menopause Society, the Faculty of Sexual and Reproductive Healthcare or the Royal College of Obstetricians and Gynaecologists) who can advise and support colleagues in managing complex menopause-related needs and risk factors affecting decision making.....'. Therefore, this could also be GPs with a special interest in menopause who have undertaken further training. This broader definition would mean a wider pool of such professionals with a positive impact on waiting times. In the context of a personal history of coronary heart disease and stroke, the committee decided that the involvement of a professional with expertise in menopause would be in the person's best interest.
Royal Pharmaceutical Society	Guideline	013	027 - 029	Consider the evidence base for TAH with RRBSO recommendation for management of familial and genetic risk of ovarian cancer as unopposed oestrogen is associated with a lower increase in risk for breast cancer vs	Thank you for your comment. The NICE guideline on identifying and managing familial and genetic risk of ovarian cancer has since been published and therefore the cross reference has been updated. This includes a section on HRT after risk-

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				combined HRT, associated with higher breast cancer risks [but combined HRT would need to be offered if the patient has only had a BSO].	reducing surgery including for people with or without a uterus.
Royal Pharmaceutical Society	Guideline	016	014	Clarify text and add in that vaginal oestrogen is contra-indicated in women with breast cancer on aromatase inhibitors - in line with statement 1.4.30	Thank you for your comment. The cited section has been reordered with the recommendation related to aromatase inhibitors (referred in the comment to as 1.4.30) moving up in the order to make this more explicit from the start. This would then place the other recommendations within this context.
Royal Pharmaceutical Society	Guideline	018	003 - 008	The guideline addresses vaginal dryness, a common and distressing symptom of menopause. It's encouraging to see that treatments for this condition are now more accessible, being available over the counter in local pharmacies. This could be highlighted more clearly within the guideline. This not only enhances access for women but also helps to reduce the burden on general practice appointments, a crucial factor in improving healthcare efficiency and patient experience.	Thank you for your comment. The availability of over the counter treatment and the reduction in GP appointments were both considered in the economic model and has been highlighted in the 'The committee's discussion and interpretation of the evidence' section of evidence review B1.
Royal Pharmaceutical Society	Guideline	019	015	Unopposed oestrogen is prescribed with TAH but with complex cases eg TAH and severe endometriosis or subtotal hysterectomy, these patients can be / would be advised to use combined HRT [ref Cochrane database; Post Reproductive Health publications 2022.]	Thank you for your comment. The committee discussed that choice between oestrogen-only and combined HRT may be different for people with a sub-total hysterectomy. They decided that they could not be prescriptive about the type of HRT to be used for people who have had a sub-total hysterectomy because their condition is clinically complex and they had not reviewed evidence about the effect of HRT on risk of endometrial cancer for this group. They acknowledged that people who were going to have, or had had, a sub-total hysterectomy would be under the care of a specialist who could discuss HRT options

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					tailored to their needs (or a relevant specialist within the MDT). Due to a lack of evidence, no specific recommendation was made for sub-total hysterectomy; however, the term "total" was added before "hysterectomy" in guidance regarding the offer of oestrogen-only HRT to those who have had a hysterectomy. This addition alerts healthcare professionals to consider other factors for patients with a sub-total hysterectomy. The committee also noted that some people have a hysterectomy for a condition that may be affected by HRT, such as endometriosis. The committee did not review evidence related to such conditions. They recognised that the decision about the type of HRT that best balances benefits and risks for the person may be affected by that condition (for example endometriosis) or having had a subtotal hysterectomy. For this reason, they added a recommendation highlighting that advice from a healthcare professional with specialist knowledge of that condition may be needed when making this choice. Due to this stakeholder comment and other related comments, this topic has been logged with NICE surveillance so that it can be considered for a possible update to either the Menopause or the Endometriosis guideline in future. The cited reference did not meet the inclusion criteria because it was not comparing HRT use versus no HRT use for the outcome of incidence of endometrial cancer.

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Royal Pharmaceutical Society	Guideline	019	006 - 007	Although this text is greyed out, we would suggest amending the sentence to say 'for people with low sexual desire associated with the menopause and causing distress if HRT alone is not effective. While testosterone treatment can be beneficial for some women, especially those with low libido, the guideline needs to provide clearer direction for clinicians. The suggestion to optimise oestrogen treatment before prescribing testosterone is a prudent approach, and the guideline could benefit from a clear statement advising clinicians to seek further guidance or consider referral when low libido is suspected to be related to testosterone levels if they do not feel confident to make sure a diagnosis. Such guidance would undoubtedly enhance patient outcomes.	Thank you for your comment. At the time when the scope of the 2024 guideline update was agreed, there was no substantive new evidence that would change the recommendation related to testosterone. It was therefore not included in the update and the committee could not comment on this. However, NICE recognises the importance of this issue and has worked with the NIHR to prioritise funding for research on the matter.
Royal Pharmaceutical Society	Guideline	022	003	As per the French EN3 study, both micronized progesterone and dydrogesterone are considered as proffering lower breast cancer risk increase and should be stated in the updated guidance as there are patient profiles who do not settle on micronized progesterone and side effects mean that a suitably low risk alternative option for endometrial protection needs to be offered. Dydrogesterone, a progestogen used in hormone replacement therapy (HRT), is perhaps not as widely utilised as it could be. The EN3 Study sheds light on the effectiveness and safety profile of dydrogesterone, suggesting it could be a valuable option for many women. Inclusion in the NICE guideline would be a positive development, bringing attention to a potentially underused treatment option.	Thank you for your comment. Some of the E3N cohort in the breast cancer review have been included as part of the IPD dataset from the CGHFB. The committee have discussed this data and agreed that the evidence is insufficient to support a recommendation that micronised progesterone and dydrogesterone have a lower breast cancer risk than other progestogenic constituents. The details of this discussion can be found in the committee's discussion of the evidence section in evidence report D. The committee considered that the number of cases of breast cancer with those using micronised progesterone were few and agreed that this supported a recommendation to highlight that there was not enough evidence to support any differences in the risk of breast cancer with micronised progesterone. The committee agreed

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					that more evidence was required to make any robust recommendations for micronised progesterone and made a research recommendation. With regard to other publications including the E3N cohort, the committee have considered that not all participants of the E3N have been included in the CGHFB meta-analysis. However, where there are separate publications with overlapping follow-up periods, and no disaggregation of participants, these have not been included, to avoid double counting of participants in the E3N cohort. As per our processes and methods, we do not reanalyse any existing IPD data as NICE does not generally have the same access to the individual participant data, and therefore the data has been used as it has been published. Due to the large size of the IPD data from the CGHFB, this has been prioritised for inclusion in the review. IPD meta-analysis is a powerful tool to summarise data across studies and enables a more detailed analysis than what would be possible if summary statistics are extracted from individual studies as would usually be the case in NICE guidelines. Fournier 2014 was included as this study had a later follow-up period of the E3N cohort that was not covered by CGHFB. However, since the data from the Fournier 2014 publication did include participants that were in the meta-analysis from CGHFB, the results were analysed separately and do not support a decreased risk of breast cancer with both micronized progesterone and dydrogesterone. NICE commissioned an independent review of the breast cancer and cardiovascular evidence review and these checks

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					supported the conclusions reached by the committee.
Royal Pharmaceutical Society	Guideline	037	016 - 028	This section looks at the definition of a health professional with expertise in menopause. Many GPs consider themselves as having expertise in menopause but are not BMS accredited. They may have done additional training but may not fulfil all the BMS criteria and may not have expertise in all four listed specialist areas in lines 20-26. Perhaps rewording this section to be more accommodating would also resolve the workload concerns of the original draft guidance and our suggested amendment at number 9.	Thank you for your comment. The definition has been reviewed and reworded and does not mandate this to be a healthcare professional in tertiary care. However, the committee thought it was important that it would be a person ' with specialist knowledge, skills and training (for example as recognised by the British Menopause Society, the Faculty of Sexual and Reproductive Healthcare or the Royal College of Obstetricians and Gynaecologists) who can advise and support colleagues in managing complex menopause-related needs and risk factors affecting decision-making'. This could be a GP with a special interest in menopause. The committee decided that their definition strikes the right balance between the knowledge that is needed and being accommodating to a wider professional group.
Royal Pharmaceutical Society	Guideline	047	012 - 018	The guideline helpfully clarifies that CBT has not been proven to help with low moods associated with menopause status. An explicit statement would be useful for health professionals.	Thank you for your comment. This section describes that the results were mixed with most of the measurement scales not showing a difference but 1 indicating an improvement. Given that the effectiveness of CBT on depressive symptoms is established (see NICE's guideline on depression in adults) the committee decided on balance that CBT should be an option. The rationale section describes the reason for this conclusion (including the mixed findings in the evidence).
Royal Pharmaceutical Society	Guideline	048	007 - 015	Natural progesterone, with biological plausibility, is being researched independently for sleep problems, including insomnia and early wakening. Research for use in menopause and sleep should be a research recommendation. Qs include could natural	Thank you for your comment. Apart from CBT other management options for sleep problems associated with the menopause were not in the scope of the 2024 guideline update. Therefore a research recommendation related to natural progesterone could not be added.

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				progesterone be used on its own in postmenopausal women over 65 for sleep benefit? Does natural progesterone a part of HRT regimen improve menopausal sleep outcomes?	
Society For Endocrinology	Guideline	General	General	The SfE welcome the new NICE draft Menopause guidance, which includes new evidence and has identified several areas of future research requirements and recommendations. The SfE would welcome the recognition from NICE that real-world data collection, outside clinical trials, is necessary to address the lack of data in groups often under-represented in research trials but who may nonetheless be prescribed treatments such as HRT for menopause—for example, minority ethnic groups and those with multi-morbidities. Furthermore, women with type 2 diabetes mellitus are a group for whom there is a dearth of data on menopause treatment outcomes, in particular risks and benefits of HRT. The NICE guidance 2015 statement, "1.4.10 Consider HRT for menopause symptoms in people with type 2 diabetes after taking comorbidities into account and seeking specialist advice if needed" has not been updated. Feedback from women, including during a recent workshop run by Diabetes UK, attended by our stakeholder members, suggests that GPs are somewhat cautious when considering	Thank you for your comment. The guideline makes research recommendations to address groups that are often underrepresented. Specifically, they made 2 research recommendations, 1 related to health outcomes of HRT for people from ethnic minority backgrounds and another addressing Health outcomes of HRT for trans men and non-binary people registered female at birth (who are not taking gender-affirming hormone therapy at the time of taking HRT or in the follow-up period). For all other research recommendation, it has been specified in the details of the population that research is particularly welcome in groups that are considered in our equality impact assessment form. Decisions about the topics to be updated are made in various stages (reports related to this can be found under the section 'is this guideline up to date' at the following link). This was followed by a scoping workshop and consultation on the scope for the 2024 guideline update. At the time of this no substantive evidence was identified related to type 2 diabetes which would change the existing recommendations. With this topic not being updated the committee could not make a research recommendation. In relation to unlicensed doses NICE usually makes recommendations in line with regulatory bodies so would only comment on licensing if a recommendation is made outside these parameters. The word 'troublesome' has been removed from the guideline. Bothersome

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				menopause treatment for women with type 2 diabetes; the result is that these women are mostly offered no treatment at all. The SfE would welcome a recommendation from NICE that more research is needed in this area and that real-world data collection would be beneficial, given that women with type 2 diabetes are generally under-represented in existing RCTs and observational studies of menopause treatments. The SfE would also support an endorsement by NICE for the need for collecting data to capture outcomes relating to the use of licensed HRT formulations, that are prescribed in unlicensed doses (post-licensing) for which side effects or risks may not, therefore, be known. The use of the terms "bothersome" and troublesome" menopause symptoms appear repeatedly in the new NICE draft document. These are arbitrary and subjective terms and may be considered somewhat paternalistic and patronising to women. Feedback from women suggesting the latter has been received by SfE members. We recommend reviewing these terms and considering using more objective terms to describe menopause symptoms, such as moderate/severe, instead of bothersome and troublesome. Social media discourse and patient feedback suggest that despite existing NICE guidance, many women in the UK continue to be unable to access HRT as recommended, often due to ongoing reticence among GPs to prescribe it	remains in one instance where the evidence refers to a scale that measures how much people are bothered by their symptom. Since this is specifically related to published evidence the committee kept it consistent with this. Access to HRT and commenting on shortages of HRT is outside the scope of the guideline and therefore the committee did not comment on this.

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				and also due to medication shortages. A recognition/acknowledgement by NICE that guidance is not always universally applied at the grassroots and that it is not within the remit of NICE to address this would go some way to reconcile ongoing concerns and distress among the women who feel "unheard" within the NHS setting, despite NICE producing best practice guidance.	
Society For Endocrinology	Guideline	General	General	The SfE would welcome recognition of the association between thyroid disease and the menopause and feel that a number of statement are missing: 5.1.3 'Identifying perimenopause and menopause' – could they include a clause to say 'consider testing for thyroid dysfunction where peri/menopause has been ruled out but patients are presenting with 'menopause-like' symptoms.' This links back to the NICE guideline on thyroid disease section 1.2.5 which states 'Be aware that in menopausal women symptoms of thyroid dysfunction may be mistaken for menopause.' 1.4 Taking comorbidities into account It would be good to have a clause to the effect of 'Be aware that patients taking levothyroxine to treat hypothyroidism may require an increase in their dose after starting oral HRT. Re-test thyroid function after starting tablet-combined HRT.'	Thank you for your comment. Identification of perimenopause and menopause' was not a topic that was updated. This would include symptoms that may overlap with other conditions. Having not reviewed the evidence, the committee could not comment on this.
South Tyneside and Sunderland NHS Foundation Trust -	Guideline	General	General	Has Interpersonal Therapy been considered within the evidence base as a psychological intervention to support people struggling with	Thank you for your comment. The effectiveness of the effectiveness of interpersonal therapy for the management of symptoms associated with the

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Gateshead Talking Therapies Service				menopause symptoms/transition? This is an evidence based therapy which has a treatment pathway specifically relating to 'transitions' and could be a beneficial therapeutic modality to recommend.	menopause was not in the scope of the 2024 guideline update. Evidence for this topic was not searched for, reviewed or discussed with the committee. The committee could therefore not comment on this.
South Tyneside and Sunderland NHS Foundation Trust - Gateshead Talking Therapies Service	Guideline	General	General	Has reference been made to people in the work place who are struggling with menopause symptoms? Could guidance involve advice for managers – or recommend training for managers to understand the potential impact this can have to ensure that staff are appropriately supported in the workplace.	Thank you for your comment. The impact of menopause symptoms on the workplace was not in the scope of the 2024 guideline update. Evidence for this topic was therefore not searched for, reviewed or discussed with the committee. The committee could therefore not comment on this.
South Tyneside and Sunderland NHS Foundation Trust - Gateshead Talking Therapies Service	Guideline	006	014	This statement could be interpreted quite dismissively; if a professional states "it is a normal transition" to a woman struggling with menopause they may disengage or feel dismissed. Could state "what is happening to the body during menopause, and although this is normal it can be a difficult transition for some"	Thank you for your comment. This has been revised to say 'in most people' it is a normal life transition. The objective of this recommendation is very general about providing information. NICE takes the reports of the debilitating symptoms, the considerable concern it causes and the impact that symptoms associated with the menopause have, seriously. Whilst an update of the list of symptoms and experiences was outside the 2024 scope of the guideline update (and therefore no evidence review was conducted), the NICE surveillance team checks regularly for new evidence for topics within guidelines to see where further work is needed.
South Tyneside and Sunderland NHS Foundation Trust - Gateshead Talking Therapies Service	Guideline	011	007	After reading the research review it appears that CBT can people with anxiety and depression associated with menopause – not as a treatment for menopause. I feel that professionals (and CBT therapists) should have more detail in this guidance about what CBT is likely to be useful for: E.g.	Thank you for your comment. The section referred to in the comment is related to discussing CBT treatment rather than the symptoms for which it is recommended which are addressed in section 1.5 on symptom management. The wording in relation to discussing CBT treatment has been revised to ensure that information is provided about what CBT is (including menopause-specific CBT) and that preferences and needs should be taken into

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				1.4.4 CBT can be a useful treatment for managing depression and anxiety associated with troublesome menopause symptoms. When discussing CBT as a possible treatment option, discuss available options, e.g.: • individual face-to-face • individual virtual • group sessions • self-help • online. [2023] CBT Therapists should be aware of the physiological and psychological symptoms of menopause and signpost people to their GP for investigation or management if appropriate. CBT has limited impact on hormonal changes, but can be an effective treatment to support people in coping with their transition, managing physical symptoms and improving quality of life.	account. In section 1.5 on symptom management (evidence showed it to be effective in the management of vasomotor symptoms, depressive symptoms and sleep problems) wording has been revised to ensure clarity about CBT 'as an option: in addition to other treatments (including HRT), for people for whom other treatments are contraindicated or for people who prefer not to take HRT'. Referral pathways from therapists to GPs and vice versa were outside the scope of the guideline. The committee acknowledged that people currently trained in providing this kind of therapy may not be familiar with menopause-specific CBT but that training in this would also raise their awareness about the symptoms of menopause and the impact.
St Erme Medical	Evidence review D	General	General	We are happy with the synthesis and overall outcome of the discussion but struggled to understand where the recommendation that transdermal carried lower breast risk than oral came from – could this be made clearer	Thank you for your comment. The committee considered the evidence for oral and transdermal routes of administration of the oestrogen component of HRT. Since some of the evidence showed a significant difference in the increased risk of breast cancer between the subgroups of oral and transdermal routes of administration in the combined HRT comparison, they made a recommendation to inform people that the increase was less with transdermal oestrogen. However, the committee revisited the evidence and discussed that since the same difference was not observed in the oestrogen-only comparison, the argument was less robust than previously

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					discussed. They also thought that this could be open to misinterpretation that transdermal oestrogen does not increase the risk. Upon reflection, the committee agreed to remove this recommendation and updated the related rationale section of the guideline and the detailed discussion of the evidence and their decision can be found in the committee discussion of the evidence section of Evidence Review D, the committee also decided to make a research recommendation for this topic (see appendix K).
St Erme Medical	Guideline	General	general	We are not sure that the BMS should be the sole arbiter of who is a Menopause Specialist. The FSRH have a MCPD which would meet the criteria	Thank you for your comment. The committee reflected on this wording and agreed that it should not be restricted to BMS criteria. To address this, the definition has been reworded to say that this professional should have 'specialist knowledge, skills and training (for example as recognised by the British Menopause Society, the Faculty of Sexual and Reproductive Healthcare or the Royal College of Obstetricians and Gynaecologists) who can advise and support colleagues in managing complex menopause-related needs and risk factors affecting decision-making.....'.
St Erme Medical	Guideline	008	006	Rec. 1.2.9 agree that women with a high risk of or previous cancer need specialist input but consider an MDT approach rather than an individual	Thank you for your comment. This recommendation is related to an initial discussion with the person. Therefore, it would be most relevant to refer to a healthcare professional with expertise in menopause in the first instance who could, if needed, refer on or seek advice from oncology.
St Erme Medical	Guideline	016	019	The very recent paper on recurrence of breast cancer with vaginal oestrogens makes the recommendation not to use with aromatase inhibitors firmer – Agrawal et al sept 2023 ACOG	Thank you for your comment. In the section referring to people with a history of breast cancer, the committee made changes to the order of recommendations so that considerations of adjuvant treatments are being made early in

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					shared decision making. They also revised the recommendation related to safety considerations for clarity. This would give this section a more logical flow and greater clarity about safety. The rationale of the guideline and the committee discussion section of the evidence were revised accordingly. A visual summary was produces for the management of genitourinary symptoms to clarify treatment options and facilitate decision making. The cited reference was not included because it was published after the search cut-off date. The study has been added to the NICE surveillance log so that it can be considered in future updates.
St Erme Medical	Guideline	017	003	Agree	Thank you for your comment in support of this.
St Erme Medical	Guideline	037	017	We are not sure that the BMS should be the sole arbiter of who is a Menopause Specialist. The FSRH have a MCPD which would meet the criteria as might an RCOG ATSM…there is a significant annual subscription for all organisations but choice should be allowed	Thank you for your comment. The committee reflected on this wording and agreed that it should not be restricted to BMS criteria. To address this, the definition has been reworded to say that this professional should have 'specialist knowledge, skills and training (for example as recognised by the British Menopause Society, the Faculty of Sexual and Reproductive Healthcare or the Royal College of Obstetricians and Gynaecologists) who can advise and support colleagues in managing complex menopause-related needs and risk factors affecting decision-making'.
St Erme Medical	Guideline	038	017	Agree this is important to clarify	Thank you for your comment in support of this.
The Disability Foundation	Guideline	General	General	We are concerned that people with disabilities have been overlooked/left behind/sidelined in this draft consultation. We urge that this draft document should be widened to include a category with the heading 'people with	Thank you for your comment and sharing your experience. The section on comorbidity that could be related to menopause is not meant to be comprehensive because possibilities and combinations could be very high. There was no

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				disabilities physical or mental; rare illnesses or underlying health conditions'. It might be that a disabled bodied person has suffered trauma in the past and is therefore more susceptible to an early menopause. Or it might be that a menopausal women is coping with Autism and ADHD, taking appropriate medication however is unable to cope with additional menopausal symptoms including severe anxiety. This case may necessitate some CBT and refloxolgy to reduce anxiety as conventional HRT may be too hormone disruptive for Autism. The use of complementary therapies may help reduce the mental, physical and emotional effects of Perimenopause and Menopause. This is the case for women who can and do use Hormonal Replacement Therapy (HRT) as well as for those are unable to use HRT. Women with pre-exisiting health conditions and disabilities may benefit significantly from using both conventional medicine together complementary therapies **What do The Disability Foundation Clients say about therapies and menopause?** "I started menopause symptoms at 46 and was on HRT by 47 years old. I've had many therapies to help deal with symptoms. Also chemo brings on menopause and exacerbates symptoms. When my menopause symptoms started, I experienced hot flushes, night sweats and burning sensation in my vaginal area and felt just exhausted from the moment I awoke. Initially the doctor tried to prescribe me anti-depressant tablets. I explained I wasn't	review question related to this section, but recommendations originated from discussions of the effects of HRT on specific health outcomes. It therefore covers these health outcomes only. The committee also felt that some issues highlighted in the comment are more pertinent to the guideline of the related condition (ADHD or autism) rather than specific to menopause. Apart from CBT we did not look at reflexology, massage and complementary therapies were not part of the 2024 guideline update. So, the committee could not comment on this. All research recommendations that were made in the 2024 guideline update have highlighted that research in groups that are underrepresented is particularly welcome to encourage diversity in research populations.

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				depressed, I was just perimenopausal. Eventually I was prescribed HRT which was amazing. Having recently gone through chemotherapy for breast cancer and having had to be taken off HRT, my symptoms came back with a vengeance. I have found that massage worked for relaxation and improved sleep, with acupuncture for hot sweats and this has been life changing and enabled me to feel more like myself again". *Client 1* "I had menopause symptoms consisting of hot and cold flushes. My body weight was fluctuating and I used to have sleepless nights. I was looking for alternative treatment because I didn't want to take HRT. It was suggested that I try acupuncture so I booked a session with The Disability Foundation's Acupuncturist. I have been receiving fortnightly acupuncture sessions for the last 6 months. This has helped me with hot and cold flushes and my insomnia. Overall, acupuncture has really helped me cope with my menopause symptoms on my daily routine". *Client 2*	
The Disability Foundation	Guideline	General	General	We ask that GPs offer advice on where women can access affordable complementary therapies to support their holistic health and wellbeing including yoga classes, acupuncture, reflexology and massage for identified vulnerable women who fall under the physical or mental health umbrella of 'disability' and therefore may be at risk of developing more serious mental health issues.	Thank you for your comment. The effectiveness of complementary therapies in the management of symptoms associated with the menopause was not in the scope of the 2024 guideline update. Evidence for this topic was not searched for, reviewed or discussed with the committee. The committee could therefore not comment on the advice that should be given about them to vulnerable women at risk of poor mental health.

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The Disability Foundation	Guideline	006		1.2.3 We ask that the draft scope details the use of complementary therapies in this section e.g. acupuncture or reflexology, as a method of alleviating some of the symptoms of menopause for women with a disability physical or mental, rare illness or underlying health concern. Complementary therapies are proven to help particularly with menopausal anxiety.	Thank you for your comment. The committee considered this and other feedback and decided that the examples in the bullet points caused confusion. They were often misunderstood as recommendations rather than examples. They were therefore removed. The effectiveness of acupuncture or reflexology was not in the scope of the 2024 guideline update. Evidence for these topics was therefore not searched for and not reviewed and discussed with the committee. The committee could therefore not comment on them.
The Disability Foundation	Guideline	011		1.4.6 We feel this statement is negatively biased towards complementary therapies and should be reframed positively. There are many complementary therapists who are well trained and belong to an assosciation which ensures some degree of confidence in the therapist and the therapy being offered.	Thank you for your comment. The section on complementary therapies was not in the scope of the 2024 guideline update. Evidence for this topic was not searched for and not reviewed and discussed with the committee. The committee could therefore not comment on this.
The Disability Foundation	Guideline	020	004	Stopping HRT. The Disability Foundation supports women who may be more vulnerable/susceptible to both physical and mental health issues during those menopausal years; either because they have a disability, a rare disease, an underlying health concern, have had mental health issues in the past or whose family history includes mental health issues. HRT brings so many benefits to our service users but we are concerned that this more vulnerable cohort of women in our society are not being given essential HRT management and withdrawal advice by their GPs or by the manufacturers of HRT medication which ultimately would	Thank you for your comment. It is agreed that all information provision (including details about starting and stopping HRT) needs to be tailored to each individual, including those with disabilities, ensuring they are heard and treated with dignity and respect. Further detail on treating people as individuals is covered in the NICE guideline on patient experience in adult NHS services as well as in the NICE guideline on shared decision-making so this information is not repeated in all other NICE guidelines (which is the reason why they are cross referred to in recommendations 1.1.1 and 1.1.2). There is an emphasis throughout the guideline on tailoring information to the individual, for example it is emphasised that information about benefits

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				save lives. Safeguarding against a 'cold turkey' stopping of HRT and advising users about the possible withdrawal effects could prevent cognitive difficulties, anxiety, menopausal depression and in the most vulnerable women, suicide. However, more importantly, women should have access to correct advice regarding any need to stop HRT in the first place. The guidelines state very clearly that for the majority of women the benefits of HRT outweigh risk and that means that stopping HRT is seldom necessary if it is proving beneficial. Why are we so concerned? We would li565ke to highlight: The unsafe and confusing NICE guidance for GPs regarding the ongoing management and withdrawal of HRT, particularly with regards to our more vulnerable service users. The current guidelines from NICE: National Institute for Health and Care Excellence for the management and withdrawal of HRT in the UK is as follows: "Menopause: diagnosis and management NICE guideline [NG23] Published: 12 November 2015 Last updated: 05 December 2019 Starting and stopping HRT 1.4.23 Offer women who are stopping HRT a choice of gradually reducing or immediately stopping treatment. 1.4.24 Explain to women that: □ gradually reducing HRT may limit recurrence of symptoms in the short term	and risks needs to be individualised to the person's age, individual circumstances and potential risk factors. There are also recommendation that highlight that a family member or carer can be involved. Making reasonable adjustments as required by the Equality Act 2010 is a statutory requirement and so this would not need to be repeated in each individual NICE guideline. The Equalities Impact Assessment has been reviewed and we have included further points in the section on disabilities to emphasise the person-centred approach that the committee has taken which they agreed would positively impact these groups. The details about how to start and stop HRT were not part of the scope of the 2024 update. So, the committee could not comment on this.

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				□ gradually reducing or immediately stopping HRT makes no difference to their symptoms in the longer term We do also note that the guidance states the following, however as mentioned above it can be confusing when read alongside other statements and is not easy to find: Diagnosis and management □ HRT can be continued for as long as it is beneficial for the woman, taking into account her individual risks and preferences. There is no arbitrary limit to the duration of HRT use, and no need to routinely withdraw HRT at a certain age or after a certain length of time - this needs to be high-lighted to everyone involved in the management and care of women during the perimenopause and menopause term	
The Disability Foundation	Guideline	020	004	Some Background Evidence to Support Why these Two Factors are Vital in Menopause Care Clinical trials carried out in the USA in 2015 on the effects of Estradiol withdrawal on mood in women with past perimenopausal depression (PMD) concluded that: 'women with past PMD had a recurrence of symptoms during Estradiol withdrawal and that a change in oestrogen can trigger an abnormal behavioural state in susceptible women.' It is heart breaking to read that suicide rates for women aged 45 to 54 – the most	Thank you for your comment. Whilst this recommendation was not part of the 2024 guideline update the committee have included a recommendation that stating that in discussions with people about HRT should include the likelihood of symptoms returning when HRT is stopped and, the possibility option of restarting treatment if necessary. The committee decided that they could not comment further because an evidence review on the topic of stopping HRT was not conducted.

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				common age for perimenopause and menopause – have risen by 6% in the past 20 years, according to the Office of National Statistic (ONS). Menopausal depression (which might sadly lead to suicide if left untreated) can happen as a direct result of an immediate or rapid loss of female hormones during the menopausal years. For some years medical professionals have known that the immediate or rapid loss of female hormone can occur after removal of the ovaries or medical treatment that causes the ovaries to fail, such as chemotherapy. UK healthcare practitioners advise to mitigate against the sudden drop in female hormones and the subsequent symptoms by advocating the administration of HRT by the appropriate medical practitioner, if any woman undergoes or suffers from one of the above. The British Menopause Society and Women's Health Concern [2020] goes on to advise that: 'The HRT dosage, regimen and duration should be individualised, with annual evaluation of advantages and disadvantages' and the North American Menopause Society [2022] goes even further to address HRT management and withdrawal issues for those women who are vulnerable to depression including a screening process: 'Most women who present with depressive disorders during the menopause transition are women with a history of depression before and are at high risk for	

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				recurrence during the menopause transition. For that reason clinical guidelines screen for depression in women with a history of depression and use antidepressants or proven psychotherapies.' The North American Menopause Society [2022] also advises a gradual HRT withdrawal on a shared decision-making basis: 'There are few studies to guide the optimal way for women to stop hormone therapy and vasomotor symptoms will recur in approximately 50% of women after discontinuation. Data directly comparing the effects of abrupt discontinuation with those of slowly tapering are lacking although clinical experts generally advise gradually decreasing hormone therapy doses over time. Ongoing assessment and shared decision making with her health care professional should be standardised.' We are calling for a change in NICE guidelines ensuring that all women are advised that withdrawal is seldom necessary, but if it is that they are advised on a managed withdrawal from HRT to mitigate against the risk of mental health issues and possible female suicide caused by peri-menopausal depression in women aged from 45-64. We are requesting for a warning notice to be added to all manufacturer's guidelines to ensure that women are aware of the implications of stopping HRT medication suddenly.	

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The Disability Foundation	Guideline	038	011	The Disability Foundation urges further research in the area of menopause/cessation of HRT and effects on mental health/risk of suicide	Thank you for your comment. The topic of menopause/cessation of HRT and effects on mental health/risk of suicide was not in the scope of the 2024 guideline update. In accordance with NICE processes, research recommendations can only be made on topics that are systematically searched for and reviewed. The suggested research recommendation could therefore not be added.
The Disability Foundation	Guideline	047		1.49 In March 2023 Office for National Statistics (ONS) suggested disabled people had the highest rate of dying by suicide compared to other groups.19 disabled women per 100,000 – 3.8x more - ended their lives, compared to 5 non-disabled women. Note that these numbers are based of recorded suicides and of course there are many more that are suspected suicides but for various reasons are recorded as 'open' or 'accidental death' verdicts by the coroners office. We are therefore urging for CBT to be offered automatically by GPs to any menopausal 'disabled' person.	Thank you for your comment. The provision of CBT for people who have suicidal ideation is outside the scope of the current guideline and would fall into the remit of the NICE guideline. With regards to CBT for vasomotor, depressive symptoms and sleep problems, the recommendations were revised that this would be an option in addition to other treatments (including HRT), where other treatments are contraindicated or where people prefer not to have other treatments. This clarifies that people could have this as an option if they want it.
The Menopause Charity	Evidence review A	general	general	The evidence review document underpinning the CBT recommendations repeatedly says the quality of the evidence was low or very low and some was downgraded. So I'm not sure if the validity of the research. Under the heading for Vasomotor symptoms the committee ,Agreed that CBT should NOT be offered routinely, but rather rather considered as an option. A similar comment under Difficulty with Sleeping and Psychological Symptoms. The underlying report	Thank you for your comment. CBT has been offered as a treatment option for certain symptoms associated with menopause based on the benefit of CBT observed for the outcomes vasomotor symptoms, depressive symptoms and sleep. The committee reflected on the wording of the recommendations related to CBT and revised them to ensure clarity about this ' as an option: in addition to other treatments (including HRT), for people for whom other treatments are

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				doesn't make strong recommendations, so I don't understand how come CBT rates so highly in the list of options? I cannot see or understand how CBT (a talking therapy) can cure the symptoms of the Menopause and peri-menopause, it can only help the sufferers to deal with and possibly manage living with the symptoms. Would you offer CBT to diabetics sufferers or low thyroid sufferers or testicular cancer sufferers rather than giving them testosterone? Too much emphasis is given to CBT and not enough on curing the symptoms, ie HRT."	contraindicated or for people who prefer not to take HRT'. This makes it clear that CBT is not seen as a first line treatment but as an option where this is a preferred choice. Note NG23 has undergone a partial updated in 2024 following the NICE surveillance outcome in 2019 and 2021 published in the related guideline update scope. The recommendations made previously (NG23 2015) on areas that have not been updated still apply. For the comprehensive list of recommendations see the revised guideline document.
The Menopause Charity	Evidence Review C			Of 30 RCTS included the most recent is Prentice 2020. I have to question whether the doses, routes and types of HRT in studies prior to 2020 match the changes in prescribing- now transdermal oestrogen + oral or vaginal utrogesten or patches and sprays. How many of the RCTs included are of less commonly prescribed HRT- in other words irrelevant.	Thank you for your comment. A systematic review of evidence summarises all evidence that matches a review protocol that was signed off by the committee. Whether older routes and types are less effective or risky can only be concluded if all the relevant evidence is systematically analysed. There was evidence on different routes of administration and different types of preparations, but it was insufficient to conclude whether one type (for example micronised progesterone) was safer than another. Therefore, , the committee made a research recommendation to address whether different types of progestogens (for example, micronised progesterone) alter the risk of breast cancer, endometrial cancer and cardiovascular disease.
The Menopause Charity	Evidence Review D			Include use up to 15 years as more are using HRT for longer now. Tables should be included for women under 45. There is growing use of HRT in women under age 45.	Thank you for your comment. Evidence review D includes only the age group 45 and older. Evidence review I looks specifically at an age group of 40- to 44-year-olds. There was very limited data on the age group between 40 to 44

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					(early menopause) and ages below that were not in the scope of the 2024 guideline update. A table of the risk of breast cancer for the age group 40 to 44 is included in the tables of absolute numbers. However, in evidence review D, there was data for usage of over 10 years and there are forest plots that show this, and the GRADE quality assessment also presents this data. However, committee decided not to include these in the table with absolute numbers to keep the level of detail manageable for discussions between the person and the healthcare professional.
The Menopause Charity	Evidence Review D			Evidence should be consulted on how micronized progesterone shows no increased risk of breast cancer. **Bioidentical, Synthetic, and Animal Based Hormone Replacement Therapies and Risk of Breast Cancer [1M]** https://journals.lww.com/greenjournal/abstract/2017/05001/bioidentical,_synthetic,_and_animal_based_hormone.473.aspx Abenhaim, Haim Arie MD, MPH; Czuzoj-Shulman, Nicholas; Spence, Andrea R. PhD; Azoulay, Laurent PhD; Suissa, Samy PhD; Tulandi, Togas MD, MHCM, FRCS(C) Author Information Obstetrics & Gynecology 129(5):p S132, May 2017. | DOI: 10.1097/01.AOG.0000514672.45180.59 • Buy **Abstract** **INTRODUCTION:** Hormone Replacement Therapy (HRT) has been associated with an increased risk of breast cancer. Our study objective was to	Thank you for your comment. The reference you refer to in your comment have been checked. The team note that the cohort addressed in this reference comes from the United Kingdom Clinical Practice Research Datalink between 1995 and 2014. These women have already been included in our review on breast cancer risk following HRT use, as part of the meta-analysis from the Collaborative Group on Hormonal Factors in Breast 2019 (referred to as CGHFB 2019 in Evidence Review D). Since there is overlap between the cohort dates, the team cannot include the data in the reference you provide as this would double count the women already in the review. The review also includes evidence on the risk of breast cancer with difference progestogenic constituents. The committee discussed the evidence for progestogenic constituents in the 'committee discussion of the evidence' section of evidence review D. The evidence in the review shows that there is an increased risk of breast cancer with most progestogenic constituents in combined HRT when compared to no HRT use. The committee discussed whether certain

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				evaluate whether the increased risk is dependent on the formulation used. **METHODS:** We carried out a population-based case-control study using data from the United Kingdom Clinical Practice Research Datalink on women aged >50. Newly diagnosed breast cancer cases were age-matched with women of comparable follow-up time with no history of breast cancer at a 1:10 ratio. Exposures were classified as ever/never for the HRT formulations: Bioidentical Estrogens (BE), Conjugated Equine Estrogens (CEE), Micronized Progesterone (MP), and Synthetic Progestogens (SP). Logistic regression estimated adjusted effects of HRT formulation on breast cancer. **RESULTS:** Between 1995-2014, 43,183 cases of breast cancer were identified and matched to 431,830 controls. Compared with women who had never used HRT, HRT use was associated with an overall increased risk of breast cancer OR 1.12 (1.09-1.15), p < 0.0001. Compared to never users, estrogens were not associated with breast cancer: BE (OR 1.04 (1.00-1.09), p=0.07), CEE (OR 1.01 (0.96-1.05), p=0.78), both (OR 1.32 (0.30-5.77), p=0.25). As compared to never users, progestogens appeared differentially associated with breast cancer: MP (OR 0.99 (0.55-1.79), p=0.98), SP (OR 1.28 (1.22-1.35), p < 0.0001), both (OR 1.32 (0.30-5.77), p=0.72). **CONCLUSION:** While HRT use is associated with an overall increased risk of breast cancer, this association	progestogenic constituents should be mentioned in the recommendations based on the evidence available, please see evidence report D. The committee decided not to recommend that micronized progesterone shows no increased risk of breast cancer as the evidence did not reflect this statement. The committee made a research recommendation so that this is investigated further. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). However, they highlighted that RCT, and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. These and other evidence reviews have been revised to implement these changes accordingly.

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				appears to be uniquely in women having been given synthetic progestogens. Synthetic progestogens should not be given as part of HRT and counseling regarding the risk of breast cancer should consider the effect of formulation used.	
The Menopause Charity	Evidence review D	023	002	It is not possible to make an informed decision for women using HRT more than 5 years. The lack of a recommendation for research to assess the incidence of endometrial cancer beyond 5 years is puzzling when Breast cancer is assessed up to 10 years with some data for 15 years.	Thank you for your comment. Evidence review E (endometrial cancer) contains data from some studies that include duration of HRT use of equal to or above 15 years. The committee considered this to be sufficient and decided not to prioritise this for a research recommendation.
The Menopause Charity	guideline	006	018	There are many more symptoms to menopause that should be included to aid clinical diagnosis and appropriate treatment.	Thank you for your comment. Whilst an update of the list of symptoms and experiences (for the purposes of diagnosis and appropriate treatment) was outside the current scope of the 2024 guideline update and therefore no evidence review was conducted, the NICE surveillance team checks regularly for new evidence for topics within guidelines to see where further work is needed.
The Menopause Charity	Guideline	006	019	'may vary in severity from minor to more troublesome' is downplaying and patronising, varies mild to extreme severe is more suitable.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline. In the sentence that the comment refers to 'more troublesome' has been replaced with 'severe'.
The Menopause Charity	Guideline	006	020	'over long or short time periods' – vague, should be more specific, can stary 7-10 years before menopause and last for decades after	Thank you for your comment. Whilst this section was not part of the 2024 guideline update, the committee reflected on this feedback but agreed that this is meant to be intentionally vague since the duration of symptoms can vary. They decided that they were not able to provide a specific

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					timeframe because evidence for this was not reviewed.
The Menopause Charity	Guideline	006	024	Cognitive and mental health effects should be clearly emphasised with brain fog, low mood, anxiety, sleeping difficulties rather than just those known about 2015 guidance	Thank you for your comment. Whilst an update of the list of symptoms and experiences (for diagnosis and appropriate treatment) was outside the current scope of the 2024 guideline update and therefore no evidence review was conducted, the NICE surveillance team checks regularly for new evidence for topics within guidelines to see where further work is needed.
The Menopause Charity	Guideline	007	004	Troublesome is downplaying & unquantifiable clinically, should be 'discuss individualised treatment with patient consulting with menopausal symptoms'	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline. Individualised care is already highlighted in a section on 'individualised care' which is the preceding section. Therefore, the committee did not repeat this in the wording of the recommendation that the comment refers to.
The Menopause Charity	Guideline	007	006	Hormonal should include vaginal oestrogen and hormone replacement therapy (HRT)	Thank you for your comment. Recommendation 1.2.3 is in the information section and highlights that all options should be discussed with examples given for each category of treatment. However, the committee reflected on this and related feedback and have removed the examples because they agreed that they were causing confusion and were misunderstood to be recommendations. The categories of options were also now put into alphabetical order so that no particular priority of treatment is suggested.
The Menopause Charity	Guideline	007	010	Ensure the potential benefits and risks associated with these treatments is negative – emphasise that benefits of menopause management (non hormonal and hormonal) is individual and for most the benefits outweigh risks	Thank you for your comment. This section is outside the scope of the 2024 update. The concept of tailoring the approach to the person is covered in the 'individualised care' section. However, the committee reflected on this feedback and decided that the discussion a healthcare

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					professional has with the person about the full range of management options should cover 'potential benefits and risks'. Whether benefits then outweigh the risks should then be part of the shared decision-making process.
The Menopause Charity	Guideline	007	019	Need emphasising - Ensure the potential risk and management of menopause is informed to those undergoing medical or surgical treatment before they have that treatment:	Thank you for your comment. In NICE style the wording 'offer' and 'discuss' are strong instructions to carry out the associated action. It is therefore expected that information should be provided, and referral offered.
The Menopause Charity	Guideline	008	006	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	008	021	A wider section on extremely heavy bleeding is required. This common symptom can be detrimental to people, careers and result in anaemia and forced changes of lifestyle. GPs should be encouraged to ask about it and offer options so that people don't think they have to live with it. Only 12.5% of people worldwide have a 'normal' menstrual cycle. A consumer panel highlighted 39% of women believe there is no medical reason for heavy flow and thought it was 'one of those things to get on with'.	Thank you for your comment. Identifying perimenopause and menopause (including changes in menstrual bleeding) was not in the scope of the 2024 guideline update. Evidence for this topic was not searched for and not reviewed and discussed with the committee. The committee could therefore not comment on this.
The Menopause Charity	Guideline	008	024	Whilst it is reassuring to see some specific information relating to the differences in ethnicities, this requires further research, more prominence and greater understanding to prevent communities suffering. Furthermore, those with disabilities, neuro diversities and long term conditions are not considered, nor is there recognition of menopause support across	Thank you for your comment. The committee made this recommendation related to time of menopause and potential differences by ethnic background based on their knowledge and experience. It was not a specific research question that was part of the scope of the 2024 guideline update. They reflected on this and decided based on consensus to add that people with lifelong medical conditions may also experience menopause at a younger age to this

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				The prevalence of chronic disease varies in different ethnic groups. For example, people from South Asian and Black ethnic groups are more likely to be obese and suffer from type 2 diabetes. The prevalence of cardiovascular disease is highest in people from South Asian and Pakistani groups (45). 29.1% of Pakistani women suffer from a MSK condition, compared with 16.4% of people from other ethnic groups (39). Women from Black Asian and minority ethnic groups are more likely to suffer from mental ill-health, but less likely to receive support and treatment compared with White women (46). Despite differences in chronic disease risk, a recent survey revealed that only 8% of menopausal women from Black and minority ethnic groups are currently using HRT, compared with 15% of White menopausal women (40). Women from different ethnic groups experience menopause differently and have different cultural beliefs and attitudes about HRT. Research is needed to identify barriers to seeking help for menopause symptoms and explore ways of engaging with women from different cultural backgrounds, to ensure equitable access to HRT for all women who are likely to benefit from it (47). HRT use also varies according to area deprivation. Prescribing rates are 29% lower in GP practices in deprived areas, and women in deprived areas are more likely to be prescribed older, oral HRT that has an inferior safety profile compared with newer HRT formulations (48).	recommendation. However, the committee has also logged prevalence of menopause (including in different age groups and populations) with the NICE surveillance team so that this could be considered for future updates. The studies referred to in the comment do not meet the inclusion criteria of any of the review protocols because this was not part of the scope of the update but the information has been passed on to the NICE surveillance team so that they are aware of some of the key information related to prevalence of menopause in people from different ethnic background and health inequalities related to these groups. Management of menopause symptoms with systemic HRT including differences in access or uptake of HRT was outside the scope of the guideline. Therefore, the committee were unable to comment on this.

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				There are strong associations between ethnicity and deprivation, and between deprivation and most health outcomes. Women living in the most deprived areas have a shorter life expectancy. People in Bangladeshi, Pakistani and Black ethnic groups are more likely to live in deprived neighbourhoods, and chronic conditions present at an earlier age in people from ethnic minority groups. Consequently, the gap between the least and most deprived is even wider for 'healthy life expectancy' – women living in more affluent areas remain healthy for on average 20 years longer than women from the most deprived areas (45). Improving access to HRT for all women is likely to reduce morbidity, increase longevity, and narrow the gap in healthy life expectancy between women living in the most and least deprived areas. Evidence listed in: https://www.themenopausecharity.org/wp-content/uploads/2023/10/The-Menopause-Charity-Transforming-Womens-Long-Term-Health.pdf	
The Menopause Charity	Guideline	009	018	There is ample evidence to support earlier menopuase in ethnic groups and this is missed leading to heath disparity so it would be good to have that presented here as common ethnic groups as the addition is unlikely to looked at by all: https://pharmaceutical-journal.com/article/research/should-menopause-management-differ-between-ethnic-groups	Thank you for your comment in support of this. A link to the cited article could not be included because it did not meet inclusion criteria for any protocol of the 2024 guideline update.

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The Menopause Charity	Guideline	010	001	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	010	008	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	010	009	explain the risks and benefits associated with 10 those treatments. [2023] - usually phrased benefits and risks	Thank you for your comment. This has been revised accordingly.
The Menopause Charity	Guideline	010	013	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	011	007	We know that body identical HRT is safe and more effective at managing vasomotor symptoms. Recommend 'Consider CBT for troublesome vasomotor symptoms associated with the 6 menopause. [2023]' for those who cannot or choose to not take HRT. Highlight current waiting lists for CBT so that patient can make an informed decision.	Thank you for your comment. This specific recommendation focuses about information to be given when discussion CBT and what options are available. Further details have been added to this recommendation, such as giving an explanation of what CBT is (including menopause specific CBT) and to take people's preferences and needs into account when making a shared decision about this option. In section 1.5 on symptom management (evidence showed it to be effective in the management of vasomotor symptoms, depressive symptoms and sleep problems) wording has been revised to ensure clarity about CBT 'as an option: in addition to other treatments (including HRT), for people for whom other treatments are contraindicated or for people who prefer not to take HRT'. This clarifies that CBT is not recommended to replace HRT. The committee

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					acknowledged in the impact section of the guideline that there are long waiting times for CBT. They also noted that people currently trained in providing this kind of therapy may not be familiar with menopause-specific CBT and training on this may incur costs and increase waiting times in the short term. However, online and group CBT may be easier and less costly to adapt to menopause-specific CBT. There are also resources available to train people in providing menopause-specific CBT (and could also inform the adaptation of online CBT), which could facilitate implementation. Your comment will be considered by NICE where relevant support activity is being planned. In section 1.5 on symptom management (evidence showed it to be effective in the management of vasomotor symptoms, depressive symptoms and sleep problems) wording has been revised to ensure clarity about CBT 'as an option: in addition to other treatments (including HRT), for people for whom other treatments are contraindicated or for people who prefer not to take HRT'.
The Menopause Charity	Guideline	011	007	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	011	016	Explain to people with menopause symptoms that the efficacy and safety 17 of unregulated hormone preparations are unknown. Add – this includes bioidentical hormones.	Thank you for your comment. Whilst this recommendation was not part of the 2024 guideline update, it is referring to all unregulated hormone preparations but not all bioidentical hormones are unregulated. The committee therefore thought that adding this would cause confusion.
The Menopause Charity	Guideline	012	013	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this

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					wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	012	015	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	013	002	Consider transdermal rather than oral HRT for people with menopause 3 symptoms who are at increased risk of venous thromboembolism (VTE), including those with a body mass index (BMI) over 30 kg/m2- should be a firm recommnedation given the evidence we have	Thank you for your comment. The impact of HRT on risk of VTE was not in the scope of the 2024 guideline update. Evidence for this topic was therefore not searched for, reviewed or discussed with the committee. The committee could therefore not comment on this. Some stakeholders have provided a list of related references and this has been passed on to the NICE surveillance team to consider for a future update.
The Menopause Charity	Guideline	013	005	Consider referring people with menopause symptoms who are at high risk 6 of VTE (for example, those with a strong family history of VTE or a 7 hereditary thrombophilia) to a haematologist for assessment before 8 considering HRT. [2015] - this is dated and should be colloration between haematologist and menopause specialist as haematology alone do not advise.	Thank you for your comment. The impact of HRT on risk of VTE was not in the scope of the 2024 guideline update. Evidence for this topic was not searched for, reviewed or discussed with the committee. The committee could therefore not comment on this. Some stakeholders have provided a list of related references and this has been passed on to the NICE surveillance team to consider for a future update.
The Menopause Charity	Guideline	014	002	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline
The Menopause Charity	Guideline	014	005	We know that body identical HRT is safe and more effective at managing vasomotor symptoms. Recommend 'Consider CBT for troublesome vasomotor symptoms associated with the 6 menopause. [2023]' for those who cannot or choose to not take HRT.	Thank you for your comment. The committee reflected on this and thought that CBT could also be an option in addition to HRT or for those who prefer not to have HRT. The committee has revised the wording to clarity this matter with CBT 'as an option: in addition to HRT, for people for

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					whom HRT is contraindicated or for people who prefer not to take HRT'.
The Menopause Charity	Guideline	014	005	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	015	005	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	015	008	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	015	010	We are concerned that including the word 'serious' implies there are safet concerns pertaining HRT use.	Thank you for your comment. The emphasis here is on 'serious' because there can be adverse events however serious adverse events are rare. If 'serious' was removed it sounds as if any adverse events are rare.
The Menopause Charity	Guideline	015	011	The MHRZ link talks about the increased risk of breast cancer with HRT use, but we know that body identical HRT does not increase your risk.	Thank you for your comment. This link has been included because the MHRA included a statement related to vaginal oestrogen which is relevant for the section referred to ('Low-dose vaginal estrogens do not appear to increase breast cancer risk for women in whom this is a therapeutic option'). The evidence related to the use of systemic HRT and risk of breast cancer is summarised in evidence review D. This included some studies using micronised progesterone or dydrogesterone. A separate analysis was carried out which divided by different types of progestogen. The committee concluded from this that there is insufficient evidence to recommend one type over another. They therefore prioritised this topic for a research recommendation.

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The Menopause Charity	Guideline	015	016	if they choose this option, they should report vaginal bleeding to their 17 GP. [2023] - persistent vaginal bleeding as some minnor bleeding can happen at initiaion of treatment.	Thank you for your comment. This bullet point was removed because the committee reflected on this and agreed that this was not a common side effect of vaginal oestrogen.
The Menopause Charity	Guideline	015	018	If vaginal oestrogen does not relieve genitourinary symptoms, consider 19 increasing the dosage, within the standard therapeutic range, after 20 seeking advice from a healthcare professional with expertise in 21 menopause. [2023] - why does this need an expert? Doses are very small and can be increased by GPs	Thank you for your comment. The committee reflected on this and decided that there was generally no clear consensus about the standard therapeutic range in relation to vaginal oestrogen. The committee therefore decided to remove this recommendation. The guideline contains recommendations about reviewing treatment and recommends that treatment for symptoms associated with the menopause should be reviewed at 3 months to assess efficacy and tolerability and annually thereafter, unless there are clinical indications for an earlier review (such as treatment ineffectiveness, side effects or adverse events). It is also recommended to 'refer people to a healthcare professional with expertise in menopause if treatments do not improve their menopause symptoms or they have ongoing side effects.' This means that if symptoms are not resolved after vaginal oestrogen is prescribed treatment is reviewed and other differential diagnoses could be considered.
The Menopause Charity	Guideline	015	022	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	015	026	Consider non-hormonal vaginal moisturisers and lubricants for people with 27 troublesome genitourinary menopause symptoms in whom vaginal	Thank you for your comment. This recommendation was specifically related to people in whom vaginal oestrogen preparations are contraindicated or for people who would prefer not to use vaginal oestrogen. However, on reflection it

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				28 oestrogen preparations are contraindicated or who would prefer not to 29 take vaginal oestrogen. [2023] - these can be used and help in conjunction with vaginal oestrogen.	was recognised that the order of recommendations could have led to confusion. The recommendation stating that vaginal oestrogen and non-hormonal moisturisers or lubricants can be used alone or in combination has therefore been moved up to a position before this recommendation to clarify this point.
The Menopause Charity	Guideline	015	017	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	016	001	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	016	004	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	guideline	016	004	Consider ospemifene as an oral treatment option for troublesome 5 genitourinary menopause symptoms, if locally applied treatments are 6 impractical, for example, because of disability. [2023] - much more likely under guidance of menopause expert or urogynaecologist.	Thank you for your comment. Ospemifene could not be recommended for everyone with genitourinary symptoms because of resource constraints identified in the economic analysis. Therefore, it was only recommended where it would be impractical to prescribe a locally applied option. The committee decided that a referral to a urogynaecologist before doing this would lead to treatment delays and it is an equality consideration for those people who cannot apply a treatment on their own to get another option if available as a reasonable adjustment required under the Equality Act 2010.
The Menopause Charity	Guideline	016	011	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this

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					wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	016	014	WHY - Only consider vaginal oestrogens for people with a personal history of 15 breast cancer and troublesome genitourinary menopause symptoms that 16 have continued despite trying non-hormonal treatments. We have evidence of lack of systemic absorption and why should vaginal oestrogen be second line? This is dated. Contradiucting self later in 1.4.29.	Thank you for your comment. The regulatory licensing classifies a history of breast cancer as a contraindication for vaginal oestrogen. Therefore, whilst the committee agreed that it could be used if non-hormonal treatments were ineffective, they agreed that it should not be a first line treatment. They did this because treating menopausal symptoms less effectively is a smaller concern than a possible increased risk of breast cancer. The order of recommendation and revisions to other recommendations in the section have been made to improve clarity in the pathway. A visual summary has also been added as a navigation aid related to the treatment of genitourinary symptoms.
The Menopause Charity	Guideline	016	015	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	016	021	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	017	021	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	018	003	Contradicts page 15.26 - stick to this statement	Thank you for your comment. One of these recommendations was specifically related to people in whom vaginal oestrogen preparations are contraindicated or for people who would prefer not to use vaginal oestrogen. However, on reflection it was recognised that the order of

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					recommendations could have led to confusion. The recommendation stating that vaginal oestrogen and non-hormonal moisturisers or lubricants can be used alone or in combination has therefore been moved up to a position before this recommendation to clarify this point.
The Menopause Charity	Guideline	018	006	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	018		People with PMDD are not considered within comorbidities. Explain that swings in hormones associated with perimenopause and the lack of regular cycle can have a serious effect on your mental health for people more sensitive to these swings. Consider the need to increase the dose of SSRIs used to treat PMDD during perimenopause.	Thank you for your comment. The effectiveness of SSRIs in the treatment of symptoms associated with the menopause was not part of the scope of the 2024 guideline update. The committee could therefore not comment on this.
The Menopause Charity	Guideline	018	010	Consider HRT to alleviate mild depressive symptoms with onset in 11 association with other menopause symptoms. Why mild, remove mild – we know depression is common and affects all cases – why categorise here? Unhelpful. Abstract at BMS conference – organ – severity of psychological symtoms and impact on qol showed this.	Thank you for your comment. Depressive symptoms was used to differentiate this from diagnosed depression which is covered in the NICE guideline on depression in adults. A definition of this has been added to clarify this.
The Menopause Charity	guideline	019	002	Oestrogen replacement has proven effects on helping sleep as well as progesterone – why only mention CBT here? https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5509066/	Thank you for your comment. The CBT recommendation related to sleep was reworded to state that CBT is an option in addition to other treatments (including HRT), for people for whom other treatments contraindicated, and for people who prefer not to have other treatments. Sleep as an outcome following the use of HRT was not in

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				Efficacy of menopausal hormone therapy on sleep quality: systematic review and meta-analysis Dahima Cintron,[1] More research needed but HRT cannot be ignored. Research has illustrated that effective HRT treatment of vasomotor symptoms significantly improves quality of sleep.	the scope of the 2024 guideline update. This guideline update looked at the effects of CBT on sleep disturbance associated the menopause. The study you have provided a reference to has been looked at but as it does not meet the criteria for any of the evidence reviews updated in the 2024 update the committee are unable to comment on it.
The Menopause Charity	Guideline	019	006	Consider testosterone supplementation for people with low sexual desire 7 associated with the menopause if HRT alone is not effective. Needs guidance on how to assertain as many struggle with this – using questionnaire? What about tiredness and fatigue? Needs expansion to say – full dose HRT, vaginal oestrogen and lubricants. https://thebms.org.uk/wp-content/uploads/2022/12/08-BMS-TfC-Testosterone-replacement-in-menopause-DEC2022-A.pdf	Thank you for your comment. At the time when the scope of the 2024 guideline update was agreed, there was no substantive new evidence that would change the recommendation related to testosterone. It was therefore not included in the update and the committee could not comment on this. However, NICE recognises the importance of this issue and has worked with the NIHR to prioritise funding for research on the matter.
The Menopause Charity	Guideline	019	011	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	019	015	oestrogen alone to people who have had a hysterectomy. [2023] What about endometriosis/complex gynaecology? This should be more suggestive of management of vast majority of patients.	Thank you for your comment. The committee discussed that choice between oestrogen-only and combined HRT may be different for people with a sub-total hysterectomy. They decided that they could not be prescriptive about the type of HRT to be used for people who have had a sub-total hysterectomy because their condition is clinically

					complex, and they had not reviewed evidence about the effect of HRT on risk of endometrial cancer for this group. They acknowledged that people who were going to have, or had had, a sub-total hysterectomy would be under the care of a specialist who could discuss HRT options tailored to their needs (or a relevant specialist within the MDT). Due to a lack of evidence, no specific recommendation was made for sub-total hysterectomy; however, the term "total" was added before "hysterectomy" in guidance regarding the offer of oestrogen-only HRT to those who have had a hysterectomy. This addition alerts healthcare professionals to consider other factors for patients with a sub-total hysterectomy. The committee also noted that some people have a hysterectomy for a condition that may be affected by HRT, such as endometriosis. The committee did not review evidence related to such conditions. They recognised that the decision about the type of HRT that best balances benefits and risks for the person may be affected by that condition (for example endometriosis) or having had a subtotal hysterectomy. For this reason, they added a recommendation highlighting that advice from a healthcare professional with specialist knowledge of that condition may be needed when making this choice. Due to this stakeholder comment and other related comments, this topic has been logged with NICE surveillance so that it can be considered for a possible update to either the Menopause or the Endometriosis guideline in future.

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The Menopause Charity	Guideline	020	011	Add benefits and risks of HRT are back to baseline within 5 years of discontinuation,	Thank you for your comment. This recommendation was not part of scope of the 2024 guideline update which means that a new evidence review was not conducted. The committee could therefore not comment on this.
The Menopause Charity	Guideline	021	006	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	021	009	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	021	012	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	021	020	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	021	009	they have troublesome menopause symptoms **despite treatment** and contraindications to HRT This is confusing and could result in over referring when there are not enough experts or secondary care clinics to cope and hence create work, frustration adn clog of gynaecology clinics.	Thank you for your comment. This was not a recommendation that was updated in 2024. However, the updated guideline includes a definition of a 'healthcare professional with expertise in menopause.' This definition clarifies that such an expert would have specialist knowledge, skills and training (for example as recognised by the British Menopause Society, the Faculty of Sexual and Reproductive Healthcare or the Royal College of Obstetricians and Gynaecologists). This means that they would not be restricted to secondary care. When there are contraindications or there is uncertainty, the

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					committee agreed that specialist input would be required and did not change this recommendation.
The Menopause Charity	Guideline	021	021	There are plausible benefits to taking HRT on the impact of life expectancy as using body-identical hormones reduces inflammation, blood pressure, blood cholesterol, and the risk of diabetes; factors that are all associated with an increased risk of coronary heart disease and stroke	Thank you for your comment. The evidence reviews in the guideline that were updated did not have inflammation, blood pressure, blood cholesterol or diabetes as outcomes of interest. Therefore, the committee are unable to comment on whether the impact of taking HRT on life expectancy is related to any of the outcomes listed.
The Menopause Charity	Guideline	021	021	Where it says 'taking either oestrogen-only or combined HRT is unlikely to increase or decrease life expectancy' (and where repeated in the draft guidelines): This is contradicted by a number of research analyses that suggest up to a 30% decrease in all-cause mortality. See, for example, Boardman HM, Hartley L, Eisinga A, Main C, Roque i Figuls M, Bonfill Cosp X, et al. Hormone therapy for preventing cardiovascular disease in post-menopausal women. Cochrane Database Syst Rev. 2015(3):CD002229. Management of menopause: a view towards prevention May 5th, 2022. https://doi.org/10.1016/S2213-8587(21)00269-2 Prof. Roger. A. Lobo MD & Prof. Anne Gompel MD. The Committee needs to explain what is flawed in these findings, if their guidelines are to justifiably contradict them.	Thank you for your comment. Boardman 2015 was assessed for inclusion but was not included as a systematic review because they did not separate results by combined and oestrogen-only HRT. This was criteria set out in the pre-specified protocol and cannot be changed. The committee therefore cannot comment on the conclusions the Boardman 2015 systematic review reached. The individual studies included in Boardman were checked against the protocol criteria, and where relevant they were included in the review. The excluded studies list in Appendix J of Evidence Review H has been updated to show the exclusion reason for Boardman 2015. Thank you for highlighting Lobo and Gompel 2022 which is a narrative review, therefore the committee are unable to include or quote any of their figures in the evidence review as the study design does not meet the criteria set out in the review question. Confounding factors are relevant for observational studies only, and randomisation of participants in randomised controlled trials removes any confounder bias. The review relevant to life expectancy (Evidence Review H) specified the inclusion of randomised controlled trials only. This

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				'Confounding factors' in research studies are often referred to in the draft guidelines, as a justification for excluding their findings but, in the interests of public accessibility, it would be very useful to provide further explanation as to why these factors are indeed confounding, and how they affect research results in a detrimental way (to the point of exclusion).	is because there is the potential for too many unknown confounders related to life expectancy that would not be possible to adjusted for. Relevant confounders are listed in each protocol for each review where appropriate. A protocol is a methodological document and for the readership of such documents confounding is terminology that is readily understood; therefore it is not further described. Whilst protocols are technical, we reviewed the guideline document for the use of lay language and removed technical language where possible and substituted it with explanations of the related concepts.
The Menopause Charity	Guideline	021	021	Incorrect as per evidence we have in 30% reductionin all cause mortality	Thank you for your comment. The committee noted that high-quality evidence showed no difference in mortality with either oestrogen-only or combined HRT. A decrease in all-cause mortality was reported for 1 isolated subgroup (women starting oestrogen-only HRT aged between 50 and 59). In isolation, it was a statistically significant figure. But in a wider context, it cannot be interpreted as good evidence of a different effect in this group. This is because: • there was not any identifiable pattern of changes in risk happening as people age and • the statistical subgroup analysis shows that this observed decrease could be accounted for by the play of random chance and therefore does not represent a real difference between age groups. As a result, the committee did not refer to this decrease in the recommendation. The rationale section has been updated with this information.
The Menopause Charity	Guideline	022	002	Infographic inclusion on BMS would be much more practical and user friendly than these referenced tables:	Thank you for your comment. NICE has produced a discussion aid document that includes visualisation of the data. This discussion aid has

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				https://thebms.org.uk/wp-content/uploads/2023/01/WHC-Infographics-JANUARY-2023-BreastCancerRisks.pdf These show relative risk in comparison and reduce exageration as this is misleading for less informed.	undergone user-testing and was refined based on user feedback. However, unlike the BMS infographic, the NICE document focuses on HRT only (rather than including smoking or alcohol intake). The guideline includes a separate recommendation emphasising that healthcare professionals should provide information on 'interventions or changes the person can make to support their health and wellbeing'.
The Menopause Charity	Guideline	022	010	Include consideration of chronic diseases, quality of life and impact on mental health	Thank you for your comment. The recommendation states that the information should be tailored to the person's age, personal circumstances and potential risk factors. This may feature considerations of chronic disease, quality of life and impact on mental health where appropriate.
The Menopause Charity	Guideline	022	016	'Do not offer combined or oestrogen-only HRT for primary or secondary prevention of cardiovascular disease.' This is contradicted by a number of research analyses that suggest up to a 30% decrease in all-cause mortality. See, for example, Boardman HM, Hartley L, Eisinga A, Main C, Roque i Figuls M, Bonfill Cosp X, et al. Hormone therapy for preventing cardiovascular disease in post-menopausal women. Cochrane Database Syst Rev. 2015(3):CD002229. Management of menopause: a view towards prevention May 5th, 2022. https://doi.org/10.1016/S2213-8587(21)00269-2	Thank you for your comment and highlighting the mentioned research papers. The committee were aware of the Boardman 2015 review, and it is listed under the excluded studies section of Evidence Review C and H. This systematic review combined data for participants who received combined HRT and oestrogen-only HRT. As this does not meet the criteria set out in the protocol of our review, Boardman 2015 could not be included as a whole. However, the committee commented on whether the conclusions the authors made differed from the findings of Evidence Review C. Although there were some differences, overall the conclusion was that HRT does not increase coronary heart disease. The 30% reduction in mortality from the Boardman 2015 review is based on data where combined HRT and oestrogen-only HRT data has been combined, therefore does not match our protocol. However, the included

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				Prof. Roger. A. Lobo MD & Prof. Anne Gompel MD. The Committee needs to explain what is flawed in these findings, if their guidelines are to justifiably contradict them. 'Confounding factors' in research studies are often referred to in the draft guidelines, as a justification for excluding their findings but, in the interests of public accessibility, it would be very useful to provide further explanation as to why these factors are indeed confounding, and how they affect research results in a detrimental way (to the point of exclusion).	individual studies from Boardman 2015 were considered separately and checked against the protocol for Evidence Review C and H. Those that met the protocol were included individually. The paper by Lobo and Gompel does not meet the criteria set out in the protocol for Evidence Review C as this is a literature review, and therefore does not meet the study design criteria listed. Again, the committee cannot comment on the results or conclusions from this review. With regard to confounders, the committee listed a few relevant important confounders in each protocol, however this list was not exhaustive. The committee specified in the protocol that studies would be excluded if there were no adjustments made for any confounders. The committee recognised that it is difficult to identify every important confounder associated, therefore did not specify exclusions based on specific confounders. A protocol is a methodological document and for the readership of such documents confounding is terminology that is readily understood, therefore the term is not defined anywhere in the guidance documentation, nor the reasons why confounding would be detrimental to research.
The Menopause Charity	Guideline	022	016	In addition, this seems to contradict NICE guidance at **p.74, line 6**: 'For people with premature ovarian insufficiency, HRT is offered for bone health and fracture prevention (because oestrogen helps maintain bone density) as well as cardiovascular health (because oestrogen is known to maintain vascular function).'	Thank you for your comment. The committee did not think that this was a contradiction because whilst they did not review the topic of POI they were aware that POI within itself increases fracture risk and could be detrimental for cardiovascular health. However, they did not feel that this applies to the same extent to women reaching menopause at an average age and that there are a range of other potential preventative options for these conditions available. The evidence also did not suggest this to be a

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					generally effective option for all. They therefore decided that HRT should not be offered for primary or secondary prevention of cardiovascular disease.
The Menopause Charity	Guideline	022	016	If HRT ist started early enough, this may mitigate neurological changes that can increase the risk of Alzheimer's disease https://www.themenopausecharity.org/wp-content/uploads/2023/10/The-Menopause-Charity-Transforming-Womens-Long-Term-Health.pdf	Thank you for your comment. A systematic review was carried out looking at the evidence of the effect of HRT on dementia compared to not taking HRT. Studies meeting the inclusion criteria for this review did not find evidence that HRT decreased the risk of dementia. The wider topic of neurological changes which may or may not be affected by HRT was outside the scope of the 2024 guideline update and the committee could therefore not comment on this.
The Menopause Charity	Guideline	022	021	HRT reduced CVD significantly as per evidence however at present there is insufficient evidence to offer this as sole prevention of cardiovascular disease without a symptomatic menopause. https://www.themenopausecharity.org/wp-content/uploads/2023/10/The-Menopause-Charity-Transforming-Womens-Long-Term-Health.pdf	Thank you for your comment. The committee reviewed the evidence on cardiovascular outcomes, which can be found in Evidence Review C. They reached the conclusion that HRT does not increase cardiovascular disease. Please see the committee's discussion of the evidence in Evidence Report C for full details on the decisions and discussions the committee made with regard to the available evidence. Given the findings about the effect of HRT on coronary heart disease and stroke, the committee agreed that the evidence did not support taking combined or oestrogen-only HRT for primary or secondary prevention of cardiovascular disease. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). However, they highlighted that RCT and observational study evidence should be discussed separately and given equal prominence throughout. The

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					independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. These and other evidence reviews have been revised to implement these changes accordingly.
The Menopause Charity	guideline	023	003	It is said that 'Combined HRT increases the risk of breast cancer compared with not taking HRT' This is potentially dangerously misleading without putting it into context. For example, Lobo and Gompel state that 'even if we assume an increased risk of breast cancer with oestrogen or synthetic progestogen over time, the absolute risks are low, in the range of six more cases per 10000 women per year in low risk women, which is considered to be a rare event according to WHO classification of events'. Physical inactivity, alcohol consumption and obesity present greater risk factors for breast cancer. This needs to be made very clear, to avoid dangers associated with misinformation, misreporting and sensationalism. Reporting of the findings of the WHI from 2002, with subsequent wide-spread abandoning of both prescribing and taking HRT, illustrates the importance of this point. In addition, research analyses contradict such a claim. Even the WHI authors now endorse the use of HRT for younger symptomatic women. For example, the WHI reported, as early as 2012, that women randomized to	Thank you for your comment. The committee agreed that presenting the risk in absolute terms would be the most useful way of conveying risks to people who might take HRT. The cited Lobo and Gompel publication is a narrative review which therefore the committee are unable to include or quote any of their figures in the evidence review as the study design does not meet the criteria set out in the review question. The committee agreed that risks in absolute terms will be of different significance to different people, therefore they agreed not to quantify the size or rarity of the risk. The scope for this guideline update did not specify a review of physical inactivity, alcohol consumption and obesity as risk factors for breast cancer, therefore the committee cannot comment on these and so are unable to compare them to the risks associated with HRT use. However, the guideline recommends that healthcare professionals share information about 'lifestyle changes and interventions that can support health and wellbeing'. The committee discussed that the absolute risks presenting in the guideline could be a tool that healthcare professionals could use to guide the conversation regarding a risk and benefit profile for women with menopausal symptoms, who wish to take HRT for their symptoms. With

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				postmenopausal estrogen were less likely to die of breast cancer —and less likely to die of all causes after a breast cancer diagnosis —than women taking a placebo. See also: The Controversial History of Hormone Replacement Therapy Angelo Cagnacci and Martina Venier**.** Medicina, 2019, 55, 602. Hormone Replacement Therapy After Breast Cancer It Is Time Avrum Zvi Bluming, MD (Cancer J 2022;28: 183–190)	regards to breast cancer related mortality for combined HRT the results of observational and RCT studies both showed a higher mortality in people taking HRT compared to those not taking HRT. Therefore, the committee concluded that 'there is a very small increase in risk of death from breast cancer with combined HRT'. The pattern is different for oestrogen only where results from RCT and observational studies differ and the committee took this into consideration to conclude that there 'is little or no increase in the risk of breast cancer mortality with oestrogen-only HRT'. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). However, they highlighted that RCT and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. These and other evidence reviews have been revised to implement these changes accordingly.
The Menopause Charity	Guideline	025		Combined HRT does not increase mortality from cardiovascular disease. [2023] This is potentially dangerously misleading without putting it into context. For example, Lobo and Gompel state that 'even if we assume an increased risk of breast cancer with oestrogen or synthetic progestogen over time, the absolute risks are low, in the range of six	Thank you for your comment. The committee agreed that presenting the risk in absolute terms would be the most useful way of conveying risks to people who might take HRT. The committee reflected on the presentation of information and used the appendix to produce a discussion aid document that includes visual presentation aimed to facilitate the shared decision making process

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				more cases per 10000 women per year in low risk women, which is considered to be a rare event according to WHO classification of events'. Physical inactivity, alcohol consumption and obesity present greater risk factors for breast cancer. This needs to be made very clear, to avoid dangers associated with misinformation, misreporting and sensationalism. Reporting of the findings of the WHI from 2002, with subsequent wide-spread abandoning of both prescribing and taking HRT, illustrates the importance of this point. In addition, research analyses contradict such a claim. Even the WHI authors now endorse the use of HRT for younger symptomatic women. For example, the WHI reported, as early as 2012, that women randomized to postmenopausal estrogen were less likely to die of breast cancer —and less likely to die of all causes after a breast cancer diagnosis —than women taking a placebo. See also: The Controversial History of Hormone Replacement Therapy Angelo Cagnacci and Martina Venier**.** Medicina, 2019, 55, 602. Hormone Replacement Therapy After Breast Cancer It Is Time Avrum Zvi Bluming, MD (Cancer J 2022;28: 183–190)	between the person and the healthcare professional. This discussion aid has undergone user-testing and was refined based on user feedback. Thank you for highlighting the Lobo and Gompel paper, which is a narrative review, therefore the committee are unable to include or quote any of their figures in the evidence review as the study design does not meet the criteria set out in the review question. The committee agreed that risks in absolute terms will be of different significance to different people, therefore they agreed not to quantify the size or rarity of the risk. The scope for this guideline update did not specify a review of physical inactivity, alcohol consumption and obesity as risk factors for breast cancer, therefore the committee cannot comment on these and so are unable to compare them to the risks associated with HRT use. The committee discussed that the absolute risks presenting in the guideline could be a tool that healthcare professionals could use to guide the conversation regarding a risk and benefit profile for women with menopausal symptoms, who wish to take HRT for their symptoms. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). However, they highlighted that RCT and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where

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					possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. These and other evidence reviews have been revised to implement these changes accordingly.
The Menopause Charity	guideline	026		There is limited evidence suggesting that HRT may improve muscle mass and strength – there is quite a lot of evidence for this. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4261347/ https://www.frontiersin.org/articles/10.3389/fphys.2020.596130/full NHS website on benefits of HRT state this https://www.nhs.uk/medicines/hormone-replacement-therapy-hrt/benefits-and-risks-of-hormone-replacement-therapy-hrt/	Thank you for your comment. The effectiveness of HTT on muscle mass and strength was not in the scope of the 2024 guideline update. Evidence for this topic was therefore not searched for and not reviewed and discussed with the committee. The committee could therefore not comment on this. The references listed have been checked and none of them meet the criteria set out in the protocols for the evidence reviews that were updated.
The Menopause Charity	Guideline	027		Emphasise oral more as can be misread - Combined HRT containing oral oestrogen increases the risk of stroke and the increase	Thank you for your comment. NICE house style does not allow us to emphasise a word in bold or italics.
The Menopause Charity	Guideline	030		Again use infographic – much better and easier to understand https://thebms.org.uk/wp-content/uploads/2023/01/WHC-Infographics-JANUARY-2023-BreastCancerRisks.pdf	Thank you for your comment. NICE has produced a discussion aid document that includes visualisation of the data. This discussion aid has undergone user-testing and was refined based on user feedback. However, unlike the BMS infographic, the NICE tool focuses on HRT only rather than including lifestyle factors. The guideline includes a separate recommendation emphasising that information should be shared about 'lifestyle changes and interventions that can support health and wellbeing'.

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The Menopause Charity	Guideline	033		varies from one person to another – obvious and useless	Thank you for your comment.
The Menopause Charity	Guideline	035	004	Evidence is lacking about possible benefits or risks of using HRT in 5 relation to most health outcomes considered in this guideline. Untrue and incorrect. https://www.themenopausecharity.org/wp-content/uploads/2023/10/The-Menopause-Charity-Transforming-Womens-Long-Term-Health.pdf	Thank you for your comment. The references included in the link provided could not be included in this evidence review as the protocol population was restricted to people aged between 40-44 years to capture early menopause. The need for further evidence reviews in the area of early menopause i.e., early menopause prevalence, risks of early menopause on health outcomes, and treatment for the prevention of health outcomes in early menopause, have been acknowledged and logged with the NICE surveillance team for consideration in future menopause guideline updates.
The Menopause Charity	guideline	035	010	It is said that 'Combined HRT increases the risk of breast cancer compared with not taking HRT' This is potentially dangerously misleading without putting it into context. For example, Lobo and Gompel state that 'even if we assume an increased risk of breast cancer with oestrogen or synthetic progestogen over time, the absolute risks are low, in the range of six more cases per 10000 women per year in low risk women, which is considered to be a rare event according to WHO classification of events'. Physical inactivity, alcohol consumption and obesity present greater risk factors for breast cancer. This needs to be made very clear, to avoid dangers associated with misinformation, misreporting and sensationalism. Reporting of the findings of the WHI from 2002, with subsequent wide-spread	Thank you for your comment. This statement has been removed from the recommendation. The recommendation for this section now reads as follows: 'When discussing HRT as a treatment option, explain to people experiencing early menopause, that, for them, the benefits and risks of either taking or not taking HRT are likely to lie between those for people with premature ovarian insufficiency and those for people aged 45 or over'. The need to assess the consequences of early menopause on health outcomes has been acknowledged and has been logged with the NICE surveillance teams for consideration in future updates.

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				abandoning of both prescribing and taking HRT, illustrates the importance of this point. In addition, research analyses contradict such a claim. Even the WHI authors now endorse the use of HRT for younger symptomatic women. For example, the WHI reported, as early as 2012, that women randomized to postmenopausal estrogen were less likely to die of breast cancer —and less likely to die of all causes after a breast cancer diagnosis —than women taking a placebo. See also: The Controversial History of Hormone Replacement Therapy Angelo Cagnacci and Martina Venier**.** Medicina, 2019, 55, 602. Hormone Replacement Therapy After Breast Cancer It Is Time Avrum Zvi Bluming, MD (Cancer J 2022;28: 183–190)	
The Menopause Charity	Guideline	036	018	https://so-daisy-uploads.s3.amazonaws.com/uploads/2016/11/ESHRE-POI-GUIDELINE_Patient-version_non-iatrogenic-POI.pdf This section contradicts the above for early menoapuse: the importance of starting hormonal treatment either with HRT or a combined hormonal contraceptive and continuing treatment until at least the age of natural menopause	Thank you for your comment. The scope of the question related to early menopause was very limited and was only addressing whether taking compared to not taking HRT impacts specific health outcomes. Limited evidence was identified for this. NICE and the committee recognise that this did not cover the important topics of consequences or management options for early menopause. NICE is therefore considering these specific questions for surveillance so that future guidance can make recommendations to address these points.

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The Menopause Charity	Guideline	037	020	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	040	002	Radio frequency and HRT are possible treatment modalities available to use to address age related Vaginal laxity, atrophy, vulvovaginal appearance due to decreased collagen and Oestrogen leading to smooth muscle dysfunction related concerns such dyspareunia, stress urinary incontinence, pain , itching which can impact the woman's quality of life and sexuality https://www.researchgate.net/publication/364371248_The_effect_of_dynamic_quadripolar_radiofrequency_on_genitourinary_atrophy_and_sexual_satisfaction_A_systematic_review_and_meta-analysis Comparative effects of fractional radiofrequency and microneedling on the genitalia of postmenopausal women: Histological and clinical changes - PMC (nih.gov)	Thank you for your comment. Radiofrequency was not an intervention that was listed as an intervention in the review protocol for reviews B1 or B2 on genitourinary symptoms. The protocol was pre-specified by the committee before the review was undertaken and cannot be changed. Therefore, the cited systematic review by Elbiss et al is not included in this review as the intervention and study designs of the included studies (case series) do not meet the protocol criteria. The study by Maia 2022 also does not meet the protocol criteria as the interventions were not listed in the protocol for Review B2 on genitourinary symptoms. The committee could therefore not comment on the radio frequency intervention.
The Menopause Charity	Guideline	042	018	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	042	025	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	043	029	When counselling individuals around duration of use, it is important to explore that symptoms may return once HRT is stopped. Although	Thank you for your comment. The recommendation has been reworded for clarity. The focus remains on duration of use, and it is

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				individuals can be reassured that it is safe to continue to use HRT indefinitely so long there are no new medical conditions that may inhibit ongoing use.	now divided into a discussion about possible duration of HRT treatment at the outset, to rediscuss the benefits and risks of continuing HRT at every review and also to make people aware that there is an option of restarting HRT if necessary. However, the committee did not agree that it should be stated that HRT could be taken 'indefinitely'.
The Menopause Charity	Guideline	044	023	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	045	003	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	049	007	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	052	012	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	052	021	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	054	014	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	056	003	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this

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					wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	057	024	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	067	012	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	072	020	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	076	005	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	077	016	Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	078		Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Charity	Guideline	083		Remove and replace troublesome - downplaying & unquantifiable clinically.	Thank you for your comment. Based on this and other feedback the committee reflected on this wording and consequently 'troublesome' has been removed from the guideline.
The Menopause Consortium Limited	Evidence Review A	General	General	While the draft guidelines rightly highlight cognitive behavioural therapy (CBT) as a non-hormonal option, there is a notable absence in the assessment of another proven and effective non-hormonal therapy—clinical hypnosis. This	Thank you for your comment. The effectiveness of hypnosis on symptoms associated with the menopause was not in the scope of the 2024 guideline update. Evidence for this topic was therefore not searched for, reviewed or discussed

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				omission is particularly significant given the substantial evidence supporting the efficacy of clinical hypnosis in managing menopausal symptoms. The North American Menopause Society's position statement on nonhormonal therapies has recommended hypnosis based on level 1 evidence ("good and consistent scientific evidence") since 2015, with the latest update in 2023 [1]. I have included pertinent information and references below for your consideration. Clinical hypnosis, a mind-body therapy involving deep relaxation and personalized mental imagery, has demonstrated its effectiveness in reducing hot flashes and improving mood and sleep. Studies, such as the one involving breast cancer survivors, showed a 68% reduction in hot flash scores and significant improvements in anxiety, depression, and overall quality of life for those who received hypnosis intervention [2]. Another study of 187 postmenopausal women reported a 74% reduction in hot flash frequency and an 80% reduction in hot flash scores for those undergoing clinical hypnosis compared to controls [4]. The positive outcomes were not related to women's expectations, emphasizing the therapy's genuine impact. Furthermore, a randomized controlled trial involving 90 menopausal women revealed that a self-hypnosis program significantly improved sleep quality, a crucial aspect often disturbed during menopause [6]. In contrast to the draft guidelines' characterization of CBT primarily reducing symptoms, hypnotherapy has demonstrated a	with the committee. The committee could therefore not comment on this. The references listed have been reviewed, and none of them meet the criteria outlined in the updated evidence review protocols, but they were logged with the NICE surveillance team so that they could be considered for future updates.

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				substantial mean reduction of 70% to 80% in objectively measured hot flushes, comparable to hormone replacement therapy but without its possible adverse effects [3]. It is concerning that the 2015 full NICE menopause guideline initially included hypnosis as one of the interventions to be assessed, only to be excluded based on an outdated study protocol. Despite the study results being published in 2013 and referenced in the guidance, it appears that NICE has repeatedly overlooked assessing clinical hypnosis in subsequent surveillance updates in 2019 and 2021. Notably, a large NIH-funded multicentre RCT for Clinical Hypnosis is underway in the USA, with results expected by June 2024. If NICE decides to evaluate Clinical Hypnosis, these findings could be valuable for the final version of the updated guidelines. Considering the compelling evidence supporting the efficacy of Clinical Hypnosis, we strongly urge NICE to reconsider and assess its inclusion in the final version of the menopause guidelines. Women deserve access to a range of safe and effective non-hormonal interventions, and the evidence supporting clinical hypnosis should not be overlooked. This would not be difficult to implement as a guideline or have any cost implications.	
The Menopause Consortium Limited	Evidence Review B1	General	General	While we note that there are minimal studies in psychosexual medicine it is nevertheless recognised in many cases that to be an adjunct	Thank you for your comment. Psychosexual medicine was not within the scope of this guideline so evidence was not searched, systematically

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				in the treatment of dyspareunia. At the time of the menopause dyspareunia is more prevalent due to GSM and can often unmask significant psychosexual difficulties that have previously remained quiescent. We feel that this specialised branch of medicine should not be ignored in the guidelines in as much as a psychosexual cause of menopausal symptom should always be considered particularly when discussing GSM. This would not be difficult to implement or have any cost implications.	reviewed and discussed with the committee. The committee were therefore unable to make recommendations around it.
The Menopause Consortium Limited	Guideline	General	General	All Documents The whole guidelines refer to treatment of menopause as Hormone Replacement Therapy (HRT). The current term being used by Menopause Specialists is Menopause Hormone Therapy (MHT). We feel the Guidelines should reflect the current terminology of MHT used by professionals in the field of menopause and avoid confusion with other hormonal treatments for conditions such as Hypothyroidism or diabetes. This would not be difficult to implement or have any cost implications.	Thank you for your comment. There terminology was discussed, and it was acknowledged that terminology has evolved particularly in the professional and academic world. However, it was decided to retain the terminology as is because in UK practice and in the general population Hormone Replacement Therapy as well as the acronym HRT are more readily understood.
The Menopause Consortium Limited	Guideline	General	General	We note that we can see no mention of Fezolinetant which has been licensed by the MHRA in December 2023 for the treatment of vasomotor symptoms, not including it the guidelines when published will be significantly	Thank you for your comment. Fezolinetant was not part of the scope of this guideline. However, NICE is conducting a Health Technology Appraisal of Fezolinetant. Once completed it will then be

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				out of date and potentially denying patients of a full range of treatment options. This would not be difficult to implement or have any cost implications.	considered whether a cross reference to this can be added to the menopause guideline.
The Menopause Consortium Limited	Guideline	023	General	Table 1 Table 1 Combined HRT: effect on health outcomes The wording in the 4th column, is ambiguous and open to misinterpretation, it could be read that transdermal HRT could lead to an increase in breast cancer rather than what is meant by the statement which is the opposite. It could read *"The increase in breast cancer is less with transdermal MHT preparations as opposed to oral MHT preparations where this is an increased risk"* Column 5 is at odds with current and accepted understanding that micronized progesterone and dydrogesterone is not associated with a greater risk as other progesterones.	Thank you for your comment. The committee considered the evidence for oral and transdermal routes of administration of the oestrogen component of HRT. Both transdermal and oral combined HRT showed an increase in the risk of breast cancer. Since some of the evidence showed a significant difference between the subgroups of oral and transdermal routes of administration in the combined HRT comparison, they had made a recommendation to inform that the increase was smaller with transdermal than oral. This now also includes a study by Vinogradova (2020) which include data on transdermal versus oral HRT but did not provide greater clarity on this matter. The committee considered this and the Brusseler 2018 evidence and discussed that since the same difference was not observed in the oestrogen-only comparison, the argument was less robust than previously discussed. Upon reflection the committee agreed to remove this recommendation and the rationale section revised accordingly as well and a detailed discussion of the evidence and their decision was updated and can be found in the committee discussion of the evidence section of Evidence Review D. The committee also decided that more evidence is needed to clarify this and prioritised this for a research recommendation.

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The Menopause Consortium Limited	Guideline	049	008 - 023	CBT should be recommended as an alternative to MHT for those patients not wishing to or unable to take MHT. Alternative treatment options should not replace traditional proven MHT for patients that are able to take it. The guidance should be careful and not suggest CBT as an easy option for overworked GPs who have little to no interest in menopause and thus provide an option to no long-term commitment to care.	Thank you for your comment. The wording of the recommendation has been revised to make it explicit that this is an option which could be in addition to HRT, for people in whom HRT is contraindicated or for those who prefer not to take HRT. The related rationale has been revised accordingly.
The Menopause Exchange	Guideline	General	General	I am happy with the draft guideline as it is. However, can information on Complementary Medicines and Therapies be updated next time there is a draft guideline?	Thank you for your comment. The NICE surveillance team regularly checks topics within guidelines (such as complementary medicine) for new evidence which could trigger future updates.
The Royal College of Psychiatrists	Guideline	General	General	**[This text was identified as confidential and has been removed]**	Thank you for your comment. The experience and impact of menopause as well as associated symptoms or conditions were not part of the 2024 guideline update. NICE takes reports of the impact of menopause on mental health seriously. The NICE surveillance team regularly looks for evidence related to topics in guidelines to identify evidence that can be considered for future updates. The cited reference has been logged with this team so that it can be taken into account.
The Royal College of Psychiatrists	Guideline	General	General	*Mental Illness, Menopause & Health Inequality* Women experiencing mental disorder have poor physical health outcomes and are at risk of diagnostic overshadowing. They are less likely to have their health needs met. The guidance should highlight this risk to ensure correct identification and interventions for menopause are offered to this group otherwise this risks furthering health inequality for this group of women.	Thank you for your comment. The experience and impact of menopause as well as associated symptoms, conditions or populations were not part of the 2024 guideline update. NICE takes reports of the impact of menopause on mental health seriously. The NICE surveillance team regularly looks for evidence related to topics in guidelines to identify evidence that can be considered for future updates.

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				In addition, women experiencing mental disorder are more likely to have characteristics that put them at risk of 'early' or 'troublesome' symptoms of menopause as highlighted in the evidence in the Equality Impact Assessment for this guideline (as below). We recommend that these risks should be outlined in the main guidance document rather than only referenced in the NICE guideline on 'patient experience in adult NHS services' and 'shared decision making' as suggested in the Equality Impact Assessment. There is a risk that without clear acknowledgement to this in the guidance, we will continue to fail to identify or offer evidence-based interventions for this group, with negative impacts on physical and mental health. ○ *'For some women with cognitive or physical disabilities, troublesome symptoms of menopause might be missed or misinterpreted.'* ○ *Women from different ethnic backgrounds may experience different menopausal symptoms and their symptoms may not be recognised as being related to the menopause.* ○ *Black and minority ethnic women can experience that their concerns are not taken seriously, understood or*	

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				listened to by healthcare professionals. ○ *Lower average age of menopause in women from disadvantaged background.*	
The Royal College of Psychiatrists	Guideline	006	018	*Menopause and symptoms* 1.2.2 This does not reference any of the cognitive effects of menopause. In particular this should include 'brain fog', but also consider reference to there being other diverse cognitive symptoms. While women may report 'brain fog' cognitive domains and symptoms should be included with appropriate terminology for differential diagnosis, different treatment approaches and, of course, prognosis. This would help to identify - for example - early onset dementia or cognitive symptoms due to major depressive disorder.	Thank you for your comment. Whilst an update of the list of symptoms and experiences (including brain fog) was outside the current scope of the 2024 guideline update and therefore no evidence review was conducted, the NICE surveillance team checks regularly for new evidence for topics within guidelines to see where further work is needed.
The Royal College of Psychiatrists	Guideline	018	014	We advise that the NICE guidance for depression, anxiety and 'mania or hypomania'	Thank you for your comment. The recommendations in this section only refer to

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				are cross referenced or signposted to. We note that only depression guidance is cross referenced (1.4.36) currently.	depressive symptoms for which evidence had been identified. Referring to other NICE guidelines would be confusing because it would assume a link between these topics and menopause.
The Royal College of Psychiatrists	Guideline	018	014	*Menopause and symptoms* 1.4.36 (and onwards). We strongly recommend the inclusion of anxiety symptoms alongside depression, when referring to 'troublesome menopause symptoms' given the evidence base and their overlap with depression and insomnia.	Thank you for your comment. This section only includes depressive symptoms because the 2024 update only looked at CBT as an intervention and CBT was not found to be effective for anxiety in the context of menopause. It was not in the scope of the 2024 guideline to specify the range of menopause symptoms and all possible treatments for them.
The Royal College of Psychiatrists	Guideline	019	002	*CBT* 1.4.37 There are recommendations for CBT for difficulties with sleep - as well as for depression (1.4.35 - line 12, page 18) and vasomotor symptoms (1.4.16 - line 5, page 14) associated with menopause. There are significant challenges effecting CBT intervention via NHS Talking Therapies (NHSTT). Whilst it is good to see 90% of referrals to NHSTT starting treatment within the 6-week target, the programme is considerably behind schedule in terms of expansion with only around two-thirds of the expected numbers accessing services each year – c1.2 million compared to the 1.8 million expected in 2022/23.	Thank you for your comment. The committee acknowledged in the impact section of the guideline that there are long waiting times for CBT. They also noted that people currently trained in providing this kind of therapy may not be familiar with menopause-specific CBT and training on this may incur costs and increase waiting times in the short term. However, online and group CBT may be easier and less costly to adapt to menopause-specific CBT. There are also resources available to train people in providing menopause-specific CBT (and could also inform the adaptation of online CBT), which could facilitate implementation. Your comment will be considered by NICE where relevant support activity is being planned. Evidence showed CBT to be effective in the management of vasomotor symptoms, depressive symptoms and sleep problems. However, there were mixed results and the wording has been

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				We are also concerned that there are not enough adequately trained practitioners in specific CBT treatment for these symptoms as part of the menopause. This could result in delayed intervention for women recommended this treatment pathway. In addition, women with severe existing mental disorders are usually not eligible for standard 'NHS talking therapies' which highlights a potential treatment inequality faced by this group, should they experience new menopausal symptoms. To address these challenges action from Government is required. This needs to include a commitment to additional funding for NHSTT services as well as investment in retaining and recruiting the psychiatric and wider healthcare workforce. We would also welcome NHSE reviewing the current exclusion criteria for accessing NHSTT services and consider the factors affecting the number of people who do not complete treatment.	revised to ensure clarity about CBT not being a routine treatment but 'as an option: in addition to other treatments (including HRT), for people for whom other treatments are contraindicated or for people who prefer not to take HRT'. This is also easing pressure on services.
The Royal College of Psychiatrists	Guideline	076	020	We acknowledge that the NICE Guidance committee membership for menopause does not include a psychiatrist. Given the overlap and interplay with mental health symptoms we recommend that this specialist input is sought in any further guidance in this area.	Thank you for your comment. NICE considered the committee composition during scoping. For psychological symptoms only CBT was considered in the 2024 guideline update. The committee a co-opted clinical psychologist with expertise in such treatments. Future updates of the guideline may consider different committee compositions depending on the topics that are updated.

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The Thyroid Trust	Guideline	008		1.3 Due to the fact that Thyroid disease and menopause have cross over symptoms such as changes to menstrual cycle, anxiety, depression, joint and muscle aches, hot flushes, problems with sleeping and weight gain we would like to see that a recommendation for a TSH blood test to rule out a thyroid disorder added in this section.	Thank you for your comment. Identifying perimenopause and menopause was not in the scope of the 2024 guideline update. Evidence for this topic (including the potential impact of thyroid disease) was not searched for and not reviewed and discussed with the committee. The committee could therefore not comment on this. The issue of thyroid function tests has been logged with the NICE surveillance team for consideration for future updates.
The Thyroid Trust	Guideline	012	019	We would like to see thyroid patients who are taking Levothyroxine mentioned in this section. As we know that some thyroid patients starting on HRT require additional (blood test) monitoring of their thyroid levels and some as a result may need to alter thyroid hormone medication dose.	Thank you for your comment. The impact of thyroid conditions on the menopause and symptom management specifically related to this were outside the scope of the 2024 guideline update. Evidence for these topics were not searched for, reviewed or discussed with the committee. The committee could therefore not comment on this.
The YES YES Company Ltd	Guideline	018	003	Recommendations for advising people with vaginal dryness that moisturisers and lubricants can be used alone or in combination with vaginal oestrogen, does not provide further information about the importance of formulation in these products. Many OTC and prescribable moisturisers and some lubricants contain excipients that render them hyper-osmotic. The Review Paper authored by Dr David Edwards and Nick Panay and published in Climacteric the IMS Journal in 2015 https://www.tandfonline.com/doi/full/10.3109/13697137.2015.1124259 made the following recommendations as part of the conclusion. *"Personal lubricants and moisturizers are effective treatment options in the management of vaginal dryness with a variety of causes.*	Thank you for your comment. The pH level and osmolarity of moisturisers and lubricants was not in the scope of this review question. This means that different levels of pH and osmolarity were not compared with each other to investigate the impact on genitourinary outcomes associated with the menopause. The article by Panay was not included because it did not meet protocol criteria (it was a narrative review). The committee could therefore not comment on this.

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				However, differences exist between commercially available products. Given that non-physiological pH and osmolality, and the presence of excipients such as parabens and microbicides, are associated with a variety of proven or potential detrimental effects, the recommended safe values for pH and osmolality should be carefully ensured when choosing or prescribing a personal lubricant. This provides a stimulus for both regulatory authorities and manufacturers to work together in reformulating preparations to be more patient-friendly. *It is advised that women choose a product that is optimally balanced in terms of both osmolality and pH and is physiologically most similar to natural vaginal secretions. Table 2 contains a series of recommendations for the use of vaginal lubricants and moisturizers, either on their own or in combination with systemic or topical hormone replacement therapy."* Unfortunately many HCPs are not aware of this, and if people choose a product which is hyper-osmotic or has a hight pH value above 4.5pH, this can lead to side effects such as irritation, infection or potential damage to the epithelial cells. In turn, this may cause poor compliance and a waste of NHS funds.	
Theramex UK	Guideline	010-011	026-005	1.4.3 • Alongside discussing the duration of treatment at the outset, and likeliness of symptoms returning, HCPs should also be encouraged to ensure a follow up appointment is put in to assess	Thank you for your comment. The committee reflected on this and the word 'prolonged' has been removed from this recommendation. It has been rephrased to read 'discuss the possible duration of treatment at the outset', followed by 'rediscuss the benefits and risks of continuing treatment at every review'. Therefore, it is a

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				whether the dosage is sufficient and effective. In addition to discussing the risks associated with prolonged use of HRT, there should also be guidance for HCPs to discuss the potential benefits of prolonged use of HRT as outlined by NICE.[i]	general discussion about the potential duration which would then be revisited at each review.
Theramex UK	Guideline	021-022	019-008	1.6.1 • When discussing the potential benefits and risks with HRT, there is a disproportionate mention of risks within the guidelines compared to the potential benefits of taking HRT. This is despite the fact that HRT prescribed before the age of 60 or within 10 years of the menopause has a favourable benefit/risk profile.[ii] • For example, in the section on the effect of HRT on health outcomes, the table focuses solely on the risks from HRT. These guidelines should also highlight the potential benefits in a similar format for conditions like osteoporosis and cardiovascular disease.[iii] • Alongside discussing the duration of treatment at the outset, and likeliness of symptoms returning, HCPs should also be encouraged to ensure a follow up appointment is put in to assess whether the dosage is sufficient and effective. In addition to discussing the risks associated with prolonged use of HRT, there should also be guidance for HCPs to discuss the potential	Thank you for your comment. The 2024 guideline update focused on some specific health outcomes (breast cancer, endometrial cancer, ovarian cancer, cardiovascular disease, all-cause mortality and dementia). One of the reasons the 2015 guideline required updating was the pharmacovigilance risk assessments by the MHRA to and the EMA, concerning the impact of HRT on the risk of breast cancer. NICE is required to consider the impact of regulatory guidance from MHRA in its guidance and as such the additional information on breast cancer does change the balance of risks and benefits from that in the original 2015 guideline.

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				benefits of prolonged use of HRT as outlined by NICE.[iv]	
Theramex UK	Guideline	048-049	028-007	The list of uncertainties relating to CBT should be emphasised more clearly throughout the guideline.	Thank you for your comment. The committee reflected on the wording of the recommendations related to CBT and updated it to make it explicit that this was not recommended as a first line treatment. It is now stated that it is an option (1) in addition to other treatments (including HRT) (2) for people in whom other treatments are contraindicated or (3) for people who prefer not to have other treatments. It is NICE style to use the wording 'consider' indicating a recommendation where there is some uncertainty about the evidence. The rationale then describes the uncertainties and why the committee, on balance, concluded that CBT could be an option.
Theramex UK	Guideline	008	012 - 020	1.3.1 • This section needs more detail on the other symptoms of menopause including mental health repercussions and other less obvious physical symptoms such as joint pain. This section should also acknowledge the difficulty some women face in getting a menopause diagnosis from their GP.	Thank you for your comment. Identifying perimenopause and menopause was not in the scope of the 2024 guideline update. Evidence for this topic was not searched for and not reviewed and discussed with the committee. The committee could therefore not comment on this.
Theramex UK	Guideline	008	024-026	1.3.3 • This section should note that Black women have been found to be more likely to experience more intense menopause symptoms than white women,[v] however they are less likely to be offered HRT.[vi] This section should also acknowledge that there are additional barriers to care for women from some ethnic minority backgrounds as a	Thank you for your comment. A review of the experience of symptoms was not in the scope of the 2024 guideline update. Evidence for this topic was not searched for and not reviewed and discussed with the committee. The committee could therefore not comment on this.

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				result of cultural taboos and stigmas, as well as language barriers.	
Theramex UK	Guideline	010	008-010	1.4.1 • This section should give consideration to the links between menopause and osteoporosis. Oestrogen deficiency, which occurs as a result of menopause, is linked to a number of other serious health conditions including osteoporosis.[vii] Studies show that earlier treatment of menopause symptoms can lead to improved outcomes for women in areas including bone health.[viii,ix] Osteoporosis must be placed at the forefront of menopause care to ensure women maintain good bone health throughout the menopause and beyond. • Menopause is typically characterised by oestrogen deficiency symptoms. The most common symptoms include hot flushes, night sweats, vaginal dryness and discomfort during sex, difficulty sleeping, low mood or anxiety, reduced sex drive (libido), problems with memory and concentration.[x] This section needs to better communicate that whilst all women will go through menopause and likely experience some of these symptoms, it is not necessary to endure them and there are many treatments out there which can help alleviate symptoms. • The list of symptoms provided in this section needs to be much more	Thank you for your comment. The committee decided that it was important to ensure that a person-centred approach is used which tailors the information about benefits and risks to the person's age, individual circumstances and potential risk factors. Section 1.4 sets out the broad topics that should be covered for different treatments in the guideline. The first recommendation in the section is referring to all treatment options (not restricted to HRT). Then there are some HRT recommendations prompting clinicians to cover the options available to the person and This is then followed by other aspects to consider such as possible duration and review. Topics to cover for CBT and for complementary therapies and unregulated preparations are also covered in this section. Section 1.2 covers general information and support including some information about symptoms. However, the information and support section was not updated in 2024 which means that providing a new list of symptom was outside the scope. The NICE surveillance team regularly checks for new evidence for topics in guideline that could inform future updates. The details of the effects of HRT on specific health outcomes is covered in section 1.6 including the section on osteoporosis which states that fragility fracture risk is decreased while taking HRT. During shared decision making the person can then discuss the options with the healthcare professional to make an informed choice taking into account their personal preferences and risk factors. The committee agreed that presenting tables with absolute

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				comprehensive, covering more of the 48 symptoms associated with menopause.[xi] This should include the direct symptoms of menopause but also conditions that can be caused as a result of the untreated symptoms. - Over 80% of women will experience debilitating menopause symptoms for more than one year[xii] and many women will still experience symptoms seven years after their final period.[xiii] Oestrogen deficiency is linked to a number of other serious health conditions, including osteoporosis.[vii] Of the 3,775,000 individuals with osteoporosis in 2019, 78% were women.[xiv] Moreover, one in two women over 50 will break a bone because of osteoporosis.[xv] Osteoporosis is a costly burden to the health system, currently costing the NHS £4.5 billion a year, which is projected to rise steeply. Studies show that earlier treatment of menopause symptoms can lead to improved outcomes for women in areas including bone health.[xvi,xvii]	numbers in an appendix as they were during consultation would not sufficiently facilitate this process and more information as well as a visual representation of this material was included. NICE has developed a decision support document with visual representation of the data to aid shared decision making.
Theramex UK	Guideline	010	012-025	1.4.2 • Theramex welcomes this update which recognises there is a variety of appropriate forms of HRT. In order to provide more clarity on which form of treatment is most appropriate, this list should include a schema to indicate the most appropriate form for peri-menopausal women, post-menopausal women, women with a uterus and women without a uterus. The list should also include advice on balanced	Thank you for your comment. The committee agreed that the presentation of the information could be improved upon. However, they decided that a schema as suggested would give the impression that the management option is less individualised than what is intended by this guideline. To improve presentation, numbers in the appendix have been used to create a discussion aid document including visual presentation of the data to facilitate shared decision making. This discussion aid has

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				prescribing of oestrogen and progesterone to ensure endometrial protection.[xviii] • It is crucial that all eligible women are able to access all the forms of HRT listed. Over the past 5 years the demand for HRT has doubled which has resulted in shortages of some HRT products. Consequently, some women are unable to access their prescribed HRT preparations. • When discussing the potential benefits and risks with HRT, there is a disproportionate mention of risks within the guidelines compared to the potential benefits of taking HRT. This is despite the fact that HRT prescribed before the age of 60 or within 10 years of the menopause has a favourable benefit/risk profile.[xix] For example, in the section on the effect of HRT on health outcomes, the table focuses solely on the risks from HRT. These guidelines should also highlight the potential benefits in a similar format for conditions like osteoporosis and cardiovascular disease.[xx]	undergone user-testing and was refined based on user feedback. Identifying and dealing with HRT shortages was not part of the 2024 guideline update but would be part of implementing this guideline because the offer of HRT for vasomotor symptoms has not changed. Your comment will be considered by NICE where relevant support activity is being planned.
Theramex UK	Guideline	011	006-013	1.4.4 • This section needs to recognise the list of uncertainties relating to the effectiveness of CBT for the treatment of menopause (outlined on page 48) more clearly. • As recognised on page 45 (line 025) there is already pressure on services providing CBT, therefore increasing	Thank you for your comment. The committee has revised the wording to ensure clarity about CBT 'as an option: in addition to other treatments (including HRT), for people for whom other treatments are contraindicated or for people who prefer not to take HRT'. The committee acknowledged in the impact section of the guideline that there are long waiting times for CBT. They also noted that people currently trained in

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				CBT referrals for menopause treatment will put more pressure on these services. CBT should therefore only be prescribed when absolutely necessary or when other treatment options are not suitable. This section should provide more clarity on what constitutes for the prescribing of CBT. • Alongside the potential increase in pressure on services, it is important to note that although access to talking therapies has improved in recent years, there is widespread variation in waiting times across the country[xxi] with a parliamentary review in March 2023 observing that there is "substantial variation in different parts of England. The wait for a first treatment varied from 4 days in Castle Point and Rochford (Essex) to 229 days in South Sefton (Merseyside)."[xxi] The increased prescribing of CBT risks contributing to further variation in waiting times for such services across the country. As recognised on page 47 (lines 14-18), whilst CBT is effective for the treatment of depressive symptoms it has been found to make no difference on emotional wellbeing and mental health component measurements on the Quality of Life scale. Therefore this section should clarify CBT may only be suitable for menopausal women who have depressive symptoms, as outlined in section 1.4.9 for people who have taken gender-affirming therapy in the past.	providing this kind of therapy may not be familiar with menopause-specific CBT and training on this may incur costs and increase waiting times in the short term. However, online and group CBT may be easier and less costly to adapt to menopause-specific CBT. There are also resources available to train people in providing menopause-specific CBT (and could also inform the adaptation of online CBT), which could facilitate implementation. Your comment will be considered by NICE where relevant support activity is being planned. The results of the evidence review varied according to the different measurement scales used and the committee also took into account based on expertise its effectiveness related to depressive symptoms outside the context of menopause and therefore made a recommendation to use it as an option.

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Theramex UK	Guideline	013	009-014	1.4.13 • This section should include more information on the potential benefits associated with HRT and coronary heart disease or stroke, in line with section 1.4.14 on breast cancer. • The menopause can increase your risk of heart and circulatory conditions. It has been found that HRT significantly reduces CVD in women below 60 years of age and/or at or near menopause.[xxii] Therefore, it may be beneficial to consider HRT to mitigate this risk, especially for those who have a family history of CVD.[xxiii] The lack of information compared to the quantity of information surrounding breast cancer should be considered and balanced with the potential benefits of HRT to prevent a misjudged emphasis on the risks by HCPs with patients who may not be impacted.	Thank you for your comment. The committee noted that in people with a history of cardiovascular disease taking either combined HRT (continuous and sequential) or oestrogen-only HRT, the RCT evidence did not suggest any difference in coronary heart disease risk and cardiac event composite scores, when compared to placebo. Observational evidence did not include people with a history of cardiovascular disease. The committee discussed how the evidence suggested that a history of coronary heart disease may not be a contraindication to combined or oestrogen-only HRT. However, they felt that for this group of people the use of HRT should be discussed with and initiated, if appropriate, by a healthcare professional with expertise in menopause. This would ensure that people with a history of coronary heart disease who commence HRT are advised in an individualised way that relates to their specific history of coronary heart disease. For details see the 'committee's discussion and interpretation of the evidence' section of evidence review C. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). However, they highlighted that RCT and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE

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					methodology. These and other evidence reviews have been revised to implement these changes accordingly.
Theramex UK	Guideline	014	005-006	1.4.16 • This section needs to recognise the list of uncertainties relating to the effectiveness of CBT for the treatment of menopause (outlined on page 48-49, lines 025-007) more clearly. • This section should include advice on the minimum duration women should have CBT to help resolve some of their vasomotor symptoms. • This section should clarify if it is suggesting CBT as an alternative to HRT or to be had as well as HRT. Offering CBT without HRT may risk some women missing out on the benefits of HRT in treating physical symptoms. • This section should also clarify what the next steps would be should CBT not be effective, particularly if CBT has been used before or in place of HRT. • As recognised on page 45 (line 025) there is already pressure on services providing CBT, therefore increasing CBT referrals for menopause treatment will put more pressure on these services. Detail is needed on what mitigations would be put in place to resolve this. • Alongside the potential increase in pressure on services, it is important to note that although access to talking	Thank you for your comment. The wording has been revised to ensure clarity about CBT 'as an option: in addition to HRT, for people for whom HRT is contraindicated or for people who prefer not to take HRT'. The committee acknowledged in the impact section of the guideline that there are long waiting times for CBT. They also noted that people currently trained in providing this kind of therapy may not be familiar with menopause-specific CBT and training on this may incur costs and increase waiting times in the short term. However, online and group CBT may be easier and less costly to adapt to menopause-specific CBT. There are also resources available to train people in providing menopause-specific CBT (and could also inform the adaptation of online CBT), which could facilitate implementation. Your comment will be considered by NICE where relevant support activity is being planned. The content of healthcare professional training falls outside the remit of NICE and is the responsibility of the relevant academic institutions and Royal colleges. The committee could therefore not comment on this.

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				therapies has improved in recent years, there is widespread variation in waiting times across the country[xxi] with a parliamentary review in March 2023 observing that there is "substantial variation in different parts of England. The wait for a first treatment varied from 4 days in Castle Point and Rochford (Essex) to 229 days in South Sefton (Merseyside)."[xxi] • As recognised on page 47 (lines 14-18), whilst CBT if effective for the treatment of depressive symptoms it has been found to make no difference on emotional wellbeing and mental health component measurements on the Quality of Life scale. Therefore this section should clarify CBT may only be suitable for menopausal women who have depressive symptoms. • This lack of clarity also reaffirms the need for mandatory training for HCPs, particularly GPs, on the menopause. According to one survey, only 66% of GP respondents reported feeling confident managing the menopause.[xxiv] More is needed around menopause education and training for healthcare professionals to increase their confidence on the subject matter. Without this, there is a risk that healthcare professionals will defer to prescribing CBT without having considered alternative options which may be more appropriate.	
Theramex UK	Guideline	018	009-011	1.4.34	Thank you for your comment. The section on depressive symptoms does not contain a

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				Anti-depressants should not be prescribed as an alternative to HRT. Many women who seek treatment for menopausal symptoms are prescribed antidepressants as opposed to HRT despite the fact there is no clear evidence that antidepressants improve low mood in menopausal women. Often women feel that they have been inappropriately prescribed antidepressants, echoing the responses from the call for evidence for the Women's Health Strategy where an overwhelming 84% of women felt they were not being listened to by their health care professional.[xxv,xxvi]	reference to antidepressants. The 2024 guideline update did not look at antidepressants in the treatment of menopause related depressive symptoms. The committee could therefore not add anything related to this topic to the recommendations.
Theramex UK	Guideline	019	002-003	1.4.37 • This section should consider the evidence that HRT can help restore normal sleep patterns in women with concomitant vasomotor symptoms, which may be more accessible for some women than CBT.[xxvii] This section should acknowledge that the effectiveness of CBT for helping improve sleep patterns depends on external factors including working patterns, noise levels and caring responsibilities than may disrupt sleep.	Thank you for your comment. Apart from CBT other management options for sleep problems associated with the menopause were not in the scope of the 2024 guideline update. However, the committee acknowledged that there are other options that may be used (including HRT). They have therefore reworded the recommendation to reflect this. It now states that CBT could be used as an option (1) in addition to other treatments (including HRT), or (2) for people for whom other treatments are contraindicated or (3) for people who prefer not to have other treatments. Given the constraints of the scope they could not be more specific than this.
Theramex UK	Guideline	019	011-015	1.5.1 Whilst this differentiation in appropriate HRT to prescribe is useful, this section should include a schema to provide more clarity on HRT initiation for peri-menopausal and post-menopausal women.	Thank you for your comment. The guideline recommends HRT for specific symptoms in a way that takes into account the person's preferences and assessment of the benefits and risks. This would take place in the shared decision making context. The committee decided that a schema for overall HRT would therefore not be helpful because it is an individual's decision. However, it

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					was decided that a pathway could be provided related to genitourinary symptoms and also a discussion aid document was developed that provides visualisation of the absolute numbers of the specific health outcomes described in tables 1 and 2. This discussion aid has undergone user-testing and was refined based on user feedback.
Theramex UK	Guideline	038	019-020	**2 Type of progestogen in HRT and breast, endometrial cancer or cardiovascular disease** This section should include consideration of the role of HRT in preventing osteoporosis, given oestrogen deficiency (caused by menopause) results in a decrease of bone density. Studies show that earlier treatment of menopause symptoms can lead to improved outcomes for women in areas including bone health.[xxviii,xxix] Osteoporosis must be placed at the forefront of menopause care to ensure women maintain good bone health throughout the menopause and beyond.	Thank you for your comment. As osteoporosis was not part of the 2024 guideline update the committee did not comment on this.
Theramex UK	Guideline	040	011-015	**6 Health outcomes of HRT for trans men and non-binary people registered female at birth (who are not taking cross-sex hormones as gender-affirming therapy at the time of taking HRT or in the follow up period)** • The list in this section should include osteoporosis.	Thank you for your comment. Osteoporosis was not part of the 2024 guideline update so it is unclear whether or not evidence may be available for this. Within NICE processes for research recommendation, research can only be suggested on topics where evidence was searched for.
Theramex UK	Guideline	043	016	This should make clear that the effect of HRT on the risk of dementia remains unclear, with studies reporting conflicting results. Based on current evidence, HRT is unlikely to increase the risk of dementia before the age of 60.[xxx]	Thank you for your comment. For ages below 65 there was no clear evidence whether or not HRT increased risk of dementia. One study showed no difference whereas another study showed an increase in incidence of dementia. Given these discrepancies and potential for confounding in

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					observational data, the committee based this recommendation on the available RCT data with participants that started HRT over the age of 65 and decided not to comment on people initiating HRT earlier. This is described in the rationale section. The committee decided to retain the 2015 research recommendation on the effects of HRT on dementia.
Theramex UK	Guideline	059	019-023	This rationale should consider the potential benefits of HRT for treating conditions such as osteoporosis.	Thank you for your comment. The rationale sections only cover areas that were because they contain a summary of the discussions that led to the recommendations. No new evidence review was conducted for osteoporosis, so the committee did not make new recommendations for this. The evidence and reasons for the previous osteoporosis recommendation are available in the full guideline document (https://www.nice.org.uk/guidance/ng23/evidence).
Theramex UK	Guideline	066	017-021	Given the minimal impact on the risk of ovarian cancer from HRT, the guidelines should more clearly state this throughout the document and reconsider the positioning of this information within the health outcomes framework which currently focuses on the risks.	Thank you for your comment. The health outcomes are listed in alphabetical order so as not give one specific health outcome more weight than another given that each person may have differences in their baseline risks that may mean that they would focus on specific aspects of the tables.
Theramex UK	Guideline	069	023-025	This should more clearly detail that the risk of stroke is higher in black communities[xxxi] and therefore it follows that the risk of stroke is greater in people from a black family background who take HRT.	Thank you for your comment. It is the relationship between people from black ethnic backgrounds either taking or not taking HRT which is different to the same relationship for other ethnicity groups. It is therefore not dependent on the different baseline risks across groups.
Theramex UK	Guideline	071	024-029	This should make clear that the effect of HRT on the risk of dementia remains unclear, with studies reporting conflicting results. Based on	Thank you for your comment. The evidence before the age of 65 was unclear with studies showing conflicting results. Therefore, the committee could not be certain that it is unlikely that HRT increases

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				current evidence, HRT is unlikely to increase the risk of dementia before the age of 60.[xxx]	the risk of dementia before the age of 60. The randomised controlled trail that included only women who initiated HRT treatment after the age of 65 showed in increase in dementia and therefore the committee decided to refer to this in the recommendation so that people can be made aware of this.
UK Clinical Pharmacy Association (UKCPA) Women's Health Committee	Guideline	007	012 - 014	It would be helpful to have the NHSE endorsed Selfcare Forum Menopause PIL cross referenced here for health professionals to use in consultations. It would be good if this PIL was available in different languages to ensure inclusivity	Thank you for your comment. This section of the guideline was not updated in 2024. This means that the only changes were related to wording to bring it in line with current NICE style. We could therefore not add a link to the PIL to this section because it would have needed to go through all relevant processes to ensure consistency with the current content.
UK Clinical Pharmacy Association (UKCPA) Women's Health Committee	Guideline	011		CBT 1.4.4 and reference section page 49 We note that there are already long waiting lists and capacity issues with CBT services for patients with mental health or malignancy indications. We would welcome NICE NG23 updated guidance indication that menopausal anxiety and depression needs are a priority indication. Considering the evidence base review for CBT as outlined within the consultation document, the focus should include patient profiles such as clinical depression and menopausal anxiety and depression; cancer and menopause anxiety and depression.	Thank you for your comment. Taking into account current pressures on services, your comment will be considered by NICE where relevant support activity is being planned.
UK Clinical Pharmacy Association (UKCPA)	Guideline	012		section 1.4.8 There is a need for NICE guidance on HRT dosing regimens that may be required for treatment of menopause symptoms in Trans Men and Non-binary people registered at birth.	Thank you for your comment. The effectiveness of HRT treatment was not part of the 2024 guideline update and in topics that were part of the scope of the update. No evidence was identified that specifically related to people who had taken

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Women's Health Committee				The updated guidance when published in 2024 will raise expectations in this group for HRT treatment. Experience within our clinics indicate that even if these patients are off GAT they feel that they needs higher HRT dosing. We welcome the recommendation for research in these patient groups; however guidance on prescribing should be considered now.	gender affirming hormone therapy in the past and are experiencing symptoms associated with the menopause. Without the evidence the committee could not comment on dosages.
UK Clinical Pharmacy Association (UKCPA) Women's Health Committee	Guideline	013	010 - 012	section 1.4.13 We would suggest change in sentence as follows - ...imitated on recommendation by a health professional with expertise in menopause. We already have capacity issues currently and are dealing with COVID backlogs. The expectation that the first prescription is issued by the menopause specialist will have ramifications on capacity and affect patient care adversely due to long waiting times.	Thank you for your comment. In the context of a personal history of coronary heart disease and stroke, the committee decided that the involvement of a professional with expertise in menopause would be in the person's best interest and that this professional should decide whether to initiate this or not. The recommendation is not prescriptive about this being done by referral and could be a phone call if necessary. It is not NICE style to use 'recommendation' or 'recommended' in their guidelines to avoid confusion.
UK Clinical Pharmacy Association (UKCPA) Women's Health Committee	Guideline	013	027 - 029	Please consider the evidence base for **TAH with** RRBSO recommendation for management of familial and genetic risk of ovarian cancer as unopposed estrogen is associated with a lower increase in risk for breast cancer vs combined HRT, associated with higher breast cancer risks [but combined HRT would need to be offered if the patient has only had a BSO.	Thank you for your comment. The NICE guideline on identifying and managing familial and genetic risk of ovarian cancer has since been published and therefore the cross reference has been updated. This includes a section on HRT after risk-reducing surgery including for people with or without a uterus.
UK Clinical Pharmacy Association (UKCPA) Women's Health Committee	Guideline	016	014	section 1.4.27, 1.4.28, 1.4.29 Clarify text - vaginal oestrogen is contra-indicated in women with breast cancer on aromatase inhibitors - in line with statement 1.4.30	Thank you for your comment. The cited section has been reordered with the recommendation related to aromatase inhibitors (referred in the comment to as 1.4.30) moving up in the order to make this more explicit from the start. This would

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					then place the other recommendations within this context.
UK Clinical Pharmacy Association (UKCPA) Women's Health Committee	Guideline	019		1.4.38 greyed text but we will comment as follows - ...for people with low sexual desire associated with the menopause AND CAUSING DISTRESS if HRT alone is not effective.	Thank you for your comment. This topic was not part of the 2024 guideline update. This means that a search for evidence was not conducted and the committee did not discuss the evidence related to this. However, the committee reflected on this and thought that the a person seeking help for this would in itself signify that it is causing them sufficient distress to visit a healthcare professional and ask for treatment. They therefore did not think that this additional text had to be added.
UK Clinical Pharmacy Association (UKCPA) Women's Health Committee	Guideline	019	015	1.5.1 Unopposed estrogen is prescribed with TAH but with complex cases eg TAH and severe endometriosis or subtotal hysterectomy, these patinets can be / would be advised to use combined HRT [ref Cochrane database; Post Reproductive Health publications 2022.]	Thank you for your comment. The committee discussed that choice between oestrogen-only and combined HRT may be different for people with a sub-total hysterectomy. They decided that they could not be prescriptive about the type of HRT to be used for people who have had a sub-total hysterectomy because their condition is clinically complex and they had not reviewed evidence about the effect of HRT on risk of endometrial cancer for this group. They acknowledged that people who were going to have, or had had, a sub-total hysterectomy would be under the care of a specialist who could discuss HRT options tailored to their needs (or a relevant specialist within the MDT). Due to a lack of evidence, no specific recommendation was made for sub-total hysterectomy; however, the term "total" was added before "hysterectomy" in guidance regarding the offer of oestrogen-only HRT to those who have had a hysterectomy. This addition alerts

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					healthcare professionals to consider other factors for patients with a sub-total hysterectomy. The committee also noted that some people have a hysterectomy for a condition that may be affected by HRT, such as endometriosis. The committee did not review evidence related to such conditions. They recognised that the decision about the type of HRT that best balances benefits and risks for the person may be affected by that condition (for example endometriosis) or having had a subtotal hysterectomy. For this reason, they added a recommendation highlighting that advice from a healthcare professional with specialist knowledge of that condition may be needed when making this choice. Due to this stakeholder comment and other related comments, this topic has been logged with NICE surveillance so that it can be considered for a possible update to either the Menopause or the Endometriosis guideline in future. The cited reference did not meet the inclusion criteria of the protocol because it did not compare HRT versus no HRT for the main outcome of endometrial cancer.
UK Clinical Pharmacy Association (UKCPA) Women's Health Committee	Guideline	022		Welcome Tables 1 and 2	Thank you for your comment in support of this.
UK Clinical Pharmacy	Guideline	022		Table 1	Thank you for your comment. Some of the E3N cohort in the breast cancer review has been

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Association (UKCPA) Women's Health Committee				As per the French EN3 study, both micronized progesterone and dydrogesterone are considered as proffering lower breast cancer risk increase and should be stated in the updated guidance as we have patient profiles who do not settle on micronized progesterone and side effects mean that we need to offer a suitably low risk alternative option for endometrial protection.	included as part of the IPD dataset from the CGHFB. The committee have discussed this data and agreed that the evidence did not support a recommendation that micronised progesterone and dydrogesterone have a lower breast cancer risk than other progestogenic constituents. The details of this discussion can be found in the committee's discussion of the evidence section in evidence report D. The committee considered that the number of cases of breast cancer with those using micronised progesterone were few and agreed that this supported a recommendation to highlight that there was insufficient evidence to support any differences in the risk of breast cancer with micronised progesterone. The committee agreed that more evidence was required to make any robust recommendations for micronised progesterone and made a research recommendation. With regard to other publications including the E3N cohort, the committee have considered that not all participants of the E3N have been included in the CGHFB meta-analysis. However, where there are separate publications with overlapping follow-up periods, and no disaggregation of participants, these have not been included to avoid double counting of participants in the E3N cohort. As per our processes and methods, we do not reanalyse any existing IPD data as NICE does not generally have the same access to the individual participant data, and therefore the data has been used as it has been published. Due to the large size of the IPD data from the CGHFB, this has been prioritised for inclusion in the review. Fournier 2014 was included as this study had a later follow-up period of the E3N cohort that was not covered by

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					CGHFB. However, since the data from the Fournier 2014 publication did include participants that were in the meta-analysis from CGHFB, the results were analysed separately.
UK Clinical Pharmacy Association (UKCPA) Women's Health Committee	Guideline	047	010	Thanks for clarifying that CBT has not been proven to help with low moods associated with menopause status. An explicit statement would be useful for health professionals.	Thank you for your comment. This section describes that the results were mixed with most of the measurement scales not showing a difference but 1 indicating an improvement. Given that the effectiveness of CBT on depressive symptoms is established (see NICE's guideline on depression in adults) the committee decided on balance that CBT should be an option. The rationale section describes the reason for this conclusion (including the mixed findings in the evidence).
UK Clinical Pharmacy Association (UKCPA) Women's Health Committee	Guideline	048		sleep and CBT section Natural progesterone, with biological plausibility, is being researched independently for sleep problems, including insomnia and early wakening. Research for use in menopause and sleep should be a research recommendation. Qs include could natural progesterone be used on its own in postmenopausal women over 65 for sleep benefit? Does natural progesterone aa part of HRT regimen improve menopausal sleep outcomes.	Thank you for your comment. Sleep problems associated with the menopause were only considered in the context of CBT. Therefore, the committee could not recommend other treatments (because evidence for these were not searched for) nor make a research recommendation related to this (because gaps in the evidence could not be identified).
University College London Hospitals NHS Foundation Trust	Guideline			1.4.4 1.4.9 1.4.16 1.4.35 1.4.37 Multiple pages The recommendations to consider CBT will be difficult to implement as it is largely unavailable.	Thank you for your comment. The committee has revised the wording to ensure clarity about CBT 'as an option: in addition to other treatments (including HRT), for people for whom other treatments are contraindicated or for people who prefer not to take HRT'. Your comment will be considered by NICE where relevant support activity is being planned. The options have been

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				Having multiple recommendations on CBT gives the impression it is a wonderful treatment, so patients may feel let down. The list in 1.4.4 could be reversed as online access is the most likely to be utilised.	listed in alphabetical order and it has been added that the person's preferences and needs should be taken into account.
University College London Hospitals NHS Foundation Trust	Guideline	General	General	A secondary analysis of the same study [3] confirmed the effect of clinical hypnosis on anxiety levels, with HADS-A scores in the intervention group decreasing significantly ($p<0.004$), with a large effect size, compared to the control group. In addition, a 2013 single-blind RCT [4] of 187 postmenopausal women reporting at least 50 hot flashes a week at baseline evaluated clinical hypnosis over 12 weeks against an active structured-attention control. Both clinical hypnosis and structured-attention control included 5 weekly sessions that included discussion of symptoms, attentive listening, interpersonal exchange, avoidance of negative suggestions, monitoring, measurement, and encouragement provided in a therapeutic environment with a trained clinician. The hypnosis group additionally received hypnotic inductions and cooling suggestions. Participants in the clinical-hypnosis arm reported significantly lower hot flash frequency (74% vs 17%; P < .001) and hot flash scores (frequency times severity, 80% vs 15%; P < .001) than controls. In addition, physiologically monitored hot flashes were reduced significantly more in the hypnosis group than in the attention-control group (57% vs 10%; P <	Thank you for your comment. The effectiveness of hypnosis in the management of symptoms associated with the menopause was not in the scope of the 2024 guideline update. Evidence for this topic was therefore not searched for, reviewed or discussed with the committee. The committee could therefore not comment on this. The references listed have been checked and none of them meet the criteria set out in the protocols for the evidence reviews that were updated.

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				.001), indicating a clinically significant improvement. A follow-up analysis showed that effects were not related to women's expectations about whether hypnosis would work [5]. The programme can be delivered via a trained provider or accessed via a smartphone application." In addition, in further analysis of both studies hypnosis had important effects on anxiety [6] and has also shown promise for other troublesome menopausal symptoms such as sleep quality [7] and sexual function [8]. The current NICE draft guidelines state that for CBT, "most of the benefits were seen in reducing how much women were bothered by the symptoms", rather than being effective in reducing them. By contrast, in the large RCT that demonstrated the efficacy of hypnotherapy for vasomotor symptoms of menopause [3], the mean reduction in objectively (physiologically measured) hot flushes was 70% to 80%, comparable to hormone replacement therapy (but without its adverse effects) and is clinically, as well as statistically, significant (50% or greater reduction).	
University College London Hospitals NHS Foundation Trust	Guideline	General	General	A further large NIH-funded multi-centre RCT of Clinical Hypnosis for menopause is currently being conducted in the USA. The intervention is being remotely delivered in comparison to a sham hypnosis control. Enrolment is complete and results should be available by March 2024. Should NICE decide to assess Clinical Hypnosis, this study may also be available for analysis in the 2024 update. As well as the	Thank you for your comment. The effectiveness of hypnosis in the management of symptoms associated with the menopause was not in the scope of the 2024 guideline update. Evidence for this topic was therefore not searched for, reviewed or discussed with the committee. The committee could therefore not comment on this. The references listed have been checked and none of

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				studies referenced below, a systematic review and meta-analysis of clinical hypnosis for menopausal hot flushes is also in preparation and can be made available to the NICE committee. In a response to a previous e-mail enquiry (NICE enq.ref EH87273, dated Fri, Dec 15, 2017), I (SRB) was informed that "they [the guideline developers] advised that the study was not included [in] pairwise analysis because it was not an intervention listed in the protocol and it was not an intervention that was prioritised by the guideline committee. It was also excluded from the network meta-analysis (NMA) as it did not connect to any study in the network. As the study did not meet the inclusion criteria for the review protocol it would not have been able to effect the recommendations." Contradicting the first statement is a response to a stakeholder comment ("Consultation comments and responses", 12 Nov 2015, p106) it is stated that "The protocol included "psychological interventions" as a broad category, so as not to miss any relevant outcome data on available therapies (see Appendix D.4)." Appendix D (p41) does indeed include "psychological therapies" as well as "cognitive behavioural therapy". Confusingly, two different reasons were also given in 2015 guidelines for exclusion of reference [4]: first, because the reference identified was a 2011 "study protocol" (Appendix A-G, p203-4, although in fact the	them meet the criteria set out in the protocols for the evidence reviews that were updated.

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				results were published in 2013, easily in time to be considered), and secondly, because the study was "not connected to the network" in the NMA (Appendix I-K, p218) – the only study for which this particular reason was given. A fuller explanation of the reason for its exclusion would be helpful. Even the very limited information recommendation about other therapies including hypnosis in the draft full guideline, which was supposed to compensate for the exclusion of studies from the NMA (version 1.2, p20, lines 15-18) was eventually removed from the final full guideline (version 1.5), with no apparent explanation.	
University College London Hospitals NHS Foundation Trust	Guideline	General	General	Whether it was in fact the a priori restriction of scope to CBT as the only psychological therapy worthy of consideration, or the NMA process which excluded a large (n=187), good quality RCT compared to an active attention control, the unfortunate result is an impression of systematic bias against hypnosis and in favour of CBT, given the initial recommendation for the latter based on a single, smaller RCT (n=96) compared to usual care, and a 2024 update prompted by "exceptional surveillance" of new evidence for CBT whilst continuing to ignore the existing evidence for hypnosis. We request that; a) the exclusion of hypnosis from the scope be corrected, as requested by SRB in 2017 but ignored in subsequent surveillance updates in 2019 and 2021, and an updated evidence search conducted;	Thank you for your comment. At the time when the scope of the 2024 guideline update was agreed, surveillance identified new evidence related to CBT based on the parameters of the previous guideline which did not look at the effectiveness of hypnosis. NICE has a surveillance process and the references have been passed on to the relevant team to assess this for a future update.

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				b) reference [2], which appears to have been completely overlooked, be included and assessed; c) the exclusion of reference [4] is reviewed and if upheld, a fuller justification is given. Consideration of options such as clinical hypnosis for menopausal symptom management are all the more crucial when options for treatment are limited in women who cannot take HRT or choose not to take it, such as women with hormone dependent cancers or complex medical situations. Every effective and safe option needs evaluation. NICE remains out of step with the North American [1] and Australian Menopause Society [9] in ignoring hypnosis. We urge NICE to assess the evidence for Clinical Hypnosis for the final version of these updated guidelines, both for menopausal flushes and breast cancer survivors with hot flushes. It is vitally important that women have access to, and choice of, safe and acceptable nonhormonal interventions with proven efficacy. Dr Saul Berkovitz MRCP (SRB) Clinical Director, Royal London Hospital for Integrated Medicine, UCLH Dr Vikram Talaulikar MD, FRCOG, PhD (University of London) Associate Specialist in Reproductive Medicine, UCLH Hon Associate Professor in Women's Health, UCL BMS certified Menopause Specialist	

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				Dr Amali Lokugamage MD, FRCOG Consultant Gynaecologist/Honorary Associate Professor Institute for Women's Health, UCL	
University College London Hospitals NHS Foundation Trust	Guideline	General	General	References 1. "The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society" Advisory Panel. The 2023 nonhormone therapy position statement of The North American Menopause Society. Menopause. 2023 Jun 1;30(6):573-590. doi: 10.1097/GME.0000000000002200. PMID: 37252752. 2. Elkins G, Marcus J, Stearns V, Perfect M, Rajab MH, Ruud C, Palamara L, Keith T. Randomized trial of a hypnosis intervention for treatment of hot flashes among breast cancer survivors. J Clin Oncol. 2008 Nov 1;26(31):5022-6. doi: 10.1200/JCO.2008.16.6389. Epub 2008 Sep 22. PMID: 18809612; PMCID: PMC2652097.	Thank you for your comment. The effectiveness of hypnosis in the management of symptoms associated with the menopause was not in the scope of the 2024 guideline update. Evidence for this topic was therefore not searched for, reviewed or discussed with the committee. The committee could therefore not comment on this. The references listed have been checked and none of them meet the criteria set out in the protocols for the evidence reviews that were updated. The cited references were logged with the NICE surveillance team for consideration for future updates.

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				3. Johnson AJ, Marcus J, Hickman K, Barton D, Elkins G. Anxiety Reduction Among Breast-Cancer Survivors Receiving Hypnotic Relaxation Therapy for Hot Flashes. Int J Clin Exp Hypn. 2016 Oct-Dec;64(4):377-90. doi: 10.1080/00207144.2016.1209042. PMID: 27585723; PMCID: PMC5373901. 4. Elkins GR, Fisher WI, Johnson AK, Carpenter JS, Keith TZ. Clinical hypnosis in the treatment of postmenopausal hot flashes: a randomized controlled trial. Menopause. 2013 Mar;20(3):291-8. doi: 10.1097/gme.0b013e31826ce3ed. PMID: 23435026; PMCID: PMC3556367. 5. Sliwinski JR, Elkins GR. Hypnotherapy to reduce hot flashes: examination of response expectancies as a mediator of outcomes. J Evid Based Complementary Altern Med 2017;22:652-659. doi: 10. 1177/2156587217708523 6. Roberts RL, Rhodes JR, Elkins GR. Effect of Hypnosis on Anxiety: Results from a Randomized Controlled Trial with Women in Postmenopause. J Clin Psychol Med Settings. 2021 Dec;28(4):868-881. doi: 10.1007/s10880-021-09810-3. Epub 2021 Aug 17. PMID: 34403019. 7. Otte JL, Carpenter JS, Roberts L, Elkins GR. Self-Hypnosis for Sleep Disturbances in Menopausal Women. J Womens Health (Larchmt). 2020 Mar;29(3):461-463. doi: 10.1089/jwh.2020.8327. PMID: 32186967; PMCID: PMC7097677.	

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				8. Johnson AK, Johnson AJ, Barton D, Elkins G. Hypnotic Relaxation Therapy and Sexual Function in Postmenopausal Women: Results of a Randomized Clinical Trial. Int J Clin Exp Hypn. 2016;64(2):213-24. doi: 10.1080/00207144.2016.1131590. PMID: 26894424. 9.https://www.menopause.org.au/images/stories/infosheets/docs/AMS_Lifestyle_and_behavioral_modifications_for_menopausal_symptoms.pdf	
University College London Hospitals NHS Foundation Trust	Guideline	general		Could NICE consider updating UK terminology from HRT to MHT? The term "hormone replacement therapy" could be used generically and encompass thyroxine, insulin etc. whereas "menopausal hormone therapy" is specific. It has also been argued that 'replacement' may not be strictly correct when it applies to post-menopause.	Thank you for your comment. There terminology was discussed, and it was acknowledged that terminology has evolved particularly in the professional and academic world. However, it was decided to retain the terminology as is because in UK practice and in the general population Hormone Replacement Therapy as well as the acronym HRT are more readily understood.
University College London Hospitals NHS Foundation Trust	Guideline	general		Could NICE make a generic statement in the introduction about the guideline populations "the following recommendations apply to…"? Repetition of the phrase "healthy women, trans men, and non-binary people registered female at birth" in multiple sections makes the text more difficult to read without really adding value. In today's climate it risks upsetting or annoying the women you are aiming to help.	Thank you for your comment. The guideline's introduction states that the guideline covers women, trans men and non-binary people registered female at birth. For accuracy, some of the recommendations need to list all groups. Elsewhere, the term 'people' is used to be inclusive and concise. This is used where we speak about people for whom it has already been identified that their symptoms are associated with the menopause.
University College London Hospitals NHS Foundation Trust	Guideline	General		Did the committee consider making recommendations on HRT dosage? "lowest effective dosage" leaves the door wide open. Did the committee consider making recommendations on relative dosage of	Thank you for your comment. The guideline was amended to include a statement that 'the benefits and risks of HRT described in this guideline only cover the use of HRT within the licensed doses.'

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				oestrogens and progestogen/progesterone? A current clinical concern is escalation of oestrogen dose without consideration of progestogen/progesterone.	Therefore, the lowest effective dose would be within the licensed range.
University College London Hospitals NHS Foundation Trust	Guideline	General		Did the committee consider making a recommendation on timing of initiation of HRT in relation to menopause?	Thank you for your comment. A research recommendation on the person's age at menopause or the time between the person's menopause and their first use of HRT on the long-term risk of coronary heart disease in people who take or have taken HRT has been added to the guideline.
University College London Hospitals NHS Foundation Trust	Guideline	023 - 034		Table 1 The column headings are useful, thank you, these reflect the important questions for women.	Thank you for your comment in support of this.
University College London Hospitals NHS Foundation Trust	Guideline	023 - 034		Table 1 There is a discrepancy between the type of information given for different adverse events. For breast cancer you state "It is not known whether preparations containing … have a different increased risk." thus acknowledging that it is an important question for which there is not enough evidence. This is the only such statement, though surely the same question applies to other adverse events and different preparations?	Thank you for your comment. The research recommendation also covers endometrial cancer and cardiovascular disease. However, the committee decided that it is most relevant to highlight insufficient evidence for breast cancer where otherwise an increased risk with HRT is highlighted. For endometrial cancer it is already established that combined is favoured so it is only an additional consideration and the same applies to cardiovascular disease where coronary heart disease does not increase with combined HRT and stroke risk is unlikely to increase with the use of combined HRT that includes transdermal oestrogen. Therefore, in circumstances where there is already an otherwise relatively clear picture, uncertainty about progestogen type was not specifically highlighted.
University College London Hospitals	Guideline	023 - 034		Table 1 There is conflicting information on breast cancer risk; you state that for combined HRT	Thank you for your comment. The statement has been removed and a research recommendation

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NHS Foundation Trust				there is less risk with transdermal oestrogen than oral, but for oestrogen-only HRT the two routes are the same. This is implausible. You are making two strong statements based on interpretation of evidence "without seeing the wood for the trees". The breast cancer evidence has been controversial with multiple interpretations over the last 20 years, but the strength of these statements is the same as "oestrogen-only HRT increases the risk of endometrial cancer" where the evidence is irrefutable. Can you be more nuanced?	was added aimed to clarify matters related to different routes of administration.
University College London Hospitals NHS Foundation Trust	Guideline	023 - 034		Table 1 A similar problem occurs with stroke risk. Combined HRT is given 3 bullet points but oestrogen-only HRT has two. You are focussed on the available evidence, but to the reader it looks as though black women are being left out.	Thank you for your comment. The recommendations were based on the available evidence. Data divided by ethnicity was available only for combined HRT but not for oestrogen-only HRT. The committee could therefore not comment on this in both tables equally.
University College London Hospitals NHS Foundation Trust	Guideline	010 -019		We would like to point out that whilst suggesting cognitive behavioural therapy (CBT) as an non-hormonal option for menopausal vasomotor symptoms, the draft NICE menopause guidelines have once again omitted an assessment of another effective non-hormonal therapy, namely clinical hypnosis. This is a major omission, since there is significant evidence in favour of this therapy. The North American Menopause Society position statement on nonhormonal therapies for menopause has recommended hypnosis based on level 1 evidence ("good and consistent scientific evidence") since first publication in 2015, including the 2023 update	Thank you for your comment. The effectiveness of hypnosis was not in the scope of the 2024 guideline update. Evidence for this topic was not searched for and not reviewed and discussed with the committee. The committee could therefore not comment on this. The topic of hypnosis has been logged with the NICE surveillance team for consideration for future updates.

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				[1]. I reproduce the relevant information and references here since you are unable to accept attachments. "Clinical hypnosis is a mind-body therapy that involves a deeply relaxed state and individualized mental imagery and suggestion. It has been widely used to manage other chronic symptoms such as pain and anxiety. Hypnosis has been studied for the treatment of hot flashes in two trials—one randomized trial in survivors of breast cancer and one RCT in women with at least seven hot flashes per day. In both trials, clinical hypnosis involved 5 weekly in-person sessions of hypnotherapy with at-home self-hypnosis practice. In a study of 60 women with a history of breast cancer [2], clinical hypnosis was significantly better at reducing hot flashes and improving mood and sleep than no treatment. Sixty female breast cancer survivors with hot flashes were randomly assigned to receive hypnosis intervention (five weekly sessions) or no treatment. Eligible patients had to have a history of primary breast cancer without evidence of detectable disease and 14 or more weekly hot flashes for at least 1 month. The major outcome measure was a bivariate construct that represented hot flash frequency and hot flash score. Fifty-one randomly assigned women completed the study. By the end of the treatment period, hot flash scores (frequency x average severity) decreased 68% from baseline to end point in the hypnosis arm	

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				(P < 0.001). Significant improvements in self-reported anxiety, depression, interference of hot flashes on daily activities, and sleep were observed for patients who received the hypnosis intervention (P <0.005) in comparison to the no treatment control group.	
University College London Hospitals NHS Foundation Trust	Guideline	012		1.4.8 The exception is this specific recommendation, which is valuable as it ensures that transmen or non-binary people will not be excluded from menopause care.	Thank you for your comment in support of this.
University College London Hospitals NHS Foundation Trust	Guideline	013		1.4.13 This has replaced the previous recommendation (1.5.5 in previous guideline) which mentioned cardiovascular risk factors. Hypertension is a very common clinical concern when initiating HRT and was addressed by the old recommendation ("Be aware that the presence of cardiovascular risk factors is not a contraindication to HRT as long as they are optimally managed".) The new recommendation is only for past history of CHD or stroke. Did the committee consider hypertension? Note that, in contrast, the previous recommendation on pre-existing diabetes has been retained (1.4.10)	Thank you for your comment. This originated from an evidence review which was updated and therefore the previous recommendation was stood down. The committee noted that in people with a history of cardiovascular disease taking either combined HRT (continuous and sequential) or oestrogen-only HRT, the RCT evidence did not suggest any difference in coronary heart disease risk and cardiac event composite scores, when compared to placebo. Observational evidence did not include people with a history of cardiovascular disease. The committee discussed how the evidence suggested that a history of coronary heart disease may not be a contraindication to combined or oestrogen-only HRT. However, they felt that for this group of people the use of HRT should be discussed with and initiated, if appropriate, by a healthcare professional with expertise in menopause. This would ensure that people with a history of coronary heart disease who commence HRT are advised in an individualised way that relates to their specific history of coronary heart disease. For details see the 'committee's discussion and interpretation of

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					the evidence' section of evidence review C. Tailoring the information about benefits and risks to the person's age, individual circumstances and potential risk factors is recommended in the 'discussing treatment options' section of the guideline because it does not only apply to cardiovascular but could involve risk factors for other conditions. The diabetes recommendation has been retained because this was not a topic that was updated.
University College London Hospitals NHS Foundation Trust	Guideline	016		1.4.28 Please review the clarity of this recommendation. With respect to reduction of efficacy [of vaginal oestrogen], surely you mean oestrogen receptor blockers not aromatase inhibitors… …With respect to reduction of efficacy of anti-oestrogens, the concern is using vaginal oestrogen with aromatase inhibitors.	Thank you for your comment. The recommendation related to uncertainty about efficacy of vaginal oestrogen in the context of a history of breast cancer has been removed.
University College London Hospitals NHS Foundation Trust	Guideline	038		Recommendations for research We commend these helpful research recommendations, which address important clinical uncertainties and patient questions.	Thank you for your comment in support of this.
University College London Hospitals NHS Foundation Trust	Guideline	042		Rationale and impact Thank you for the helpful discussion section. There is much here to help interpretation of recommendations. However, we have concentrated comments on the recommendations because they are usually read and utilised in isolation from the supporting evidence and need to be robust and self-explanatory.	Thank you.
University Hospitals Dorset	Guideline	General	General	We welcome that the 2015 guideline is being updated. The 2015 guideline has been an invaluable document that has been the basis for education and training for the last 8 years. We	Thank you for your comment. The need to assess the impact of early menopause on health outcomes has been acknowledged and will be

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				notice the guideline has a section on early menopause but it is unfortunate that this overlooked the adverse effects of early menopause on bone, cardiovascular health and cognitive function. This does not give proper balance to this section of the document.	passed onto the NICE surveillance teams for prioritised consideration during future updates.
University Hospitals Dorset	Guideline	General	General	We are perplexed by the methodology that has been used for assessing the data in certain sections of this guideline. One of the strengths of NICE guidance in general, and the previous NG23, was to look at the totality of the data and not excluding anything simply because it doesn't suit a particular view point. The Guidance should be guided by the data not by committee opinion. It's unfortunate that this guideline does not live up to the normally high standards of NICE. Throughout the guideline there is inconsistency around the interpretation of observational data and RCT data and the relevant weight of each. There appears to be inconsistent weight put on studies with more emphasis on negative findings. The decision-making and reasoning for prioritising RCT data for CVD and observational for breast need to be transparent and explained more clearly. In a number of areas a statistically significant benefit was shown in the analysis but the recommendations state 'no increase in risk' rather than acknowledging a benefit. For example: Cardiovascular disease in women starting HRT under the age of 60 where the collective observational evidence show a significant reduction in risk. In addition, the long	Thank you for your comment. The evidence reviews in this guideline followed rigorous NICE methods and processes, with details outlined in a supplement available on the website (supplement 1 - methods), consistent with the NICE guideline manual. Studies are included or excluded based on pre-specified protocol criteria agreed upon with the committee before work on the evidence review commences, ensuring transparency and reproducibility. Even frequently cited papers may be excluded if they fail to meet inclusion criteria as was, for example, the case with a Cochrane review (Boardman et al. 2015). The reasons for exclusion are explicitly detailed in appendix J of each evidence review. To make exclusion of some key papers (such as Boardman et al. 2015) explicit we have added information about the reasons for the exclusions of these to the rationale of the guideline and the 'committee's discussion and interpretation of the evidence' section of evidence review C. There were some isolated findings of significant differences but tests for subgroup analysis by age at initiation of HRT were not statistically significant. This was likely based on the limited power in these analyses to detect subgroup differences, and lack of interpretable trends of effects. NICE also commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post

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				term 13 year follow up RCT data from WHI clearly demonstrated a significant reduction in risk in women who commenced oestrogen at the age of 50-59. For both areas, the recommendations stated 'no increase in risk'	consultation). However, they highlighted that RCT, and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. These and other evidence reviews have been revised to implement these changes accordingly.
University Hospitals Dorset	Guideline	General	General	Much of the new data referred to in this guideline is based on the findings of the CGHFBC 2019 Lancet observational meta-analyses. We are surprised that these data have not been subject to further re-analysis by the NICE statistical team as usually happens with NICE guidance. Although the published analysis was new, the data were not new and were largely based on the Million Women Study) which was reviewed in the previous guideline. Re-analysis doesn't reduce the limitations and biases inherent within these studies. We would like an explanation as to why was it not felt necessary to apply normal NICE procedure to this paper? It is of concern to us that one of the authors of this 2019 paper was present on the guideline committee and contributed to the discussions. We therefore question the impartiality in the interpretation of these data and the decision not to re-analyse the CGHFBC 2019 data.	Thank you for your comment. The evidence reviews in the 2024 guideline update followed rigorous NICE methods and processes, with details outlined in a supplement available on the website (supplement 1 - methods), consistent with the NICE guideline manual. In line with the manual systematic reviews are included when they meet the criteria of the review protocol which the Lancet publication did. The Lancet meta-analysis is also an individual patient data (IPD) analysis and NICE would not have the same access to the individual patient data that the epidemiologist had who conducted this work. IPD meta-analyses are also more powerful than taking individual statistics from each study (which would commonly be used in NICE guidelines) because they make use of the overall combined data and can make better adjustments for potential confounding factors. Observational studies have limitations, but they also have particular strength, such as larger data sets, longer follow-up and real-world data. NICE has followed its standard methods and processes in developing the 2024 guideline update, including the way in which we manage conflicts of interest in

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					topic experts and committee members. The details of conflicts of interest and how they have been managed are available in the published register of interests.
University Hospitals Dorset	Guideline	General	General	We would like to raise concerns about a conflict of interest in the discussions relating to the observational meta-analysis published in the Lancet 2019. This is presented as significant new evidence and had a big impact on the subsequent interpretation of the data and dominates several sections of the Guideline which cover cancer to the exclusion of other data from Randomised trials. One of the main authors of this paper is on the guideline committee. We understood that it is normal practice with NICE and indeed other "independent" organisations, to exclude someone with significant vested interests from the relevant discussions. Yet the minutes state that although this person did not lead the discussion, they were present during the discussions and influenced the committee's decision making, NICE has excellent statisticians who can give an unbiased assessment of the data so this person should have been excluded. We feel their presence and involvement contravenes your conflict-of-interest policy and devalues the conclusions of this guideline.	Thank you for your comment. The evidence reviews in the 2024 guideline update followed rigorous NICE methods and processes, with details outlined in a supplement available on the website (supplement 1 - methods), consistent with the NICE guideline manual. In line with the manual systematic reviews are included when they meet the criteria of the review protocol which the Lancet publication did. The Lancet meta-analysis is also an individual patient data (IPD) analysis and NICE would not have the same access to the individual patient data that the epidemiologist had who conducted this work. IPD meta-analyses are also more powerful than taking individual statistics from each study (which would commonly be used in NICE guidelines) because they make use of the overall combined data and can make better adjustments for potential confounding factors. Observational studies have limitations, but they also have particular strength, such as larger data sets, longer follow-up and real-world data. NICE has followed its standard methods and processes in developing the 2024 guideline update, including the way in which we manage conflicts of interest in topic experts and committee members. The details of conflicts of interest and how they have been managed are available in the published register of interests.
University Hospitals Dorset	Guideline	General	General	Throughout the guideline we notice that quite directive and judgemental language is used which is unlike previous NICE guidance. NICE's	Thank you for your comment. The wording related to 'awareness of risk' was reviewed. This phrase was used twice and in both cases, it was in the

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				strength is it looks at the totality of the data and draws conclusions form the data presented. For example the guideline states "that women need to be aware of these risks" without any balance about the benefits. It is important that the document reflects good clinical practice which is to discuss the benefits and the risks of any proposed treatment such as HRT not just the risks. In the committee discussion (P43 line 5) it states "using an individualised approach with discussions about benefits and risks of treatment options and tailoring information to individual circumstances and potential risk factors". We support this statement which reflects good clinical practice but would like to see this reflected consistently throughout the recommendations instead of the more negatively framed "need to be aware of these risks"	context of a rationale related to an increased risk for a specific health outcome. Since the section describe a reason for why a particular risk is highlighted in the recommendation, we cannot balance this out with a benefit that is not described in the related recommendation. However, these two instances have been rephrased to say, 'people should be made aware of this' and have removed the work 'risk' from this.
University Hospitals Dorset	Guideline	021 - 029		Table 1 Combined HRT: effect on health outcomes Column 3: ''Combined HRT increases the risk of breast cancer mortality compared with not taking HRT' This statement is solely based on the MWS research letter (2019). Why has a research letter been included as evidence when so many other relevant papers have been excluded? It is not a peer-reviewed paper but it is noted that one of the authors of this letter is on the guideline committee. Under what criteria was this letter deemed to be admissible evidence? The MWS finding could simply reflect the higher number of diagnoses of breast cancer and not an adverse impact of prognosis and does not	Thank you for your comment. The inclusion of the MWS research letter was deemed appropriate since the MWS has previously published work describing the cohort and methodology, which fits our protocol. The research letter also describes the analysis was adjusted. Given the critical nature of mortality from breast cancer, information from such a source was deemed important and underwent standard quality assessment using GRADE methodology. It was taken into consideration in the critical appraisal of the letter that the publication was not a full publication. Any other papers that have been excluded have all been listed in the excluded studies section (Appendix J) of the evidence report (report D for breast cancer) with a reason for exclusion. NICE has followed its standard methods and processes

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				provide information to counter this. There should be some context provided if women are to make a fully informed choice. Other studies evaluating breast cancer mortality were not reviewed, including the RCT WHI and Wang T et al 2020 Int J of Cancer, which did not show an increased risk. All of these can be criticised (including the MWS) for lack of control for stage at diagnosis, diagnosis method and treatments used, which influence prognosis. Transparency, honesty and the totality of the data should be the hallmark of a NICE guideline not selective interpretation and inclusion or exclusion of the data to suit a particular viewpoint. The recommendation that women are advised that breast cancer mortality is increased needs to be put in context when the impact of HRT on overall mortality is not increased. Any possible increase in risk is thus probably offset by other mortality benefits (e.g., CVD deaths Holm M et al BJOG 2019). All-cause mortality is arguably a more useful single measure of major risks and benefit over time. This statement should be adequately explained and the uncertainty of the data fully explained.. Column 4: "Combined HRT preparations containing transdermal oestrogen increase the risk of breast cancer less than combined HRT preparations containing oral oestradiol." The evidence to support this is not conclusive and this statement could be widely misinterpreted. It is	in developing the 2024 guideline update, including the way in which we manage conflicts of interest in topic experts and committee members. The details of conflicts of interest and how they have been managed are available in the published register of interests. The Women's Health Initiative (WHI) data on mortality was included in this review and is described in the evidence report, please see evidence review D. Wang, T et al, 2020 Int J of Cancer was assessed at full text and was not included in the review as the data on HRT use was collected after the outcome of interest was known. This was one of the criteria set out in the protocol before the review was conducted. The study is also listed in the excluded studies section of the full evidence report D (Appendix J). All the reviews in this guideline were carried out according to NICE methods and processes. The methods as described in Supplement 1 set out the process of how data is included and excluded in the guideline. Pre-specified protocols are drafted and agreed with the guideline committee before the review is carried out. Studies are included and excluded according to the requirements set out in the pre-specified protocol and are not included or excluded based on a particular viewpoint post-hoc. Any risk of bias, or methodological limitations that have not been listed as a reason for exclusion in the protocol, are addressed in the critical appraisal of the studies and reflected in the GRADE quality of the evidence. Interpretation of the evidence is based on a committee discussion of the evidence and details of each discussion can be found in the relevant evidence report (See section 'Committee discussion of the evidence'). The committee reviewed the evidence related to specific-cause

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				entirely based on one low quality study (Brusselaers et al 2018). This statement contradicts the statement about what is said about oestrogen only HRT. Column 5: "It is not known whether preparations containing micronised progesterone or dydrogesterone have a different increased risk for breast cancer compared with preparations containing other protestogens". There are a handful of studies suggesting risk with micronized progesterone or dydrogesterone is elevated to a lesser degree compared with preparations containing synthetic progestogens. Although more confirmatory clinical evidence is required, it shouldn't stop discussion of these studies and the limitations of the CGHFBC results, that were based on very small numbers with longer follow-up. The E3N cohort should at least be acknowledged, it has limitations but so does the CGHFBC. Why has the Fournier 2008 paper not been included but the 2014 paper has? Consistency about interpretation and presentation of the evidence here and across the guideline would be welcome as these messages are very confusing. When the data are not clear, as on this point, a clarifying statement to that effect would be helpful as the reported differences are widely referred to in clinical guidance and this concept is commonly considered in clinical practice	mortality, as well as all-cause mortality. They agreed that based on the evidence they would highlight specific-cause mortality as well as all-cause mortality in the recommendation, as it was important to present the available evidence. The evidence reviewed in this guideline did not specifically highlight whether no increase or decrease in overall mortality was offset by other mortality benefits, in addition the 2024 update of this guideline did not cover all outcomes that may be relevant to the use of HRT. The committee considered the evidence for oral and transdermal routes of administration of the oestrogen component of HRT. Since some of the evidence showed a significant difference between the subgroups of oral and transdermal routes of administration in the combined HRT comparison, they had made a recommendation to inform of the reduced risk. However, the committee revisited the evidence, and discussed that since the same difference was not observed in the oestrogen-only comparison, the argument was less robust than previously discussed. Upon reflection the committee agreed to remove this recommendation and an updated detailed discussion of the evidence, and their decision can be found in the committee discussion of the evidence section of Evidence Review D. The committee have reviewed the available evidence on the different progestogenic constituents. Some of the participants of the E3N cohort have been included in the IPD dataset from the CGHFB, which has been included in our review. It has been noted

					that not all participants of the E3N have been included in the CGHFBC. However, where there are separate publications with overlapping follow-up periods, and no disaggregation of participants, these have not been included to avoid double counting of participants in the E3N cohort. As per our processes and methods, we do not reanalyse any existing IPD data and therefore take the data as it has been published. Due to the large size of the IPD data from the CGHFB, this has been prioritised for inclusion in the review. Fournier 2014 was included as this study had a later follow-up period of the E3N cohort that was not covered by CGHFB. However, since the data from the Fournier 2014 publication did include participants that were in the meta-analysis from CGHFB, the results were analysed separately. The committee considered that the number of cases of breast cancer with those using micronised progesterone were few and agreed that this supported a recommendation to highlight that there was insufficient evidence to support any differences in the risk of breast cancer with micronised progesterone. The committee agreed that more evidence was required to make any robust recommendations for micronised progesterone and made a research recommendation. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). However, they highlighted that RCT, and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside

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					each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. These and other evidence reviews have been revised to implement these changes accordingly.
University Hospitals Dorset	Guideline	030 - 034	Table 2	Breast Cancer and Oestrogen only HRT Column 2: "Oestrogen-only HRT slightly increases the risk of breast cancer compared to not taking HRT". This statement is completely at odds with the results in the WHI study. The committee argue that the average age of women (63) and greater proportion who were overweight/obese in the WHI are unrepresentative of the target population for HRT. However, they have opted to disregard that limitation when assessing the CVD data. With regard to age, the WHI subgroup analysis (50-59) showed no significant risk increase or reduction in the risk of diagnosis. Regarding BMI, the CGHFBC 2019 reported a reduced risk in women with a higher BMI and suggests the large proportion of overweight women in WHI accounts for the findings with CEE. Subgroup analysis by BMI in the WHI shows no increased risk in women with a low or normal BMI range. The WHI report on the effect of being overweight or obese on the risk of breast cancer does not appear to be referred to in this guidance. WHI actually showed that women who had a body mass index (BMI) > 35 had a significantly increased risk of invasive breast cancer compared with women of normal weight (HR 1.58; 95% CI 1.40–1.79). In addition, obesity was associated with an increase in estrogen receptor-positive and	Thank you for your comment. Due to the differences in RCT and observational study findings, committee revised the recommendation to state that 'there is very little or no increase in breast cancer risk with oestrogen-only HRT' and further details pertaining to duration of use, current and past use and a remaining risk after stopping have been removed. The committee discussed that the RCT evidence from the Women's Health Initiative (WHI) showed results that were not consistent with results from the observational studies. The decision to consider the different population groups between the studies were specific to this outcome since the committee tried to find an explanation for the inconsistent findings. The committee reconsidered the wording of the recommendation and have since updated the wording to describe the direction of evidence from both the RCT and observational studies. As a result, the committee discussion of the evidence section in Evidence Review D has been updated to provide details of the discussion that took place. With regard to subgroup analysis for age at first use, the evidence does not show a statistically significant subgroup difference between the risk of breast cancer and the different subgroups for age at first use, therefore the committee were unable to draw any meaningful conclusions. This is discussed in more detail in the committee's discussion of the evidence in Evidence Review D.

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				progesterone receptor-positive breast cancers (HR 1.86; 95% CI 1.60–2.17), an increase in advanced diseased (HR 2.12; 95% CI 1.67–2.69). Neuhouser ML et al JAMA Oncol. 2015 doi: 10.1001/jamaoncol.2015.1546. PMID: 26182172; PMCID: PMC5070941. The very most than can be concluded from the data is that oestrogen-only HRT *may* increase the risk of breast cancer and the guideline should add that CEE may not increase risk, although we acknowledge that further study is needed. Column 3: "There is no difference in the increase of breast cancer risk between transdermal and oral oestrogen." This contradicts the comments in the previous table and is going to cause confusion. Either there is no difference or transdermal is better. Given the limited evidence presented in the previous Table we would favour making no distinction consistently across the board. Column 4: "There is no difference in the increase in breast cancer risk between oestradiol and conjugated equine oestrogen when given at standard therapeutic dosage" This statement ignores the data from WHI which was a randomised trial. The committee argue that the average age of women (63) and greater proportion who were overweight/obese in the WHI are unrepresentative of the target population for MHT. However the WHI subgroup analysis showed no significant risk increase or reduction in the risk of diagnosis	The subgroup analysis by BMI from the WHI was not included (Neuhouser 2015) as it does not meet our specified criteria in the protocol. The paper referred to in your comment (Neuhouser 2015) is a secondary analysis of the WHI including women from 3 trials, one of these trials does not compare HRT use to no HRT use (the intervention is dietary modifications). They have obtained information on HRT use in the participants, but since approximately 59% of the participants were not randomised to the interventions as specified in our protocol (HRT use or no HRT use) the study has to be treated as observational data. As specified in our protocol, observational studies have to make adjustments for confounders to be included in the review, and the data provided by Neuhouser 2015 on BMI, HRT use and breast cancer incidence has not been adjusted for confounders, therefore we are unable to include it in our review. With regard to the Hazard ratios quoted in your comment, it is also not possible to include these as they are not a comparison between HRT use and no-HRT use, but they compare different BMI ranges to each other. The committee did discuss BMI but did not feel that a separate recommendation was required. The committee considered all the available evidence for oestrogen-only HRT, however because there were inconsistent findings between the RCT data and the CGHFB findings which was informed by observational data, they had to consider which data were more relevant to the population in question, as well as other pros and cons of the available data. The committee have since revisited the recommendations and the wording and have changed the wording to 'for oestrogen-only HRT there is little or no increase in

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				with age. The CGHFBC 2019 reported a reduced risk in women with a higher BMI and suggests large proportion of overweight women in WHI accounts for the findings with CEE. However, subgroup analysis by BMI in the WHI shows no increased risk in women with a low or normal BMI range. It is perplexing why observational data are being favoured over RCT data. There are also other plausible explanations for a difference between the effect of CEE and E2 e.g., the former has pro-apoptotic properties and the latter anti-apoptotic properties. This is an area that requires further clinical evaluation. Given the uncertainty of the data is inappropriate to dismiss the WHI results. A statement that CEE may not increase risk but further evaluation is required would seem a more rational conclusion.	the risk of breast cancer compared to not taking HRT'. They agree that this wording includes the conclusions between both RCT and observational data, and since the findings were inconsistent it is necessary to reference both. The committee considered the evidence for oral and transdermal routes of administration of the oestrogen component of HRT. Since some of the evidence showed a significant difference between the subgroups of oral and transdermal routes of administration in the combined HRT comparison, they had made a recommendation to inform of the reduced risk. However, the committee revisited the evidence, and discussed that since the same difference was not observed in the oestrogen-only comparison, the argument was less robust than previously discussed. Upon reflection the committee agreed to remove this recommendation and an updated detailed discussion of the evidence, and their decision can be found in the committee discussion of the evidence section of Evidence Review D. Regarding column 4, as already mentioned, the committee considered all the evidence included in the review which included RCT evidence and observational evidence. The committee discussed that the population in the WHI had different characteristics to the average population in the observational evidence. They discussed that this could be a reason why the data showed conflicting results. BMI of the women was one of the factors discussed. The reasons for the exclusion of the subgroup analysis of the WHI data by BMI have been provided and therefore the committee cannot make conclusions using this data. The committee agreed that the subgroup analysis by constituent, as reported in the review,

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					showed that both conjugated equine oestrogens and oestradiol had an increased risk of breast cancer. Following changes to the recommendation on overall breast cancer risk with oestrogen-only HRT, which now stands at 'there is little or no increase in the risk of breast cancer', the committee agree that the recommendation 'there is no difference in the increase in breast cancer risk between oestradiol and conjugated equine oestrogen when given at standard therapeutic dosage', is still relevant as it is in line with the data that does show an increased risk. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). However, they highlighted that RCT, and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. These and other evidence reviews have been revised to implement these changes accordingly.
University Hospitals Dorset	Guideline	087 - 089		**Tables** The actual numbers presented in the Tables are just point estimates which is not a scientific way of presenting that data. In reality these figures maybe lower or higher, they are just a guide and readers need to be aware of this. The guideline does not make this clear and we would ask that confidence intervals be included.	Thank you for your comment. For the draft guideline, the committee opted for a written format complemented by tables, providing estimates of absolute numbers from a single source rather than from two different study types. This differs from the approach used in the published version of NG23. This decision was made to facilitate conversations between clinicians and individuals, enabling

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				This is an honest and open approach and one that was used very successfully in the previous guideline. This proved very helpful in educating and drawing a distinction between uncertainties and certainties and was widely acclaimed by menopause experts around the world as a constructive way to present the data. As they stand these tables don't report any uncertainty/sensitivity which is clearly not the case.	shared decision-making regarding Menopause management. The appendix has been used to produce a discussion aid document including visualisation of the data. This provides details about the type of evidence data originated from, how to interpret the numbers and information about uncertainty. It also links to the relevant evidence reviews which contain details of the estimates from different study types as well as the confidence intervals. It also includes links to a separate supplement file which provides the details of each calculation. This discussion aid has undergone user-testing and was refined based on user feedback.
University Hospitals Dorset	Guideline	097 - 098		Number of breast cancer cases over a 5-year period per 1,000 people who never used HRT. This should clearly state the control group are women with early menopause who have a significantly lower risk of breast cancer (not age matched premenstrual women). As stated previously the breast cancer argument for early menopause makes no biological sense and the data in the table on p96 adds to this confusion and should be explained appropriately	Thank you for your comment. The statement related to an increased risk for breast cancer in the early menopause group was removed because it was the only evidence identified for the comparison specified in the protocol (people in early menopause taking HRT versus people in early menopause not taking HRT). The committee decided that having only this one piece of information could be detrimental to decision-making and used it in the rationale underpinning a related research recommendation. The topics of prevalence of early menopause, impact of early menopause on specific health outcomes and management of early menopause, whilst not part of the 2024 guideline update, have been logged with the NICE surveillance team (together with key publications as cited by stakeholders) to be considered for future updates.
University Hospitals Dorset	Guideline	098 - 099		Table 17 showed that women aged 40 who took HRT for 10 years had a similar risk of breast cancer to women who did not take HRT. The	Thank you for your comment. The comparison addressed in the related evidence review is women with early menopause taking HRT versus

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				recommendations should clearly reflect these findings.	women in early menopause not taking HRT. Whether or not women in early menopause have a lower risk of breast cancer to start with was not the focus of the question posed. In table 17 (related to oestrogen-only HRT) differences are statistically significant even if in one of them the difference is too small to show up as a difference per 1000. The committee reflected on this and decided that the limited evidence identified (only evidence for breast cancer incidence) was a reason for a research recommendation in this area and removed the reference to this from the recommendation. Topics related to early menopause that were mentioned as important by stakeholders and were not addressed in the 2024 guideline update were logged with surveillance so that they could be considered for future updates.
University Hospitals Dorset	Guideline	010	012	1.4.2 we welcome this focus on a balanced discussion with the patient. This should be reflected consistently throughout the document.	Thank you for your comment. The committee agreed that a person-centred approach is of critical importance. To facilitate this, the data in the appendix have been used to produce a discussion aid document including visual presentation to aid decision making. This discussion aid has undergone user-testing and was refined based on user feedback. It is not NICE style to repeat recommendations in every section. Once mentioned recommendations would apply to throughout.
University Hospitals Dorset	Guideline	011	001	1.4.3 The word "prolonged" sounds judgmental. There is no arbitrary age cut off or time limit for HRT use. The guideline should say 'explain that the risks may increase with duration of HRT use'. In the committee discussion (page 43 line 22) it states "it is impossible to recommend one	Thank you for your comment. The committee reflected on this and the word 'prolonged' has been removed from this recommendation. It has been rephrased to read 'discuss the possible duration of treatment at the outset', followed by 'rediscuss the benefits and risks or continuing

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				specific duration of use because this would depend on several factors, including the reason for starting HRT and a person's health history, age and symptoms." We support this statement which reflects good clinical practice. The term "prolonged use" implies longer than advised which as the committee acknowledges is not something that can be generalised at the outset.	treatment at every review'. Therefore, it is a general discussion about the potential duration which would then be revisited at review.
University Hospitals Dorset	Guideline	011	001 - 005	1.4.3 We agree that the potential risks must be discussed at the outset but this should be balanced with the benefits in this section as stated in 1.4.1.and 1.4.2. It is important that the document reflects good clinical practice which is to discuss the benefits and the risks of any proposed treatment such as HRT not just the risks. In the committee discussion (P43 line 5) it states "using an individualised approach with discussions about benefits and risks of treatment options and tailoring information to individual circumstances and potential risk factors". We support this statement which reflects good clinical practice but would like to see this reflected consistently throughout the recommendations.	Thank you for your comment. The committee agreed that this has to be a person-centred approach and in recommendation 1.4.2 state: 'tailor the information about benefits and risks to the person's age, individual circumstances and potential risk factors.' It is in the sections about what and how options should be discussed and is therefore an overarching recommendation. It is not NICE style to repeat recommendations or rationales for recommendations throughout documents.
University Hospitals Dorset	Guideline	013	005	1.4.12 We recognise this section is not being updated but referral to a haematologist will not change management. There is already good quality observational data indicating transdermal HRT does not affect risk of VTE. Unnecessary referrals waste patient's time and NHS resources. If referral is needed this could be to a menopause specialist or a haematologist.	Thank you for your comment. This was not part of the scope of the 2024 guideline update and therefore the committee could not comment on this. However, because of this and other stakeholder comment the topic has been logged with the NICE surveillance team so that it can be considered to be included in a future update.

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University Hospitals Dorset	Guideline	013	027	1.4.14 People at high familial risk of ovarian cancer: There are already national and international recommendations already guidelines in place Vermeulen RFM et al Climacteric 2019:22:352-60, Manley K et al Post Repro Health 2023;29:42-52 Whilst we are pleased to hear NICE are reviewing this topic, and we look forward to the guideline, this is not yet published.	Thank you for your comment. The NICE guideline on identifying and managing familial and genetic risk of ovarian cancer has since been published and therefore the cross reference has been updated. This includes a section on HRT after risk-reducing surgery.
University Hospitals Dorset	Guideline	015	001	The term "Genito-urinary symptoms" or "Genito-urinary symptoms of the menopause" or "genito urinary menopause symptoms" has been introduced in this guideline and is used variably. It is not a term that is used in the mainstream literature. It is not clear what this is referring to. The previous guideline referred to symptoms of uro-genital atrophy and it is not clear why this has been changed. It is entirely separate entity form Genito-urinary *syndrome* of the menopause which is a term now used in some of the literature to reflect a syndrome of symptoms. However, this term is North American and not universally accepted. Correct and consistent terminology is important in a national guideline. Whilst "Genito-urinary symptoms" is a potentially useful term, if the committee wish to introduce this term, it should be clearly explained in the glossary with supporting standardised and validated evidence for the change in terminology. If it is to be used we would recommend using the term "genitourinary symptoms associated with the menopause", as used in Evidence Review B2, consistently across the document otherwise	Thank you for your comment. The guideline has now included a definition of genitourinary symptoms associated with the menopause which consists of vulvovaginal dryness, pain with sex, vulvovaginal discomfort or irritation, and discomfort or pain when urinating. This is consistent with the terminology used in evidence reviews B1 and B2.

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				there will be significant confusion about what is being discussed.	
University Hospitals Dorset	Guideline	015	014	1.4.20 "some oestrogen is absorbed but, compared with systemic HRT, the amount is small " This statement is confusing and we think will cause alarm for both patients and GPs and raise concern that progestogens maybe required for endometrial protection. The amount of oestrogen absorbed with the widely used ultra-low doses of vaginal estrogen is not clinically significant (not just "small"). After a small spike in oestradiol levels in the first few days of treatment the levels fall to normal postmenopausal levels. The MHRA has reviewed all the data and approved vaginal oestrogen 10mcg for over-the-counter use. We recommend re-phrasing to: "the amount absorbed is not clinically significant effect and has no stimulatory effect on the endometrium"	Thank you for your comment. This bullet point was reworded to say that vaginal oestrogen is absorbed locally - a minimal amount is absorbed into the bloodstream (when compared with systemic HRT), but this is unlikely to have a significant effect throughout the body. It is then described in the rationale section that 'the committee agreed to highlight this because it means that there is no need to combine low-dose vaginal oestrogens with systemic progestogen treatment to protect the person against endometrial hyperplasia and cancer'.
University Hospitals Dorset	Guideline	015	023	1.4.22 The terminology here is confusing. Vaginal oestrogens are a treatment for the symptoms of an overactive bladder such as urinary urgency and frequency. An overactive bladder is a condition not a symptom. Whilst oestrogens may improve some of the symptoms there are many other causes.	Thank you for your comment. This recommendation is creating a link between this guideline and a recommendation to 'offer intravaginal oestrogens to treat overactive bladder symptoms in postmenopausal women with vaginal atrophy' in NICE's guideline on managing urinary incontinence and pelvic organ prolapse which is relevant in the context of genitourinary symptoms associated with the menopause and overactive bladder symptoms.
University Hospitals Dorset	Guideline	016	019	1.4.28 This statement is confusing. Why is there uncertainty about the effectiveness of vaginal oestrogens in this group? The issue is the use of Aromatase inhibitors is generally considered a contra-indication. We accept there	Thank you for your comment. The recommendation related to uncertainty about efficacy of vaginal oestrogen in the context of a history of breast cancer has been removed.

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				are limited data on their efficacy in this situation but there is no reason, or evidence, that they shouldn't be effective if used. The main concern here is safety. We would recommend a stronger statement regarding the use of vaginal oestrogen in women using an aromatase inhibitor. Conversely the consensus is that vaginal oestrogens can be used with tamoxifen if indicated.	
University Hospitals Dorset	Guideline	017	003	1.4.29 This section is unduly negative and may deter women being prescribed vaginal oestrogens when appropriate. The data, such as they are, are reassuring and this should be stated. It is appropriate to acknowledge that the data are limited but no study has suggested an increased risk of recurrence. A recent UK meta-analysis (McVicker L et al JAMA Oncol 2023 doi:10.1001/jamaoncol.2023.4508) showed no evidence of increased early breast cancer mortality in patients using vaginal oestrogens. Although we recognise that this publication was after the relevant discussion, nevertheless it provides further important information from a large UK cohort that is consistent with existing data and should provide further reassurance	Thank you for your comment. The committee considered the data available and concluded that there was uncertainty regarding the risks of breast cancer recurrence which is reflected in the recommendations. The reference linked in the comment is not a meta-analysis but a cohort study. This study would not have met the criteria specified in the protocol for the review question related to vaginal oestrogens as breast cancer recurrence was not reported and mortality was not one of the outcomes listed in the protocol. The committee reflected on this recommendation and agreed to make some revisions to it for clarity (including further detail to the rationale section).
University Hospitals Dorset	Guideline	018	006	1.4.33 reference NICE guideline IPG967	Thank you for your comment. A reference to IPG967 has been added.
University Hospitals Dorset	Guideline	019	002	1.4.37 It is not clear why only CBT is considered for sleep difficulties given that HRT can also be of benefit by alleviating night sweats (and possibly having a direct effect on the hypothalamic sleep centre). HRT should also be considered if sleep problems occur in conjunction with other menopausal symptoms.	Thank you for your comment. Apart from CBT other management options for sleep problems associated with the menopause were not in the scope of the 2024 guideline update. However, the committee acknowledged that there are other options that may be used (including HRT). They have therefore reworded the recommendation to reflect this. It now states that CBT could be used

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					as an option (1) in addition to other treatments (including HRT), or (2) for people for whom other treatments are contraindicated or (3) for people who prefer not to have other treatments. Given the constraints of the scope they could not be more specific than this.
University Hospitals Dorset	Guideline	021	022	1.6.1 This recommendation does not adequately reflect the data, particularly for oestrogen only HRT. There is a large body of evidence (e.g., Salpeter RE et al, the WHI RCT (Manson et al) and Cochrane (Boardman et al) that all-cause mortality is reduced by hormone replacement therapy if commenced before the age of 60. However, this beneficial effect is not reflected in the updated guideline. Why have the guideline committee ignored this evidence? These and several other studies have been excluded from the analysis on the grounds that they did not report separate results for combined and oestrogen only HRT. Some of the relevant data could be extracted and some similarly designed studies in other disease areas are included reflecting inconsistency in the way these criteria have been applied. These studies were all published in high quality peer-reviewed journals and there results are very pertinent to the discussion. Their exclusion, on whatever grounds, is a significant weakness in this Guideline.	Thank you for your comment. The reference to Salpeter 2006 in your comment is a report for coronary heart disease events and not for all-cause mortality. However, there are 2 systematic reviews listed in the excluded studies section of Evidence Review H that might be relevant to your comment, and so will be referred to in this response. Boardman 2015 and Salpeter (2004 and 2009) are systematic reviews that were assessed for inclusion but were not included as a systematic review because they did not separate results by combined and oestrogen-only HRT. This was criteria set out in the pre-specified protocol and cannot be changed. The committee therefore cannot comment on the conclusions these systematic reviews reached. The individual studies included in these systematic reviews were checked against the protocol criteria, and where relevant they were included in the review. WHI results have been included in this evidence review. The evidence in Evidence Review H shows an isolated risk reduction in the age group 50-59, for oestrogen-only HRT users, however this is part of a subgroup analysis that did not show a statistically significant difference between the subgroups, and therefore the committee could not conclude that there was a benefit in all-cause mortality that warranted a recommendation. The related rationale sections of the guideline have been updated to make it explicit why some widely

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					cited systematic reviews could not be included. The evidence reviews in this guideline followed rigorous NICE methods and processes, with details outlined in a supplement available on the website (Supporting document 1 - Methods), consistent with the NICE guideline manual. With regard to inconsistency over the exclusion criteria across reviews, the NICE processes have been followed, and that each review question follows the criteria set out in the protocol for that particular review. Some review protocols are not identical to others, see the specifics of each protocol in Appendix A of the Evidence Reviews. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). However, they highlighted that RCT, and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. These and other evidence reviews have been revised to implement these changes accordingly.
University Hospitals Dorset	Guideline	035	002 - 016	1.6.4 This whole section is misleading and does not reflect the data. The evidence review on early menopause (Page 74, lines 10-11) states: "Whether early menopause affects long-term health is uncertain". This is inaccurate and fails to consider why HRT is used in this group and fails to acknowledge the large observational	Thank you for your comment. The aim of the evidence review carried out was assessing the impact of either taking or not taking HRT on people with early menopause and the development of various health outcomes. The need to assess the consequences of early menopause on health outcomes has been acknowledged and have been

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				evidence (Muka et al JAMA Cardiol 2016; Zhu D et al Lancet Public Health 2019; Anagnostis P et al Endocrine 2019; Hao W et al Hum Reprod 2023) that shows an increased risk for CVD, cardiovascular mortality, osteoporosis and related fractures as well as all-cause mortality. Whilst evidence from controlled studies to demonstrate this is lacking, this is a very similar limitation to the evidence for POI which NICE acknowledged in 2015 and despite this made recommendations to offer HRT to women with POI. Again, this is inconsistent use of the data. The interpretation of all this evidence in guidelines globally is to recommend HRT in this group until the natural age of the menopause. POI and early menopause represent a continuum of risk that should be recognised and reflected firmly in the guideline. Indeed, in the review of evidence the Guideline committee acknowledge this (page 74 16-17) but this is not reflected in the recommendation. If adopted as it stands, this will make the NICE guideline an outlier which makes it less likely the guideline will be used and also calls into question the methodology.	logged with the NICE surveillance teams for prioritised consideration during future updates.
University Hospitals Dorset	Guideline	035	004	1.6.4 It should be made clear that lack of evidence does not mean lack of benefit. This is a continuum of risk and the data can be extrapolated from POI (Guideline page 74;16-17) and age should be taken into consideration when assessing potential adverse effects of menopause to highlight that this population is also at risk. The guideline recommendations do not reflect this.	Thank you for your comment. The aim of the evidence review carried out was assessing the impact of either taking or not taking HRT on people with early menopause and the development of various health outcomes. The need to assess the consequences of early menopause on health outcomes has been acknowledged and have been logged with the NICE surveillance teams for prioritised consideration during future updates.

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				It is very unlikely that any RCTs will randomise women with early menopause to placebo given the large observational evidence of adverse effects. Indeed one such proposed study was denied ethics approval on the grounds it would be unethical to randomise women with early menopause to placebo. Recent RCTs including an ongoing multi-centre national RCT are comparing two types of hormonal preparations rather than hormones to placebo. For both topics - early menopause and POI - there is large observational evidence showing an increased risk of osteoporosis and related fractures, cardiovascular disease, cardiovascular mortality, type 2 diabetes and increase in all-cause mortality. For both topics, however, we acknowledge that there is lack of objective evidence assessing the effect of hormone replacement on these outcomes but this is unlikely to ever be realized.	
University Hospitals Dorset	Guideline	035	010	The evaluation of the impact of HRT on women with early menopause is limited to one analysis of observational data (CGHFBC 2019 meta-analysis) pertaining to breast cancer yet the findings appear to be applied to an array of outcomes not addressed in the included paper. The "norm" for women younger than 45 is to be premenopausal. In the CGHFBC meta-analysis HRT users younger than 45 years were compared with postmenopausal women younger than 45 years not using HRT, whereas in terms of breast cancer risk, the clinically meaningful comparator would be age-matched premenopausal women. As the authors of the CGHFBC 2019 paper have previously reported,	Thank you for your comment. The committee decided the appropriate comparator for this evidence review would be people in early menopause not taking HRT/placebo. People not in early menopause were outside the scope of the review protocol. The recommendation was based on evidence from the CGHFBC 2019 meta-analysis subgroup which matched the review protocol. The committee agreed that although it would be beneficial to provide information to people in early menopause on the impact HRT can have for health outcome specific to them, early menopause as a risk factor for health outcomes was not the topic under review. Thus, highlighting breast cancer risk alone would provide a skewed interpretation of the potential health risks and

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				women who become postmenopausal before the age of 45 years have a 30% lower risk of breast cancer compared with women who remain premenopausal until the age of 45 years. In the 2019 paper the authors report that young postmenopausal women who use HRT have an increase in breast cancer risk compared with young postmenopausal women who are not using HRT but fail to acknowledge that for women with early menopause. In reality HRT may not even restore their breast cancer risk to what it would have been if they had not gone through an early menopause. This should be acknowledged as menopause before the age of 45 years is associated with epigenetic ageing, a greater risk of premature death from all causes, including premature death from cardiovascular disease, as well as substantially greater risk of osteoporosis and fragility fracture in later life. By ignoring all these data and focusing on a flawed analysis the recommendation is risking significant harm to a cohort of women and impact on their quality of life. Data from the Women's Health Initiative showed that women who had undergone bilateral oophorectomy before age 45 and who were also younger than 60 years at the time of random assignment had a significant reduction in all cause mortality with a cumulative oestrogen-associated HR for all-cause mortality of 0.60 (CI, 0.38 to 0.95). If there was evidence that HRT use put women with early menopause at greater risk of breast cancer than their normally ovulating counterparts then there would be a basis for	therefore the statement "Taking HRT increases the risk of breast cancer" has now been removed from the recommendation but has been used in the rationale to explain the need for a research recommendation. The need to assess the consequences of early menopause on health outcomes has been acknowledged and has been logged with the NICE surveillance teams for prioritised consideration during future updates.

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				advice cautioning against HRT for this age group. But as this evidence is lacking, and in the context of the overwhelming evidence of the adverse effects of early menopause, then advocating against HRT in this age group is associated with a high probability of causing harm.	
University Hospitals Dorset	Guideline	035	010	1.6.4. People in early menopause. "Taking HRT increases the risk of breast cancer." This statement is inappropriate, too strong and not supported by the data in this age group. The way this is presented in isolation and without added context is misleading and will cause considerable confusion and alarm and in our opinion this could cause long term harm to thousands of women if they stop taking HRT as a consequence of this statement. The reality is we do not know what the risk is in this age group. This statement is based on the 2019 CGHFBC meta-analysis which reported an increase in the risk of a breast cancer diagnosis in this cohort of women if they use HRT, but the control group consists of those with an early menopause not using HRT. This was not an unexpected finding as women with an early menopause have a lower risk of breast cancer. We believe that this analysis is profoundly flawed in that the effects of MHT for women who go through early menopause must be seen in the context of what is "normal" for women of this age. There is no evidence that the risk for breast cancer in women with early menopause taking HRT is increased when compared to age matched control who have normally functioning ovaries and are not taking HRT.	Thank you for your comment. The committee agreed the appropriate comparator for this evidence review would be people in early menopause not taking HRT/placebo. People not in early menopause were outside the scope of the review protocol. The recommendation was based on evidence from the CGHFBC 2019 meta-analysis subgroup which matched the review protocol. Most of the available evidence in the literature is based on HRT formulations that were previously used and may not currently be common practice, however the committee agreed this would still be useful in the absence of other evidence. The committee have subsequently made a research recommendation focussing on the risk of progesterones more commonly prescribed, as they recognised more evidence on newer HRT formulations were required. The committee agreed it would be beneficial to provide information to people in early menopause on the impact HRT can have for health outcome specific to them. Given that early menopause as a risk factor for health outcomes was not the topic under review, highlighting breast cancer risk alone would provide a skewed interpretation of the potential health risks. Therefore, the statement "Taking HRT increases the risk of breast cancer" has now been removed from the recommendation but has been used in the rationale to explain the need for a

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				Currently there is international agreement from all major international menopause societies (including the BMS) that years of HRT exposure is counted from the age of 50. This assumes that add-back HRT will delay the effect of the menopause on breast cancer risk and was indirectly supported by the 1997 CGHFBC re-analysis, which reported: a) Postmenopausal women have a lower risk of breast cancer than premenopausal women of the same age and parity and b) The increased risk of breast cancer diagnosis per year with current/recent MHT exposure (2.3%) is like that associated with each year the menopause is delayed (2.8%). The new draft recommendation should not refute this as no analysis was undertaken using a control group of normally cycling women to compare with those taking MHT who had an early menopause (Supporting information 19). We would recommend adjusting the statement to say "may increase the risk of breast cancer compared to women with early menopause not taking HRT" which more accurately reflects the data. It should also be noted that the CGHFBC paper, which was used as primary data to inform the advice, does not inform us of the impact of current recommended HRT prescribing practices on breast cancer risk for women at any age. The median year of diagnosis of breast cancer cases from North America (25% of the included data) was 1999,	research recommendation. The recommendation for this section now reads as follows: 'When discussing HRT as a treatment option, explain to people experiencing early menopause, that, for them, the benefits and risks of either taking or not taking HRT are likely to lie between those for people with premature ovarian insufficiency and those for people aged 45 or over'. The need to assess the consequences of early menopause on health outcomes has been acknowledged and has been logged with the NICE surveillance teams for prioritised consideration in future updates. NICE has followed its standard methods and processes in developing the 2024 guideline update, including the way in which conflicts of interest in topic experts and committee members are managed. The details of declarations of interest and how they have been managed are available in the published register of interests.

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				and for the European studies, 2007, with one as early as 1981. With an average use of 10 years of HRT in current users at diagnosis, and 7 years in past users, much of the exposure to HRT preceded the first publication of the Women's Health Initiative study, after which prescribing practices changed substantially. Consequently, virtually all of the included information pertains to HRT formulations and doses known to have adverse breast effects that are no longer recommended or used. This needs to be acknowledged. We note that in other parts of the guideline good data are excluded as they do not represent the current HRT population. However, here where the same is true, the data are accepted. This is contradictory and requires explanation. Regrettably we also note that one of the authors of the CGHFBC 2019 paper was present on the committee and participated in the discussions. We therefore have to question the impartiality in the interpretation of these data and the undue weight they have been given.	
University Hospitals Dorset	Guideline	048	013	Why is there no mention of HRT? HRT should also be considered if sleep problems occur in conjunction with other menopausal symptoms	Thank you for your comment. Apart from CBT other management options for sleep problems associated with the menopause were not in the scope of the 2024 guideline update. However, the committee acknowledged that there are other options that may be used (including HRT). They have therefore reworded the recommendation to reflect this. It now states that CBT could be used as an option (1) in addition to other treatments (including HRT), or (2) for people for whom other treatments are contraindicated or (3) for people

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					who prefer not to have other treatments. Given the constraints of the scope they could not be more specific than this.
University Hospitals Dorset	Guideline	049	014	"Currently, the usual treatment for vasomotor symptoms associated with the menopause is HRT" This is not normal practice. Whilst HRT is used for some, many women do not have specific treatment, use over the counter remedies or are recommended lifestyle measure as per the guidance of many professional bodies, including the BMS. Only a proportion of women have access to treatment and CBT is already offered as an option to be considered as per BMS guidelines. We welcome the greater emphasis on CBT being offered but the emphasis on it should be in line with the quality of the data supporting it and recognising the other options such as hypnosis. It should also state that HRT remains the most proven effective therapy for those that need it. Whilst the call for greater access to CBT is welcome the infrastructure is not there to support it. This should be recognised as the guideline will potentially be a powerful tool for change.	Thank you for your comment. The statement has been reworded to indicate that it is currently the recommended treatment for vasomotor symptoms because this is still the case in the guideline. The committee reflected on the wording of the recommendations related to CBT and updated it to make it explicit that this was not recommended as a first line treatment. It is now stated that it is an option (1) in addition to other treatments (including HRT) (2) for people in whom other treatments are contraindicated or (3) for people who prefer not to have other treatments. It is NICE style to use the wording 'consider' indicating a recommendation where there is some uncertainty about the evidence. The rationale then describes the uncertainties and why the committee, on balance, concluded that CBT could be an option. Taking into account current pressures on services, your comment will be considered by NICE where relevant support activity is being planned. Hypnosis was not part of the scope of the 2024 guideline update but because of this comment and cited references in other comments this has been logged with the NICE surveillance team so that it may be considered in future updates.
University Hospitals Dorset	Guideline	051	009	"The committee also decided that it was important to discuss with the person that, with vaginal oestrogen, some oestrogen is absorbed into the bloodstream, but generally much less than with systemic HRT." This statement implies there is significant absorption yet the guideline goes on to say "there is no need to	Thank you for your comment. This bullet point was reworded to say that absorption is minimal and not clinically significant. It is then described in the rationale section that 'the committee agreed to highlight this because it means that there is no need to combine low-dose vaginal oestrogens with systemic progestogen treatment to protect the

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				combine low-dose vaginal oestrogens with systemic progestogen treatment to protect the person against endometrial hyperplasia and cancer ". This is correct so the initial statement should be much clearer that any absorption is minimal, not "generally much less". The appropriate use of wording is crucial in making sure the guideline does not give mixed messages.	person against endometrial hyperplasia and cancer'.
University Hospitals Dorset	Guideline	052	029	"For example, people with physical or intellectual disabilities may find it difficult to use vaginal oestrogens". This excludes several groups of women who may choose not to use vaginal preparations, e.g. for cultural reasons or discomfort, and these women should have the option of using an effective oral therapy. We would favour the wording saying "when oral therapy is preferred" rather than restrict it to "in specific circumstances".	Thank you for your comment. The committee considered the comment but thought the clinical and cost effectiveness evidence was not strong enough to make this available to all women who prefer this as an option.
University Hospitals Dorset	Guideline	053	012	The committee acknowledged the evidence was sparse. Whilst we recognise that the recent large UK meta-analyis was published after the discussion date, the results are so pertinent to this discussion that we feel it should be acknowledged here. McVicker L et al JAMA Oncol 2023. doi:10.1001/jamaoncol.2023.4508)	Thank you for your comment. The cited UK meta-analysis includes women with a current diagnosis of breast cancer and excluded women with a previous diagnosis of any cancer. Therefore, this study does not fit the inclusion criteria for the review that your comment refers to - see the review protocol in appendix A of evidence review B2 genitourinary symptoms and breast cancer recurrence, as the review is focused on the risk of breast cancer recurrence in those with a personal history of breast cancer (or otherwise high risk).
University Hospitals Dorset	Guideline	055	003	"Genitourinary symptoms vary depending on hormone receptor status and type of adjuvant treatment." Consider re-phrasing. Adjuvant therapy may have an effect on the symptoms but not the receptor status itself. There is no	Thank you for your comment. The committee agreed with this and 'depending on hormone receptor status' was removed from this bullet.

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				evidence that women with ER +ve disease have any better or worse symptoms than women with ER-ve. It's the effect of the adjuvant therapy.	
University Hospitals Dorset	Guideline	060	016	"Evidence showed that there was no overall effect on life expectancy" In Evidence review H it states "moderate quality evidence showed an important benefit for oestrogen-only when compared to placebo or no HRT on all-cause mortality." Is there a particular reason this was not referred to in the recommendations? This is a large sample size from the WHI with long term follow up data that showed clear reduction in risk for women who started HRT at 50-59. OR 0.81; 95% CI: 0.68-0.96 in all cause mortality in women who started oestrogen only HRT age at the age of 50-59. This is further supported by the Cochrane review by Boardman et al 2015 which showed significant reduction in all cause mortality in women who commenced HRT under the age of 60.	Thank you for your comment. The evidence shows an isolated risk reduction in the age group 50-59, for oestrogen-only HRT users, however this is part of a subgroup analysis that did not show a statistically significant difference between the subgroups, and therefore the committee could not conclude that there was a benefit in all-cause mortality that warranted a recommendation. The line you refer to in Evidence Review H has been amended to make it clearer that although there was an isolated benefit, there was not a statistically significant subgroup difference. Thank you for highlighting the Cochrane review by Boardman et al 2015. This systematic review was not included in this evidence review because the intervention did not match the pre-specified protocol as combined HRT and oestrogen-only HRT were analysed together. However, the included studies from the systematic reviews were individually checked against the protocol and if they met the criteria in the protocol, they were included separately. Boardman et al 2015 has been added to the excluded studies section of this review, Appendix J. There are discussions about the exclusion of the Boardman et al 2015 and 2 other systematic reviews related to the topic in the 'other considerations relating to cardiovascular disease' in the rationale section of the guideline and also in the 'other considerations the committee took into account' subsection of the 'committee's discussion and interpretation of the evidence' section of evidence review C.

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University Hospitals Dorset	Guideline	060	022	Why is there no clear mention of benefits to give balance here? This would normally be included in the discussion and the guideline elsewhere emphasises the importance of discussing benefits and risks together.	Thank you for your comment. This has been revised accordingly.
University Hospitals Dorset	Guideline	061	002 - 005	"Most of the evidence was from a meta-analysis of individual patient data from observational studies, but there was also evidence from randomised controlled trials (RCTs)." There is no rational explanation as to why the observational meta-analyses data has been given more prominence than the large RCT. The recommendations on breast cancer almost totally overlook the large RCT evidence for HRT and breast cancer and rely heavily on a large meta-analysis of previous published research. Much of the evidence reviewed has not changed in any major way in direction or conclusions compared to that reviewed within NG23. Some of the figures may have changed slightly based on the new analysis but not in any significant way, yet the approach to reviewing the evidence appears to be very different and based almost entirely on the observational evidence instead of the totality of the evidence (both observational and RCT). The Lancet meta-analysis had 40% of its entire sample size from the Million Women Study, an observational study with significant methodological limitations and very high loss to follow up that have been highlighted in many peer reviewed published commentaries and reviews. Whilst the meta-analysis would have included very detailed and robust analyses, this	Thank you for your comment. In accordance with NICE methodology for reasons of transparency and reproducibility, studies are included and excluded from reviews on the basis of criteria set out in a pre-specified protocol agreed with the committee before a review has been started. When evidence has met the review protocol criteria it is included in the review and the committee consider this evidence when making recommendations. Agreed protocols are also published on the PROSPERO website before the analysis of data commences). The committee discuss the evidence available in the review and use this evidence to support their recommendations. The committee must take into account the quality of the evidence, as well as the applicability to current practice when considering how best to make recommendations that are supported by the evidence. Randomised controlled trials are often considered to be the gold standard in terms of study design, however the clinical question will determine which study design is the most appropriate. Factors such as sample size, follow-up periods, and incidence of the outcome of interest in the population, may mean that observational studies provide information that RCT studies cannot. The committee discussed and considered the pros and cons of all study designs that were included in each review. As the pros and cons differ depending on the outcome of interest, the discussions are different across reviews and

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				does not take away the significant limitations in the methodology of the study/studies included. We are surprised to note that one of the authors of this study who was on the guideline committee was not excluded from these discussions. This devalues the impartiality of the discussions and subsequent recommendation.	outcomes, and reasons for using some evidence over others will be specific to the review. The committee used the evidence from both RCT and observational data when making recommendations on the risk of breast cancer following HRT use. Since the evidence from RCT and observational studies were consistent for the comparison of combined HRT versus either no HRT or placebo, the recommendations made were supported by both data. However, for the comparison oestrogen-only HRT versus either no HRT or placebo, the RCT and observational data were inconsistent. To make a recommendation the committee discussed the specific characteristics of the different data and used the data they agreed was most relevant to the target population. The full details are discussed in the committee discussion of the evidence report section of evidence report D. The committee have since reconsidered the wording of the recommendations and have agreed that the data from both RCT and observational studies should be represented in the wording of the recommendations relevant to oestrogen-only HRT use, and the recommendation now reads 'there is little or no increase in the risk of breast cancer..' The committee discussion of the evidence section in evidence report D has also been updated to reflect the further discussion that took place. The evidence reviewed within NG23 in relation to RCT data has not changed because no new RCTs have been published since the publication of NG23, however the publication of the IPD data (referenced as CGHFB 2019 in evidence review D) warranted a new whole update of this evidence review (including RCT and observational) data.

					The approach to reviewing is in line with the NICE methodology, and the interpretation of the evidence is based on committee discussion. One of the reasons the 2015 guideline required updating was that the Lancet analysis was a contributing factor for the pharmacovigilance risk assessments by the MHRA and the EMA, concerning the impact of HRT on the risk of breast cancer. NICE is required to follow regulatory guidance from MHRA in its guidance and as such the additional information on breast cancer does change the balance of risks and benefits from that in the original 2015 guideline. With regard to the inclusion of the Million Women Study in the Lancet meta-analysis by the collaborative group in hormonal factors of the breast (CGHFB), it is correct that this study was a major contributor to the Lancet meta-analysis. However, there was consistency in the main findings across the numerous studies therefore any analysis excluding the Million Women Study would not have materially altered the conclusions. There are indeed limitations with any observational studies, and these have been considered in the evidence reviews, and by the committee in discussions and interpretation of the evidence for recommendations. However, the committee agree that the Lancet meta-analysis by CGHFB is a valuable source of evidence and can inform recommendations. With regard to the presence of one of the authors of the Lancet meta-analysis on the committee and at the discussions of the evidence, please be assured that we have followed NICE policy and process concerning the inclusion of committee members with special interest in topic areas.

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					NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). However, they highlighted that RCT, and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. These and other evidence reviews have been revised to implement these changes accordingly.
University Hospitals Dorset	Guideline	062	005	"The committee noted that the RCT evidence was consistent with the observational data" This is not correct. The RCT evidence did not report an increased risk of breast cancer with less than one year of HRT use. The MWS finding is implausible and highlights one of the many significant limitations of the observational evidence. These limitations should be acknowledged not dismissed. In addition the MWS reported a significantly higher incidence of breast cancer in the HRT group at 4 months from the start of the study which is likely to explain the increase noted with less than one year of use. This is biologically implausible and highlights our genuine concerns as to why this study has been given so much emphasis over RCT data. We can't help but note that one of the authors of this	Thank you for your comment. The statement refers to an overall increase in the risk of breast cancer following combined HRT use and does not specify that the data was consistent at less than one year of use. The committee discussed that the direction of effect from both the observational and RCT evidence was the same. This is discussed in more detail in the committee's discussion of the evidence section in Evidence Review D. The MWS, due to its sample size is a large contributor to the Lancet 2019 meta-analysis (references CGHFBC 2019 in Evidence Review D). The committee discussed that all observational studies are subject to bias. They discussed that randomised controlled trials are considered to be the gold standard in terms of study design, but that observational studies could provide useful information. As is the case for the observational studies in Evidence Review D, the observational data provides a larger sample size which

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				study was on the guideline committee and present for these discussions.	increases the power to detect rare outcomes such as breast cancer, and also more information on different durations of use with long follow-up periods. NICE has followed its standard methods and processes in developing the 2024 guideline update, including the way in which we manage conflicts of interest in topic experts and committee members. The details of conflicts of interest and how they have been managed are available in the published register of interests. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). However, they highlighted that RCT, and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. All sections that previously stated that RCT evidence is consistent with observational data have been revised to include a separate section on the findings from RCTs to clarify explicitly what the findings of each study type were.
University Hospitals Dorset	Guideline	062	008	This uncertainty of the data presented means there is no justification for making such specific and dogmatic recommendations about risk and mortality. These will cause unnecessary fear and confusion.	Thank you of your comment. The inclusion of the MWS research letter was deemed appropriate since the MWS has previously published work describing the cohort and methodology, which fits our pre-specified protocol. The research letter also describes the analysis was adjusted. Given the critical nature of mortality from breast cancer,

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				In fact the breast cancer mortality recommendations appears to be entirely based on a single, one page research letter with 4 authors from the MWS group that has not been published as a full manuscript and published separately from the Lancet meta-analysis. This was not authored by the collaborative group who published the meta-analysis. The letter included very limited detail. Yet this entire recommendation has been based on this letter over the findings of the WHI RCT. We would like to know the decision making in including a non-peer reviewed research letter as admissible evidence strong enough to make a recommendation about mortality, yet other studies and RCT data is ovrlooked. It is noted again that one of the authors of this letter is on the guideline committee. One of the arguments used for not including the RCT data was that the characteristics of the RCT population differed from the observational data e.g. on obesity, yet the impact of HRT is less in women who are overweight than in lean women as MWS noted. The incidence of obesity in the UK has increased since the MWS participants were recruited around 30 years ago, making the figures from this study less valuable. In fact, it makes the findings from WHI more relevant as the incidence of obesity in the US in 1980 is similar to the UK in 2020! This fact is not acknowledged anywhere in the Guideline. In addition the data from the Million Women Study were derived from a breast screened	information from such a source was deemed important and underwent quality assessment using GRADE methodology. |t wasw however taken into consideration that the publication was not a full publication in the critical appraisal of the letter. The committee considered a number of things when discussing the use of the letter to support their recommendation. They discussed the difference in sample size between the observational and RCT evidence for mortality, and they also discussed that an increase in mortality was in line with the evidence relating to an increased incidence of breast cancer. The committee's discussion of the evidence section in Evidence Review D was updated to provide more detail on the discussion the committee had on mortality. NICE has followed its standard methods and processes in developing this2024 guideline update, including the way in which we manage conflicts of interest in topic experts and committee members. The details of conflicts of interest and how they have been managed are available in the published register of interests. The results from the WHI study (Chlebowski 2020) were and are included in Evidence Review D for breast cancer incidence and mortality and now has also been included in the same forest plot. The hazard ratio from Chlebowski for those on combined HRT in this publication is HR = 1.35 [0.94 to 1.95], whilst not statistically significant, is in the direction of increased risk and in line with the findings from the observational study. The committee noted that the findings for oestrogen-only HRT from RCT and observational studies go into the opposite direction. The decision to consider the different population groups between the studies were

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				population that may have been at higher risk of breast cancer because of where the population was recruited. These potential biases cannot be completely controlled for in an observed population like the MWS. As valuable as these data are, there is still uncertainty and no justification for such a strong statement.	specific to this outcome since the committee tried to find an explanation for the findings. The committee reconsidered the wording of the recommendation and have since updated the wording to describe the direction of evidence from both the RCT and observational studies and uncertainties associated where results differ. As a result, the committee discussion of the evidence section in Evidence Review D has been updated to provide details of the discussion that took place. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). This review agree that the Beral letter is a linked report to a study that is already included, and so is appropriate to include, in the same way that it is appropriate to contact study authors for supplementary information. They suggested to add further details about this (such as it not being peer reviewed) in the GRADE quality assessment and main body of the text which has since been implemented. They also highlighted that in the consultation version 'there is a strong focus in places on statistical significance, and conflating this with clinical significance, which can suggest that RCT and observational evidence conflicts when in fact effects are in the same direction, but one achieves statistical significance and the other does not' and reflected on the Chlebowski hazard ratio in this context.
University Hospitals Dorset	Guideline	062	011	"They decided that people should be aware of these risks so that they can make an informed choice."	Thank you for your comment. The rationale sections relate to individual risks and the evidence related to them. If 'weight of the evidence' refers to the relationship between these different risks, then

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				This seems like a major weakness in the NICE methodology which seems to be using language that is not usually used in this type of guideline. There is no discussion about the weight of evidence here.	this would be an individual shared decision between the healthcare professional and the person weighing up the different risks depending on their own background risk. The revised guideline includes more detail in relation to the tables of absolute numbers that can be used in this process. These were reviewed and used to produce a discussion aid document with visualisation of the data and verbal description aimed to facilitate shared decision making. This discussion aid has undergone user-testing and was refined based on user feedback.
University Hospitals Dorset	Guideline	062	013	The committee noted that the evidence showed that there was a smaller increase associated with taking transdermal oestrogen rather than oral oestradiol" Brusselers et al 2018 showed no overall difference between transdermal and oral. A similar effect was also noted in the Lancet meta analysis and other registry reports. If this conclusion applies to combined it should apply to oestrogen only. We suggest the data are too inconclusive to be able to make this statement.	Thank you for your comment. The committee considered the evidence for oral and transdermal routes of administration of the oestrogen component of HRT. Since some of the evidence showed a significant difference between the subgroups of oral and transdermal routes of administration in the combined HRT comparison, they had made a recommendation to inform people that the increase was smaller with transdermal than oral. This now also includes a study by Vinogradova (2020) which include data on transdermal versus oral HRT but did not provide greater clarity on this matter. The committee considered this and the Brusseler 2018 evidence and discussed that since the same difference was not observed in the oestrogen-only comparison, the argument was less robust than previously discussed. Upon reflection the committee agreed to remove this recommendation and the rationale section revised accordingly as well and a detailed discussion of the evidence and their decision was updated and can be found in the committee discussion of the evidence section of Evidence Review D. The committee also decided

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					that more evidence is needed to clarify this and prioritised this for a research recommendation.
University Hospitals Dorset	Guideline	062	028	"For current users of oestrogen-only HRT the risk of breast cancer was higher in those who had been taking HRT for at least 1 year" As discussed above this is implausible and different to the breast cancer findings reported in the WHI RCT 50-79 (where also no difference was noted in the risk of breast cancer between 50-59 / 60-69 / 70-79 groups). This is a major flaw in the Lancet meta-analysis and highlights why it is scientifically wrong to give this paper so much prominence. Given that the data are so unconvincing it is inappropriate and dangerous to make such a dogmatic statement.	Thank you for your comment. The analysis of HRT and BC risk in the Million Women Study (which is included in this analysis) excluded all women with any record of breast cancer prior to recruitment. Obviously there will be some participants with undiagnosed/pre-clinical breast cancer at the start of follow-up but this is likely to be true of all observational studies (and probably some trials). Whilst it may have been the case that cancers diagnosed very soon after recruitment were present to some degree at recruitment, this does not invalidate the comparisons between HRT users and non-users in terms of subsequent breast cancer risk. All women who entered the study reported on HRT use prior to coming for screening (and hence before they had any knowledge of any abnormalities) and all women who were recruited had a routine screen at entry and so would have had the same opportunity of getting any pre-existing disease diagnosed. Thus, the observation of an increased risk of breast cancer in HRT users– even in a relatively short period after recruitment– should be robust and is likely to reflect an association between HRT and increased risk.
University Hospitals Dorset	Guideline	063	007	"The committee agreed that it is important that people are aware of these facts so that they can make an informed decision." This alarmist tone is not used with other national recommendations. Given this "finding" was different to the RCT findings such wording comes across as too negative and unrepresentative of the data. The best way of	Thank you for your comment. The conclusion and wording in this section has been reviewed and revised to reflect the uncertainty because of the differences between results from different study types. The sentence referred to was removed.

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				portraying risk is the provide a figure with a range so that people can see the level of certainty or uncertainty. This worked well with NG23 and should be replicated here.	
University Hospitals Dorset	Guideline	063	012	The committee noted that the population of the RCT studies differed from that of the observational studies in that the average age at starting HRT use was higher in the RCT (63 years, with an age 14 range of 50 to 79 years old) than in the observational studies (50 years)" Whilst the WHI RCT included women aged 50-79 they reported no difference in breast cancer risk between 50-59 / 60-69 / 70-79 age groups. Why has the Vinogradova paper (BMJ 2020; **371**: m3873) been overlooked? This reported on 98,611 women aged 50-79 with a primary diagnosis of breast cancer between 1998 and 2018, matched by age, general practice, and index date to 457,498 female controls. This paper addresses the contemporary use of HRT as opposed to the CGHFB 2019 paper which pertains to doses and formulations no longer prescribed today. It is thus more relevant than the CGHFB.	Thank you for your comment. The committee considered the evidence from both RCT and observational data. The RCT data, which included the Women's Health Initiative (WHI), and observational data were consistent for the comparison combined oestrogen and progesterone versus no HRT or placebo, and both showed an increased risk in breast cancer. The committee discussed that the RCT evidence from the WHI showed conflicting results to the observational studies, for the comparison of oestrogen-only HRT versus placebo or no HRT. The decision to consider the different population groups between the studies were specific to this outcome since the committee tried to find an explanation for the inconsistent findings. The committee reconsidered the wording of the recommendation and have since updated the wording to describe the direction of evidence from both the RCT and observational studies. As a result, the committee discussion of the evidence section in Evidence Review D has been updated to provide details of the discussion that took place. The Vinogradova 2020 study does meet the criteria for inclusion in this review. Note that some of the cohort in this publication (from the CPRD database) was already included in the review, therefore only data from the QResearch cohort have been included. The relevant sections of the review were updated with data from the study that fits our protocol. Subgroup analyses, where available, were included addressing the risk of

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					breast cancer in the different oestrogenic constituents and progestogenic constituents where newer formulations showing an increase in risk of breast cancer in line with other constituents. The committee have seen the available data and have made recommendations based on this data. In particular, the committee discussed that there are progestogenic constituents that are more commonly used in practice today, however agreed there was insufficient evidence to make a recommendation. The committee agreed that more evidence was required to make any robust recommendations for micronised progesterone and made a research recommendation.
University Hospitals Dorset	Guideline	063	024	The committee decided that they would put more weight on the observational evidence to support their recommendations, as this was more reflective of the target population" Such an admission is concerning and goes against the normal framework of how NICE operates. It has resulted in a very large well controlled randomised study findings being overlooked in favour of observational data with well known methodological flaws. The totality of the evidence should be reflected in the recommendations as was done in the previous guideline NG23.	Thank you for your comment. In accordance with NICE methodology for reasons of transparency and reproducibility, studies are included and excluded from reviews on the basis of criteria set out in a pre-specified protocol agreed with the committee before a review has been started. When evidence has met the review protocol criteria it is included in the review and the committee consider this evidence when making recommendations. Agreed protocols are also published on the PROSPERO website before the analysis of data commences). The committee discuss the evidence available in the review and use this evidence to support their recommendations. The committee considered the evidence from both RCT and observational data. The RCT data, which included the Women's Health Initiative (WHI), and observational data were consistent for the comparison combined oestrogen and progesterone versus no HRT or placebo, and both showed an increased risk in breast cancer. The committee discussed that the

					RCT evidence from the WHI showed conflicting results to the observational studies, for the comparison of oestrogen-only HRT versus placebo or no HRT. The decision to consider the different population groups between the studies were specific to this outcome since the committee tried to find an explanation for the inconsistent findings. The committee discussed that all observational studies are subject to bias. They discussed that randomised controlled trials are considered to be the gold standard in terms of study design, but that observational studies could provide useful information. As is the case for the observational studies in Evidence Review D, the observational data provides a larger sample size which increases the power to detect rare outcomes such as breast cancer, and also more information on different durations of use with long follow-up periods. The committee reconsidered the wording of the recommendation and have since updated the wording to describe the direction of evidence from both the RCT and observational studies. As a result, the committee discussion of the evidence section in Evidence Review D has been updated to provide details of the discussion that took place. The approach taken is in line with the current NICE methods and processes. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). However, they highlighted that RCT, and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside

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					each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. These and other evidence reviews have been revised to implement these changes accordingly.
University Hospitals Dorset	Guideline	063	029	"transdermal or oral routes of administration." This contradicts the earlier reference to a lower risk for transdermal. We suggest making no distinction between oral and transdermal as the evidence is inconsistent and preferencing one over the other will cause unnecessary alarm and a change in prescribing habits.	Thank you for your comment. The committee considered the evidence for oral and transdermal routes of administration of the oestrogen component of HRT. Since some of the evidence showed a significant difference between the subgroups of oral and transdermal routes of administration in the combined HRT comparison, they had made a recommendation to inform people that the increase was smaller with transdermal than oral. This now also includes a study by Vinogradova (2020) which include data on transdermal versus oral HRT but did not provide greater clarity on this matter. The committee considered this and the Brusseler 2018 evidence and discussed that since the same difference was not observed in the oestrogen-only comparison, the argument was less robust than previously discussed. Upon reflection the committee agreed to remove this recommendation and the rationale section revised accordingly as well and a detailed discussion of the evidence and their decision was updated and can be found in the committee discussion of the evidence section of Evidence Review D. The committee also decided that more evidence is needed to clarify this and prioritised this for a research recommendation.
University Hospitals Dorset	Guideline	064	013	The committee discussed the evidence from randomised controlled trials (RCTs) and 13	Thank you for your comment. The recommendation has been revised to refer to a decrease in endometrial cancer with continuous

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				observational studies. They noted that the evidence from RCTs was uncertain" This is a distorted view of the data. The WHI reported no increased risk of endometrial cancer with continuous combined HRT in a very large sample size with long term follow up. Why is that not included here? The data around endometrial cancer have been so clear for many years that it has not been feasible to do a placebo controlled randomised trial on this subject for decades.	combined HRT and the wording of the rationale has been revised to describe the findings from the WHI RCT.
University Hospitals Dorset	Guideline	064	004	The advice is not informed by new data but relies on reinterpretation of the data that informed NICE 2015 The data have just been interpretated from a different perspective. NICE guidelines should reflect the totality of the data not committee opinion on how best to interpret the data.	Thank you for your comment. The approach taken by the 2015 guideline was different to the 2024 criteria because all evidence was split by whether combined or oestrogen-only HRT was used. In NICE methodology all evidence meeting criteria of a pre-specified review protocol is systematically reviews. These protocols are agreed with the committee and quality assured internally before searches begin to avoid bias (see supplement 1 - methods). This evidence is then discussed with the committee. However, the conclusion and wording in this section has been reviewed and revised to reflect the uncertainty because of the differences between results from different study types (between RCT and observational studies).
University Hospitals Dorset	Guideline	066	011	The evidence for the potential risk of ovarian cancer seems to be derived solely from the observational meta-analysis and does not consider the long term WHI RCT long term follow up data. The WHI RCT showed no difference in the risk of ovarian cancer with HRT. This does not appear to have been considered in the	Thank you for your comment. There was data from 1 RCT that showed more people diagnosed with ovarian cancer in the combined HRT group than in the placebo group at approximately 6-year follow-up. However, the difference did not reach statistical significance because the number of diagnosed cases in both arms was very small (overall 32 people with a diagnosis of ovarian cancer). This made the finding less robust

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				recommendations or mentioned in the discussion. The figures presented in the Tables (page 92) do not support an ongoing increase as referred to in the recommendations. Why did the committee consider the RCT data (no increased risk) and the observational data (very small increased risk at 10 years) and then conclude that HRT increases the risk of ovarian cancer? The most that can be said is that there is uncertainty about whether longterm use may increase the risk. We are concerned about a potential conflict of interest in this section. A co-author on the observational meta analysis on which these ovarian cancer recommendations were based, was on the guideline committee and does not appear to have been excluded from the discussion. We would like a transparent explanation as to why the committee decided to overlook the WHI RCT ovarian cancer data and base their recommendations entirely on the observational meta analysis of which this member was an author.	because of lack of statistical power. The observational studies have both sufficient numbers overall, as well as numbers of people diagnosed with ovarian cancer (there were 2273 people with diagnosed with ovarian cancer in one study alone). The observational studies showed an increased risk of ovarian cancer with combined HRT. The committee agreed that, although the risk was increased overall, the risk was small in absolute terms, especially with the low baseline risk of ovarian cancer. In relation to the duration of use in combined HRT, the subgroup analysis by duration of use was not significant and this was therefore removed from the recommendation. The rationale section of the guideline as well as the committee discussion of the evidence review subsection of evidence review F have been updated with the RCT findings accordingly. For oestrogen-only HRT only observational studies were identified. Subgroup analysis for the impact of oestrogen-only HRT on ovarian cancer in relation to duration of use was statistically significant and therefore the reference to duration of use was retained. NICE has followed its standard methods and processes in developing the 2024 guideline update, including the way in which we manage conflicts of interest in topic experts and committee members. The details of conflicts of interest and how they have been managed are available in the published register of interests.
University Hospitals Dorset	Guideline	066	015	Oestrogen-only HRT very slightly increases the risk of ovarian cancer after 5 years of use and this risk increases with duration of use" The Table shows no increase in risk at 5 years and a slight increase at 10. It cannot be extrapolated that the risk goes up at 5 years, it	Thank you for your comment. Due to the differences in results from RCT and observational studies the related statement in table 2 has been changed to 'There is very little or no increase in breast cancer risk with oestrogen-only HRT, compared to not taking HRT.' and the reference to

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				should say 10. The observational data show no increase with up to 5 years and a very small increase with 10 years use but no data to support the statement that it goes up with increasing duration. The RCT data show no increase in risk at all. Again these data have been selectively interpreted.	duration has been removed. The absolute number table has been changed accordingly. For an explanation for this change see the related rationale section that was updated accordingly as well as the committee discussion of the evidence section of evidence review D.
University Hospitals Dorset	Guideline	067	006	One of the strengths of NICE guidance is looking at the totality of the data and not excluding anything simply because it doesn't suit the argument. We regret that this guideline does not appear to do this. The data on cardiovascular disease show a clear and statistically significant reduction in the risk of cardiovascular disease yet the committee have used their "expertise" to not recognise this or make reference to in the recommendation.	Thank you for your comment. In accordance with NICE methodology for reasons of transparency and reproducibility, studies are included and excluded from reviews on the basis of criteria set out in a pre-specified protocol agreed with the committee before a review has been started. When evidence has met the review protocol criteria it is included in the review and the committee consider this evidence when making recommendations. Agreed protocols are also published on the PROSPERO website before the analysis of data commences). The committee discuss and consider all the evidence available in the review and use this evidence to support their recommendations. The evidence in Evidence Review C consists of data from RCT and observational studies. The committee discussed that the findings between the RCTs and observational studies were inconsistent, with RCT evidence showing no increase or decrease in the risk of cardiovascular disease outcomes, and some of the observational evidence showing a reduction. The committee also discussed the data from the subgroup analyses, which also showed inconsistent findings across the evidence. The committee discussed the limitations across all of the evidence and raised concerns regarding residual confounding in the observational studies

					and some concerns regarding the population in the RCT evidence. Considering the limitations of the evidence, they agreed that the evidence did not support a recommendation that there is a reduction in the risk of cardiovascular disease following HRT use. The committee's discussion of the evidence section in Evidence Review C has been updated to reflect a more detailed discussion of the committee's decision with regard to recommendations for cardiovascular disease risk. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). With regards to the conclusion related to coronary heart disease the independent review concluded 'If considering each forest plot individually, there were subgroups where evidence suggests that HRT appears to be associated with cardiovascular benefits, which have been noted in the stakeholder comments. However, we agree with the committee's interpretation of the evidence, based on the limited power in these analyses to detect subgroup differences, and lack of interpretable trends of effects.' To address the issue of 'limited power' highlighted in this independent review a research recommendation was made to increase the evidence base. However, they highlighted that RCT, and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately

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					in accordance with NICE methodology. These and other evidence reviews have been revised to implement these changes accordingly.
University Hospitals Dorset	Guideline	067	022	"In contrast to this, the committee noted that observational evidence consistently showed an overall decrease in coronary heart disease risk in current users of either oestrogen-only or combined HRT." However despite this very clear and consistent finding in the presented evidence this is not referred to in the recommendations. This should be included in the recommendations based on the evidence presented. It is not clear why on this occasion observational data which show a benefit are overlooked when the committee has chosen to prioritise observational data for negative impacts such as breast cancer. This highlights significant methodological inconsistencies in the way the data have been interpreted and imply a bias within the committee.	Thank you for your comment. The committee considered all of the evidence and did not overlook any evidence that met the protocol criteria and was included in the review. The committee considered each outcome separately and the discussions for each outcome can be found in the committee's discussion of the evidence section of the evidence report for the relevant review. The committee discussed the evidence related to breast cancer separately from the evidence related to cardiovascular disease, as the outcomes in these reviews are difference. The committee noted that whilst confounding is a potential source of bias in all observational studies, the likely impact of confounding on any given association will vary depending on the strength of the association of potential confounders with both HRT and the outcome of interest. Therefore, the committee's discussions around confounders are specific to each review and the outcomes in that review. The committee discussed that the scope for residual confounding of associations of HRT with cardiovascular disease due to inadequate adjustment for confounding factors is likely to be considerably greater than it is for associations of HRT with other conditions such as breast cancer. The committee have chosen to prioritise observational study evidence for some outcomes over others based on the specific concerns of each outcome. The committee's discussion of the evidence in Evidence Review C has been updated to provide more detail on how the committee made recommendations. There is also further detail on

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					residual confounders in the committee's discussion of the evidence section in Evidence Review C. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). With regards to the conclusion related to coronary heart disease the independent review concluded 'If considering each forest plot individually, there were subgroups where evidence suggests that HRT appears to be associated with cardiovascular benefits, which have been noted in the stakeholder comments. However, we agree with the committee's interpretation of the evidence, based on the limited power in these analyses to detect subgroup differences, and lack of interpretable trends of effects.' To address the issue of 'limited power' highlighted in this independent review a research recommendation was made to increase the evidence base. However, they highlighted that RCT, and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. These and other evidence reviews have been revised to implement these changes accordingly.
University Hospitals Dorset	Guideline	067	013 - 021	Long term FU from the WHI RCT showed that there was a reduced risk of coronary heart disease for women starting oestrogen only HRT	Thank you for your comment. The result mentioned in your comment refers to a result in Evidence Review C for the comparison oestrogen-

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				aged 50 to 59. Manson et al 2013 showed significant reduction in coronary heart disease including MI OR 0.67 95% CI 0.46-0.98 with oestrogen only HRT in women aged 50-59. This was presented in the NICE analysis but is not reflected in the recommendations. Why not? This finding is consistent with the Cochrane review (Boardman et al) and the observational evidence (above). This should be reflected in the recommendations. Doctors and their patients need to know that if they start HRT at the time of the menopause, this is likely to be associated with CVD benefit. We agree that HRT should be used for primary prevention, but patients and doctors should be aware of the data.	only versus placebo, outcome coronary heart disease (including MI) in current and past users (unknown recency) with 5-9 years duration of HRT use at 13 years cumulative follow-up, for the age at first use 50-59, which is part of a subgroup analysis that also includes results for age at first use 60-69 and 70-79. The data shows that there is a statistically significant difference in the individual subgroup 50-59 (RR 0.67 (0.46 to 0.98)), but no statistically significant differences for 60-69 (RR 1.01 (0.83 to 1.22) or 70-79 (RR 0.98 (0.79 to 1.23)). However, it is misleading to conclude that there is a difference in effect in different subgroups, because the test for subgroup differences was not statistically significant p=0.17 (please see forest plot figure 77 in Appendix E of Evidence Review C). Therefore, it is misleading to conclude that the reduced effect shown is specific to the age group 50-59. This methodology is in line with the NICE methods and processes and the Cochrane Handbook. As a result, the committee are unable to make a recommendation highlighting any reduced risk in coronary heart disease based on this result. This is further discussed in the committee's discussion of the evidence section in Evidence Review C which has been updated. The Cochrane review (Boardman et al) was assessed for inclusion but was excluded due to the data not being presented separately for combined HRT and oestrogen-only HRT, as specified in the protocol criteria of the review. The included studies in Boardman et al were individually assessed and included where they met the protocol criteria. Boardman et al is listed in the excluded studies section of Evidence Review C. The related rationale section of the guideline has been

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					updated to explain the reason for the exclusion of this review to clarify this matter. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). With regards to the conclusion related to coronary heart disease the independent review concluded 'If considering each forest plot individually, there were subgroups where evidence suggests that HRT appears to be associated with cardiovascular benefits, which have been noted in the stakeholder comments. However, we agree with the committee's interpretation of the evidence, based on the limited power in these analyses to detect subgroup differences, and lack of interpretable trends of effects.' To address the issue of 'limited power' highlighted in this independent review a research recommendation was made to increase the evidence base. However, they highlighted that RCT, and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. These and other evidence reviews have been revised to implement these changes accordingly.
University Hospitals Dorset	Guideline	068	004	"Based on the committee's knowledge" Conclusions should be based on the body of evidence reviewed. Committee opinion should	Thank you for your comment. The committee discuss and consider all the evidence available in the review and use this evidence to support their

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				only be relevant when the data are not clear. In this context the data are conclusive and show a clear and statistically significant reduction in the risk of cardiovascular disease from the analysis conducted by the NICE team, this should not be overturned based on the personal views or knowledge of committee members. The recommendations should be based and mainly guided by what was shown in the evidence reviews. The inclusion of observational data is important in measuring uncommon events and this is true with cardiovascular episodes in women between ages 50-59. In general, observational studies are subject to bias, which is why they are GRADED lower than RCTs, although it appears there have been modifications to the application of GRADE system in this Guideline for reasons that are not entirely clear. It seems that the assessment of bias, which is subjective in itself, is used as justification. The studies adjusted for confounders. This limitation applies in equal measures to all observational evidence reviews including breast cancer and dementia. There needs to be a consistent approach to interpreting the evidence for all systematic reviews undertaken.	recommendations. The evidence in Evidence Review C consists of data from RCT and observational studies. The committee discussed that the findings between the RCTs and observational studies were inconsistent, with RCT evidence showing no increase or decrease in the risk of cardiovascular disease outcomes, and some of the observational evidence showing a reduction. The committee also discussed the data from the subgroup analyses, which also showed inconsistent findings across the evidence. The committee discussed the limitations across all of the evidence and raised concerns regarding residual confounding in the observational studies and some concerns regarding the population in the RCT evidence. Considering the limitations of the evidence, they agreed that the evidence did not support a recommendation that there is a reduction in the risk of cardiovascular disease following HRT use. The decisions made regarding recommendations are supported by the evidence in Evidence Review C and are not based on personal views of committee members. Where the evidence in the reviews is not consistent, or are not conclusive, the committee members may use their knowledge to discuss possible reasons for inconsistency. The committee's discussion of the evidence section in Evidence Review C has been updated to reflect a more detailed discussion of the committee's decision with regard to recommendations for cardiovascular disease risk. The GRADE system has not been modified for this guideline. In general, observational studies are graded lower than RCTs in the GRADE quality assessment, however there are exceptions to this and some observational studies, when assessed

					with specific critical appraisal tools, start off with the same level of quality as RCTs; they then follow the same process for rating each domain as all the evidence. The GRADE domain risk of bias is assessed at study level for each outcome using a critical appraisal tool appropriate to each study design. Where confounders are an issue, they are addressed in the critical appraisal, which is reflected in the GRADE risk of bias parameter and in turn contributes to the overall quality rating. Residual confounding is a bias that remains even after controlling or adjusting for confounders and can be as a result of unknown confounders. It is a potential source of bias in all observational studies, and although the committee refer to the GRADE rating, there may still be residual confounding from unknown factors, or factors that are difficult to adjust for which are discussed and taken into consideration. A consistent approach to analysing the evidence was taken across all reviews, however interpretation can depend on the outcome of interest. The committee discussed that the likely impact of confounding on any given association will vary depending on the strength of the association of potential confounders with both HRT and the outcome of interest. Therefore, the committee's discussions around confounders are specific to each review and the outcomes in that review. The committee discussed that the scope for residual confounding of associations of HRT with cardiovascular disease due to inadequate adjustment for confounding factors is likely to be considerably greater than it is for associations of HRT with other conditions such as breast cancer. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions

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					reached by the committee (with changes made post consultation). With regards to the conclusion related to coronary heart disease the independent review concluded 'If considering each forest plot individually, there were subgroups where evidence suggests that HRT appears to be associated with cardiovascular benefits, which have been noted in the stakeholder comments. However, we agree with the committee's interpretation of the evidence, based on the limited power in these analyses to detect subgroup differences, and lack of interpretable trends of effects.' To address the issue of 'limited power' highlighted in this independent review a research recommendation was made to increase the evidence base. However, they highlighted that RCT, and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. These and other evidence reviews have been revised to implement these changes accordingly
University Hospitals Dorset	Guideline	068	010	'For this reason, the scope for residual confounding of associations of HRT with cardiovascular disease is likely to be much greater than it is for associations of HRT with other health outcomes' This is contradicted by the fact that the same studies showed a significant increase in the risk of stroke with oral intake of oestrogen (and a	Thank you for your comment. Residual confounding is a concern across all observational studies. Residual confounding is the bias that remains even after controlling or adjusting for confounders that are known, and can be caused by unknown confounders, therefore even though the studies adjusted for confounders some concern may remain. The approach to analysing evidence was consistent across all reviews in

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				reduction in CVD) which does not support an issue with significant confounders being not adjusted for. The reference to these limitations appears to be based on an assumption rather than specified omissions noted in the published peer reviewed papers.	terms of methodological processes, however not all outcomes can be interpreted consistently as they will be affected and influenced by difference factors. The committee noted that whilst confounding is a potential source of bias in all observational studies, the likely impact of confounding on any given association will vary depending on the strength of the association of potential confounders with both HRT and the outcome of interest. The guideline rationale section has been revised to focus on similarities and differences between study types. Residual confounding was discussed so it remains in the discussion in this section, but it has been revised to clarify that this was only one of many factors that were considered. The committee's discussion of the evidence in Evidence Review C has also been updated to provide more detail on this matter. With regard to stroke outcomes, the committee discussed that since the RCT evidence, of which there is no concern regarding residual confounders, was in line with the observational evidence, they were able to support a recommendation to advise people of the increased risk of stroke with oestrogen-only HRT. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). With regards to the conclusion related to coronary heart disease the independent review concluded 'If considering each forest plot individually, there were subgroups where evidence

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					suggests that HRT appears to be associated with cardiovascular benefits, which have been noted in the stakeholder comments. However, we agree with the committee's interpretation of the evidence, based on the limited power in these analyses to detect subgroup differences, and lack of interpretable trends of effects.' To address the issue of 'limited power' highlighted in this independent review a research recommendation was made to increase the evidence base. However, they highlighted that RCT, and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. These and other evidence reviews have been revised to implement these changes accordingly.
University Hospitals Dorset	Guideline	068	014	"HRT with cardiovascular diseases should give relatively more weight to RCT evidence, particularly where the findings from observational studies and RCTs are qualitatively different" We agree but this limitation equally applies to all topics where observational evidence is reviewed including breast cancer. The committee appear to prefer to use observational data for breast cancer risks and for cardiovascular outcomes they prefer to use RCT data. Although they give an explanation	Thank you for your comment. The lines you quote in your comment are relevant to this issue of residual confounding. The committee recognised that whilst confounding is a potential source of bias in all observational studies, the likely impact of confounding on any given association will vary depending on the strength of the association of potential confounders with both HRT and the outcome of interest. Therefore, the committee's discussions around confounders are specific to each review and the outcomes in that review. The DOPS study (referenced Schierbeck 2012 in Evidence Review C) was not included in the review as it did not distinguish between oestrogen-

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				(opinion) for this inconsistent approach, it could and should be open to debate. Why has the committee not considered the data from estrogen only WHI and the DOPS trial in formulating the recommendations regarding the reduction in risk of CV disease in younger women using certain types of HRT.	only HRT and combined HRT, which was criteria set out in the pre-specified protocol. The data in Evidence Review C was stratified by age at first use of HRT where possible. The committee discussed the subgroup analysis from the RCT data and since there were no statistically significant subgroup differences, they could not conclude that there was a reduced incidence of heart disease related events when HRT was used at a particular age. The committee also considered the observational study evidence, which was also stratified by age at first use where possible. They discussed that evidence from one study supported a reduced risk in coronary heart disease which was specific to a younger age group, however this pattern was not reflected in another observational study which also presented subgroup data. Since there were inconsistent results between the observational studies as well as inconsistencies between observational and RCT evidence, and no statistically significant subgroup differences in the RCT evidence, the committee could not reach the conclusion that there was a reduced risk of coronary heart disease depending on the age at first use of HR. The related rationale section of the guideline has been updated to explain this in more detail. This committee's discussion section in Evidence Review C has also been revised accordingly. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). With regards to the conclusion related to coronary heart disease the independent

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					review concluded 'If considering each forest plot individually, there were subgroups where evidence suggests that HRT appears to be associated with cardiovascular benefits, which have been noted in the stakeholder comments. However, we agree with the committee's interpretation of the evidence, based on the limited power in these analyses to detect subgroup differences, and lack of interpretable trends of effects.' To address the issue of 'limited power' highlighted in this independent review a research recommendation was made to increase the evidence base. However, they highlighted that RCT, and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. These and other evidence reviews have been revised to implement these changes accordingly.
University Hospitals Dorset	Guideline	068	022	"The evidence showed that, for people with no history of coronary heart disease, there was no increase in mortality from cardiovascular disease from taking HRT and the committee agreed that it was important for people to know this to make an informed choice" Yet there is clear evidence of reduced mortality in the under 60s that is not referred to. The Cochrane review (Boardman et al 2015) showed a significant reduction in CVD and CVD mortality in women who commenced HRT	Thank you for your comment. The evidence in Evidence Review C does not support a reduced mortality from cardiovascular disease following HRT use in those under 60. If considering each forest plot individually, there were subgroups where observational evidence suggests that HRT appears to be associated with cardiovascular benefits. However, the committee's interpretation was that the benefit when starting under 60 was not supported by the evidence, based on the limited power in these analyses to detect subgroup differences, and lack of interpretable trends of

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				under the age of 60. This review was not included. Given the large sample size from RCTs, this is surprising and the findings should be discussed here. No evidence is presented as to why NICE methodology is preferable to Cochrane. The recommendations should be on the body of evidence not committee opinion particularly when the evidence differs from committee opinion. This and other studies (WHI, Schierbeck LL et al BMJ. 2012 Oct 9;345:e6409, PEPI and ELITE Hodis HH N Engl J Med. 2016 Mar 31;374(13):1221-31) have demonstrated cardiovascular benefit for women starting HRT below the age of 60 years. Given the large body of evidence on this topic it is concerning how conservative the guideline is regarding the possibility of cardiovascular benefit with HRT.	effects. To address the limited power a research recommendation has now been included. The Boardman et al 2015 review was assessed for inclusion but was excluded due to the data not being presented separately for combined HRT and oestrogen-only HRT, as specified in the protocol criteria of the review. The included studies in Boardman et al were individually assessed and included where they met the protocol criteria. Boardman et al is listed in the excluded studies section of Evidence Review C. NICE methodology is in line with Cochrane methodology, however where Cochrane reviews do not fit the criteria set out in the pre-specified protocols they cannot be included in the review. The related rationale section of the guideline has been updated to explain the reason for the exclusion of this review to clarify this matter. In relation to the cited RCTs, data from the WHI have been included in the review and data were stratified by age at first use. Analysis showed that the test for subgroup difference was not statistically significant between the age groups for age at first use of HRT, therefore the committee did not conclude that there was a cardiovascular benefit based on this evidence. The data from PEPI trial (referenced Anonymous 1995 in Evidence Review C) was included in the review where the outcomes matched those set out in the protocol, however there was no stratification by age at first use. Schierbeck 2012 was not included in the review as the data was not separated by type of HRT (combined HRT and oestrogen-only HRT), which was a criteria specified in the protocol. The ELITE study was not included in the

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					review as it did not report any outcomes that matched those specified in the review protocol. The reasons for exclusion for these studies have been listed in the excluded studies section in Evidence Review C. NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). With regards to the conclusion related to coronary heart disease the independent review concluded 'If considering each forest plot individually, there were subgroups where evidence suggests that HRT appears to be associated with cardiovascular benefits, which have been noted in the stakeholder comments. However, we agree with the committee's interpretation of the evidence, based on the limited power in these analyses to detect subgroup differences, and lack of interpretable trends of effects.' To address the issue of 'limited power' highlighted in this independent review a research recommendation was made to increase the evidence base. However, they highlighted that RCT, and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. These and other evidence reviews have been revised to implement these changes accordingly.

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University Hospitals Dorset	Guideline	072	016	**"**However, the committee reached a majority decision. Taking all evidence into account, they decided the evidence pointed towards a possible increased risk in dementia incidence, particularly with results showing increased risk when started at a later age. They agreed it was important that people considering HRT for troublesome menopause symptoms should be made aware of the potential risk, so that they could make an informed decision" The data referred to here is for women who started HRT at the age of 65 or above (The WHIMS study). The wording should reflect this to avoid any public misunderstanding. The current wording is misleading as it does not specify that it is only for women who start HRT over the age of 65. It is concerning that in discussing the limitations of the WHIMS trial the committee regarded the age group of the trial (65 years or over) as only "slightly different from typical users of HRT" (Page 73 Line 8) yet there is clearly a considerable difference in these age cohorts. We would like further clarification as to why the committee decide to focus on the Danish and WHIMS trials in making their recommendations. After all, they accepted that the population in WHIMS did not represent a typical HRT using population in most countries and in the breast cancer data one of the arguments for not using the RCT data was that it did not represent a typical HRT population (mean age 63). There needs to be consistency and transparency in the way data are treated.	Thank you for your comment. The wording in the guideline ' Taking all evidence into account, they decided the evidence pointed towards a possible increased risk in dementia incidence, particularly with results showing increased risk when started at a later age' has been removed and now only refers to an initialisation of HRT after the age of 65 as in the RCT findings. The word 'slightly' was also removed in the phrase 'slightly different from a typical user of HRT' in relation to starting HRT after the age of 65. The committee did not focus on the observational Danish study to inform recommendations. The committee noted that the results from the observational Danish study were in line with the findings from the RCT data (WHIMS), however they agreed that both the observational Danish study and the observational UK study had limitations. The committee discussed that the observational data were inconsistent, and since the studies did not adjust for all the relevant confounders, the committee could not decide in which direction there may have been bias. Therefore, the committee used the RCT data to inform their recommendations. See the related rationale section of the guideline and the committee's discussion of the evidence section of Evidence Review G for more detail. Thank you for highlighting Nerattini et al 2023. This systematic review was not included in Evidence Review G, as it was published after the cut-off date. Some of the studies in this systematic review do not meet our protocol criteria which specifies that data on HRT should be separated into oestrogen-only and combined HRT, therefore this systematic review would not have been included as a whole. The individual studies were also checked against our

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				As far as the Danish trial is concerned this only showed association with HRT and could not prove causation. This population could have been at increased risk of cognitive problems anyway. Also, the types of HRT used in this trial have largely been superseded by the more natural types of hormone therapy, particularly with transdermal estradiol and micronized progesterone which are less pro thrombotic and more metabolically favourable. We question why NICE has placed so much emphasis on a small Danish study yet overlooked the much larger UK general Practice CPRD study by Vinogradova et al 2021. This study included a total of 118,501 women diagnosed with dementia and 497,416 female controls. The latter study was from a UK population and the full data were presented with more detailed presentation of the adjustments and did not show an overall increase in the risk of dementia. A further significant limitation of the Danish study, was that the HRT user group in the study had significantly higher prevalence (compared to the control group) of lower level education, lower household income, and were more likely to live alone and to have hypertension, diabetes, and thyroid disease – all risk factors for dementia. The recent systematic review should be included in the data analysis. Nerattini M, et al (2023) Systematic review and meta-analysis of	protocol criteria, and of the ones that met the protocol criteria were already included in the review. Most of the studies included in the Nerattini systematic review that do not meet the protocol criteria have already been listed in our excluded studies list in appendix I of Evidence Review G.

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				the effects of menopause hormone therapy on risk of Alzheimer's disease and dementia. Front. Aging Neurosci. 15:1260427	
University Hospitals Dorset	Guideline	074	017	"The committee considered the possibility that, like premature ovarian insufficiency, early menopause may either increase or decrease the baseline risk of some health outcomes" We are very concerned as to why no mention is made here to the large observational evidence of adverse effects of early menopause on bone, cardiovascular and cognitive health. The guideline refers to 'early menopause being somewhere in between POI and menopause at and above the age of 45', this is implying (but does not specifically mention) the adverse effects that POI and early menopause have on bone, cardiovascular health and cognitive function in women. We believe this should be clearly mentioned to help guide healthcare professionals as well as the lay public.	Thank you for your comment. The aim of the evidence review carried out for the 2024 guideline update was assessing the impact of HRT on people with early menopause and the development of various health outcomes. The need to assess the impact of early menopause on health outcome has been acknowledged and will be passed onto the NICE surveillance teams for prioritised consideration during future updates.
University Hospitals Dorset	Guideline	075	003	"Evidence showed an increased risk of breast cancer for people with early menopause who used HRT compared to those not using HRT. The committee decided that it was important to explain this to people" This should clearly state that this is compared to women with early menopause not taking HRT who have a lower risk of breast cancer not to age matched premenopausal controls.	Thank you for your comment. This sentence has been removed.
University Hospitals Dorset	Guideline	083	001	Table Column 2 - "Replaced by the following statements in tables 1 and 2: Combined HRT may increase risk of dementia if started over the age of 60"	Thank you for your comment. This is in reference to the update table. The relevant recommendation stated 65 and the update table has been revised accordingly.

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				This is inaccurate: the recommendation (based on WHIMS) states over 65. WHIMS did not include women under 65. This needs to be amended.	
University of Essex	Guideline	006 - 007	011 - 015	(1.2.1 – 1.2.5) There is still confusion with practitioners on doing blood tests for diagnosing – this section might consider clearer direction for the management of this. On assessment a holistic approach is required to consider the whole range of menopause symptoms.	Thank you for your comment. The use of blood tests in the diagnosis of menopause was not in the scope of this guideline update. Evidence for this topic was therefore not searched for and not reviewed and discussed with the committee. The committee could therefore not comment on this.
University of Essex	Guideline	004	005	There needs to be a clear inclusive recognition of "others" who may experience symptoms of the menopause. These include people in transition or transgender. The language needs to be clearly inclusive.	Thank you for your comment. The guideline's introduction states that the guideline covers women, trans men and non-binary people registered female at birth. For accuracy, some of the recommendations need to list all groups. Elsewhere, the term 'people' is used to be inclusive and concise. This is used in reference to people for whom it has already been identified that their symptoms are associated with the menopause.
University of Essex	Guideline	008	012	1.3.1 Explanation of the stages of menopause – could the link be embedded here to help direct practitioners when discussing women's health across the life course link here	Thank you for your comment. Links to governmental health strategies are generally not included in guideline text. However, NICE is planning implementation support which is likely to include references to such sources.
University of Essex	Guideline	008	021	1.3.2 There are clearly more symptoms than this – the Menopause Rating Scale (MRS) lists 12 but there are clearly evidence of more symptoms and should be listed. These should be listed because of the overlap with other conditions and similarities. There is very little mention of dry eye syndrome, itching and dry skin. Other	Thank you for your comment. Whilst an update of the list of symptoms and experiences (for the purposes of diagnosis and appropriate treatment) was outside the current scope of the 2024 guideline update and therefore no evidence review was conducted, the NICE surveillance team checks regularly for new evidence for topics within guidelines to see where further work is needed.

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				symptoms increasing more than vasomotor symptoms is brain fog and fatigue. This is a useful charity with evidence based links – The Menopause Charity.	
University of Essex	Guideline	008	024	1.3.3 There has to be clearer guidance on helping those with symptoms to TRACK them. The practitioner needs more information and should enable the person to do this – either on an app, phone, watch, diary and so on. Tracking symptoms helps builds a picture for the person.	Thank you for your comment. Identifying perimenopause and menopause (including symptom tracking) was not in the scope of the 2024 guideline update. Evidence for this topic was not searched for and not reviewed and discussed with the committee. The committee could therefore not comment on this.
University of Essex	Guideline	008	027	1.3.4 TALK – for 1.3.4 more information needed i.e. local menopause cafes but the person needs to talk to those around them to make them aware. Workplaces are also providing support and since the working population is living longer these symptoms need to be managed at work. Research includes qualitative research on facilitating coping and discomfort for nurses experience menopause in the workplace paper 1 and paper 2 looks at Menopause at work – An organisation-based case study with further global guidance here from EMAS. (European *Menopause* and Andropause Society).	Thank you for our comment. Based on the content of the feedback, it appears to refer to recommendation 1.2.4 rather than 1.3.4, which concerns the sharing of information. How people experience the menopause and what peer or other support they require is outside the scope of the 2024 guideline update. Evidence for these topics was not searched for and not reviewed and discussed with the committee. The committee could therefore not comment on this.
University of Essex	Guideline	010	008	1.4.1 In order to adapt the person needs to TRACK their symptoms to help. Symptoms change. See BLOG here for TRACK, TALK, TREAT. There are apps etc but each person is different so apps or diaries or phones, and watches.	Thank you for your comment. Identifying perimenopause and menopause (including symptom tracking) was not in the scope of the 2024 guideline update. Evidence for this topic was not searched for and not reviewed and discussed with the committee. The committee could therefore not comment on this.
University of Essex	Guideline	010	012	1.4.2	Thank you for your comment. The effectiveness of lifestyle or other adjustments (such as fans or

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				Many women suffer from vasomotor issues and there is no discussion about managing the discomfort – fans and cotton clothes. Encouraging talking to others to open discuss and workplaces can help with environment and uniforms. Many women do not want to take medication, and many cannot so the management part needs clearer options.	cotton clothes) was not in the scope of the 2024 guideline update. Evidence for these topics was not searched for and not reviewed and discussed with the committee. The committee could therefore not comment on this.
University of Essex	Guideline	011	016	1.4.5 In this section on mood, low mood, or anxiety there is no mention of green exercise, meditation or other strategies before medication. This is an important aspect and clearer guidance should be given. Physical exercise e.g. walking, yoga helps with ageing well. No cost with this but assisting in understanding the changes that do occur and how exercise can help balance the majority of symtoms. However there are cases when the person does need help and early intervention would resolve complex issues and mental health issues should not be ignored.	Thank you for your comment. The effectiveness of green exercise, meditation and other physical exercise in the management of menopause was not in the scope of this guideline update. Evidence for these topics was therefore not searched for and not reviewed and discussed with the committee. The committee could therefore not comment on them.
University of Essex	Guideline	012	015	1.4.9 Vaginal atrophy and changes – this needs to be clearly articulated including vaginal dryness and itching of which there is no mention of this. This would help more to discuss embarrassing situations and alleviate discomfort. A pharmacist can be consulted for over the counter products. Vaginal pessaries should be encouraged more. There is less cost in terms of resources, GP time, and prescription.	Thank you for your comment. A definition of genitourinary symptoms has been added which clarifies that this includes vulvovaginal dryness, pain with sex, vulvovaginal discomfort or irritation, and discomfort or pain when urinating. NICE usually does not specify which healthcare professional would be consulted for this and the committee are aware that there are over the counter products. The committee decided to use a person-centred approach with regards to the type of formulation of vaginal oestrogen and recommended making a shared decision with the person about whether to use an oestrogen cream,

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					gel, tablet, pessary or ring. This is because there was no difference in effectiveness and not all people would prefer pessaries over a cream.
University of Essex	Guideline	014	010	1.4.18 Every contact counts – at cervical screening there should be mandated to discuss menopause. In my experience as a practice nurse early signs of perimenopausal symptoms can be picked up, discussed and other symptoms picked up. Simple tools can be given so the person so they can start to track. Menopause Support Pack downloadable here. The poster is useful for practitioners and has different languages. I used this a lot when screening women. There in really no cost here.	Thank you for your comment. It was not in the scope of the 2024 guideline update to identify opportunities for discussions and therefore they could not recommend details related to this. However, the guideline recommends a person-centred approach with tailored discussions that could be had with any healthcare professional with appropriate skills such as someone carrying out cervical screening.
University of Essex	Guideline	021		1.5.12 Weight bearing exercises and physical exercises not mentioned here and should be encouraged.	Thank you for your comment. The effectiveness of weight bearing exercise was not in the scope of the 2024 guideline update. Evidence for this topic was therefore not searched for and not reviewed and discussed with the committee. The committee could therefore not comment on this.
Wellbeing of Women	Guideline	General	General	We felt that the press release was misleading and caused unnecessary anger and distress for women: 1. The advice regarding 'offering' HRT has not changed and nor has the advice regarding CBT, but many didn't understand this and instead interpreted it as another blockade to accessing HRT. Women feel they should be able to get HRT if they need it without fighting battles with their GP who often knows very little about the topic. It is a subject we hear from our case studies	Thank you for your comment. NICE acknowledges that choosing key messages for press releases is complex and that lessons have been learned from this. The committee reflected on the wording of the recommendations related to CBT and updated it to make it explicit that this is optional. It is now clarified that CBT is an option (1) in addition to other treatments (including HRT) (2) for people in whom other treatments are contraindicated or (3) for people who prefer not to have other treatments. The recommendation on a discussion about CBT as a treatment option has also been updated to highlight that information about what CBT is (including menopause specific CBT) and to take

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				and in our forums frequently: *"I'm on a lot of menopause groups and women are suffering because GPs will not prescribe HRT they have very little training and don't have the time to listen and follow up appointments." – From online support group.* 2. With menopause remaining a 'taboo' subject and the continued dismissal in society, the recommendation for CBT needs to be very carefully framed. Many women saw this as a continuation of 'gaslighting' and harmful stereotypes of symptoms being 'all in your head' or derogatory comments around women being crazy. The guidelines and communications around any updates should be mindful of this. When having conversations with women about CBT, GPs should be advised to fully explain the context, validate symptoms, and reassure their patients. It is important to note that some women will want CBT (when available as few will start with self-teach methods) but many feel hormones are the best option for them and we felt the communications were misbalanced in their representation of HRT.	account of the person's preferences and needs. Having information about the principles of CBT (including menopause-specific CBT) will help people make an informed choice that is right for them. The evidence was uncertain in relation to anxiety associated with the menopause and the committee therefore did not comment on this. Where a diagnosis of depression is suspected the pathway of the NICE guideline on depression in adults should be followed.
Wellbeing of Women	Guideline	General	General	We welcome shared decision making and the encouragement of this within the guidelines however this is a difficult ask within a 10-minute appointment slot. It will be vital to develop lay-friendly resources that patients can be given	Thank you for your comment. Based on the numbers in the appendix of the consultation a discussion aid document has been developed which includes data visualisation as well as a verbal description of what the numbers mean.

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				during an initial appointment, or they can access at home, to be able to fully consider their options before having a meaningful conversation. Infographics can be helpful as long as the figures in them are correct and context provided that figures are approximate and based on a trend in results in various publications. Any resources developed must take into consideration the needs of marginalised communities – factoring in digital access and literacy, language barriers, and cultural/religious sensitivity.	Descriptions of the underlying concepts and calculation are also provided. This includes estimates and uncertainties. Since this document includes visualisations of data in arrays it is suitable for members of marginalised communities and all NICE products have to adhere to accessibility standards. This discussion aid has undergone user-testing and was refined based on user feedback.
Wellbeing of Women	Guideline	General	General	It is a very positive shift that GPs are increasingly encouraged to refer patients to a healthcare professional with expertise in menopause. Our concern is that access to these professionals is extremely limited and there isn't the resource to meet this demand on the NHS. It is vital the guidance doesn't create a socioeconomic care divide. Those with complex health needs are more likely to be those without resources to afford private care.	Thank you for your comment. The definition of 'healthcare professional with expertise in menopause' is not mandating that these professionals are in tertiary centres. They have been defined as professionals with specialist knowledge, skills and training (for example as recognised by the British Menopause Society, the Faculty of Sexual and Reproductive Healthcare or the Royal College of Obstetricians and Gynaecologists) who can advise and support colleagues in managing complex menopause-related needs and risk factors affecting decision-making....'. Therefore, this could also be a GP with a special interest in menopause who have undertaken further training. This broader definition would mean a wider pool of such professionals with a positive impact on waiting times.
Wellbeing of Women	Guideline	General	General	We would like to know if there are any plans to update the guidance to include recommendations on Fezolinetant, marketed as Veoza, which has been approved by the Medicines and Healthcare Products Regulatory Agency (MHRA) for moderate to severe	Thank you for your comment. Fezolinetant was not part of the scope of this guideline. However, NICE is conducting a Health Technology Appraisal of Fezolinetant. Once completed it will then be considered how this may be included in the Menopause guideline.

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				vasomotor symptoms associated with menopause. We feel this is an urgent need for women who can't, or don't want to, use HRT to manage their symptoms and we are concerned that is only accessible privately and leaving out those who may be in most urgent need of the medication.	
Wellbeing of Women	Guideline	General	General	We have concerns around conflict of interest relating to the Guideline Development Group for the menopause guidelines. We recognise that NICE considers relationships with the pharmaceutical industry but needs to do more to consider conflicts or bias within the academic research community. We feel it is likely that this can make objective assessment of other publications difficult. Consequently, we felt it was inappropriate to have the PI of a major study such as the Million Women Study (MWS) on a Guideline Development Group and taking part in the discussions, as this conflict might bias the findings exactly as relationships with pharma are supposed to do (based on no evidence we have ever heard of). Complex statistics are very difficult for the average clinician and researcher tlet alone the lay public to understand. We are concerned that this may impact on some of the advice and frighten women unnecessarily.	Thank you for your comment. NICE has followed its standard methods and processes in developing the 2024 guideline update, including the way in which we manage conflicts of interest in topic experts and committee members. The details of conflicts of interest and how they have been managed are available in the published register of interests.
Wellbeing of Women	Guideline	General	General	It is positive to see that CBT has been added as a treatment option for menopausal symptoms but we are concerned about resourcing and genuine access to treatment. Mental health services are already suffering with long waiting lists.	Thank you for your comment. Taking into account current pressures on services, your comment will be considered by NICE where relevant support activity is being planned.

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Wellbeing of Women	Guideline	023 - 034	Tables 1 and 2	Women are extremely worried about risks related to HRT causing other diseases. We feel these tables give an over-simplified and mis-representative view and could be very harmful for any doctor or woman who reads these without context, understanding of risk statistics and/or willingness to read and understand the underlying data (we also have concerns with this data as presented later). Our primary concern is an over-reliance on these tables and presentation of a worrying and simplified picture re. 'HRT increases risk of cancer, dementia and stroke', which could be a significant deterrent to women using HRT. We don't think it's reasonable to expect GPs working in an overburdened health system to find more accurate and nuanced data to present to patients as some are likely to be at greater risk of particular diseases than others. Better data tables with detailed and balanced information are needed for GPs to be able to discuss this with their patients in a short time. This should be generated and provided in a lay-friendly format that women can take away to consider their options rather than trying to do everything in one appointment. From our communities: *"I'm using them [HRT] but don't really like the thought of using hormones. Are they safe?"* *"At this point I'll consider HRT if others can convince me it's safe. I fear cancer risks."* From GP: *"I wouldn't click through to read the underlying data sources as they're too complicated and*	Thank you for your comment. In NICE methodology all evidence (meeting pre-specified protocols that are agreed with the committee and separately quality assured before the data is searched for), is systematically reviewed and presented to the committee who have drawn conclusions from it. The wording within the tables has been reviewed and no longer start with 'HRT increases' but focused on risk that is increased with HRT which was considered to change the tone of the tables. For the draft guideline, the committee opted for a verbal format complemented by tables, providing estimates of absolute numbers from a single source rather than from two different study types. This decision was made to facilitate conversations between clinicians and individuals, enabling shared decision-making regarding Menopause management. In the consultation absolute numbers per 1000 people for each health conditions were presented for people who have taken HRT compared to people who have never taken HRT for symptoms of menopause. Based on the numbers in this appendix a discussion aid document has been developed which includes data visualisation as well as a verbal description of what the numbers mean. This document can be used in shared decision making between the person and the healthcare professional to facilitate making treatment choices. This discussion aid has undergone user-testing and was refined based on user feedback.

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				take too long. I use other resources to understand the details of risk – like the risk of HRT compared to obesity for instance - that are quicker and easier to process. Not all GPs would do extra reading though, some would just state what's written in these tables"	
Wellbeing of Women	Guideline	010 - 011	026 - 005	1.4.3 We agree that the risks, benefits, and duration should be discussed. We don't feel that the tables referenced (table 1 and table 2) are adequate information for an informed conversation and would generate a strong and disproportionate fear response to HRT (i.e. being told HRT increases risk of cancer, dementia and stroke without further context). Better data tables with detailed and balanced information are needed for GPs to be able to discuss this with their patients. This should be generated and provided in a lay-friendly format that women can take away to consider their options rather than trying to do everything in one appointment.	Thank you for your comment. The recommendation referred to in this comment has been reworded to focus more clearly on possible duration of treatment, re-discussing continuing treatment at every review and the option of restarting treatment if necessary. Since the focus of this recommendation has changed, the links to the tables were removed. On the general point raised about data presentations in the tables a discussion aid document has been developed using the data in the appendix of the consultation version. This includes visualisation of the extent of risks for specific health outcomes in a lay friendly way and could be taken away by people to look at in detail before making a shared decision with the healthcare professional. This discussion aid has undergone user-testing and was refined based on user feedback.
Wellbeing of Women	Guideline	007	010 - 011	We feel there needs to be a clearer reference for why HRT is considered in women with early menopause in the first instance and we feel this is important for the women affected to understand. This should cover the significantly increased risk of CVD and osteoporosis in women with early menopause due to oestrogen deficiency and reference HRT being considered in clinical practice in this situation to counter that effect.	Thank you for your comment. The need for evidence reviews in the area of early menopause has been acknowledged, particularly for the risks of early menopause on health outcomes, and subsequent management options (including HRT). This has been logged with the NICE surveillance team for consideration when conducting future updates.

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				We had understood that the evidence of adverse effect of oestrogen deficiency in this group being *uncertain* is inaccurate and does not appear to acknowledge research in this area. Experts have informed us of the increased risk for cardiovascular disease and osteoporosis. The interpretation of this evidence in guidelines globally is to offer HRT in this group until the natural age of the menopause. We are aware of a large trial comparing two types of hormonal preparations rather than hormones to placebo for these reasons. We have been advised that for both topics - early menopause and POI - there are large studies showing an increased risk of osteoporosis and related fractures, cardiovascular disease, cardiovascular mortality, type 2 diabetes and increase in all-cause mortality. For both topics, however, there is lack of evidence assessing the effect of hormone replacement on these outcomes.	
Wellbeing of Women	Guideline	008	024	1.3.3 We are pleased to see inclusion of information/awareness of differences in menopause onset for those from ethnic minority backgrounds. We know that women from ethnic minority backgrounds are less likely to engage in health-seeking behaviours, which is driven by historical mistreatment and significant barriers within health systems. Clinicians should be encouraged to practice culturally sensitive communication, offer translators if needed, and provide resources or signposting to	Thank you for your comment. Identification of the menopause was outside the scope of the 2024 guideline update. Recommendation 1.3.3 was a consensus recommendation made in the context of a discussion related to the effect of either taking or not taking HRT in early menopause. Therefore, a full search was not conducted for prevalence of early menopause or average age of menopause in different groups of people. This is why the current wording was used rather than a more active or direct wording with a detailed age or action associated with this information. The committee's

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				organisations that can that meet the needs of these women.	aim was to raise awareness about this so that both clinicians and women from minority backgrounds could initiate conversations about this earlier if they may experience signs and symptoms of the menopause. The committee acknowledge that this needs to take place in a person-centred way and have cross referred to the NICE guideline on patient experience in adult NHS services and the NICE guideline on shared decision-making. For example the patient experience guideline highlights that healthcare professionals should ensure that factors such as physical or learning disabilities, sight, speech or hearing problems and difficulties with reading, understanding or speaking English are addressed so that the patient is able to participate as fully as possible in consultations and care. It also includes recommendations related to culture and beliefs. These recommendations do not have to be repeated in all other NICE guidelines.
Wellbeing of Women	Guideline	035 075	010 003 - 005	Our understanding is that women who go through an early menopause have a lower risk of breast cancer than either those on HRT or those in the same age bracket who still have periods. Surely the comparator group should be the girls with periods?	Thank you for your comment. The section on early menopause has been revised and only the message to explain to people experiencing early menopause that, for them, the benefits and risks of either taking or not taking HRT are likely to lie between those for people with premature ovarian insufficiency and those for people aged 45 or over has been retained from the consultation version. In accordance with the systematic review protocol only evidence on breast cancer was identified but it was decided that this highlighted that further research is necessary to clarify the benefits and risks. The committee also noted that the focus of this topic was too narrow to cover early menopause adequately and suggested several topics that based on stakeholder feedback which

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					were logged with the NICE surveillance team for future consideration in an update. This also includes the topic of the impact of early menopause itself on various health outcomes and what the best options are to manage potential negative impact. However, this was not part of the 2024 guideline update and so the committee could not comment on this.
Wellbeing of Women	Guideline	061	010	It should be made clear that the impact of HRT is less in women who are overweight than in lean women. Since obesity is on the increase, we're concerned that the figures quoted are irrelevant to today's women.	Thank you for your comment. The committee decided it was generally good clinical practice to encourage a healthy lifestyle and changed to wording to indicate that the absolute risk of HRT may be different in those with a greater risk of breast cancer to start with. The interpretation of evidence that the increased risk of breast cancer was lower in those with a higher BMI is complex because it is still an increase from a higher baseline for the individual woman with a high BMI (which is higher because their breast cancer risk already is higher than that of people with a BMI in the normal range who have a lower risk to start with).
Wellbeing of Women	Guideline	061	025	The old guideline said that some trial evidence didn't report an increased risk of breast cancer with less than one year of HRT use, it is also unlikely from a biological perspective.	Thank you for your comment. The analysis of HRT and BC risk in the Million Women Study (which is included in this analysis) excluded all women with any record of breast cancer prior to recruitment. Obviously there will be some participants with undiagnosed/pre-clinical breast cancer at the start of follow-up but this is likely to be true of all observational studies (and probably some trials). Whilst it may have been the case that cancers diagnosed very soon after recruitment were present to some degree at recruitment, this does not invalidate the comparisons between HRT users and non-users in terms of subsequent breast

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					cancer risk. All women who entered the study reported on HRT use prior to coming for screening (and hence before they had any knowledge of any abnormalities) and all women who were recruited had a routine screen at entry and so would have had the same opportunity of getting any pre-existing disease diagnosed. Thus, the observation of an increased risk of breast cancer in HRT users– even in a relatively short period after recruitment– should be robust and is likely to reflect an association between HRT and increased risk.
Wellbeing of Women	Guideline	063	029	If transdermal oestradiol appears safer than oral, we'd like further clarification as to why it's not recommended as a first line treatment.	Thank you for your comment. Within combined HRT there was some evidence that the increase was smaller with transdermal than with oral HRT, however this finding was not replicated in oestrogen-only. A further study was included which did not provide greater clarity on this. The committee therefore decided to remove the statement related to route of administration altogether from the breast cancer section and agreed prioritise this for a research recommendation. This would also avoid any confusion related to safety because both routes increased the risk.
Wellbeing of Women	Guideline	066	011	We feel the very small numbers of cases do not justify the strength of the conclusions. The figures and recommendations appear to make no consideration or reference to the full literature and we are aware that it showed no increase in the risk of ovarian cancer with HRT (oestrogen only or combined). The oestrogen only should make reference to women with ovaries as women who would have	Thank you for your comment. The RCT (with a follow-up of 5.6 years) had higher numbers of women with ovarian cancer in the HRT group compared to the no HRT group, but this was not statistically different. It was discussed that this was most likely due to the low number of people diagnosed with ovarian cancer (overall 32). The observational studies had both a larger population as well as more people diagnosed with ovarian cancer (over 2000 people diagnosed with ovarian

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				had their ovaries removed would have a significantly lower risk.	cancer) therefore higher statistical power to find differences. The committee therefore concluded that there was an increased risk with combined HRT but that this was a 'very slight increase' overall given the low baseline risk. The rationale has been amended accordingly.
Wellbeing of Women	Guideline	067	013 - 022	We are concerned that some of the clear and consistent evidence related to a decreased coronary heart disease risk with HRT has not been included in the recommendations. It is important that doctors and their patients should know that while they are taking HRT they are likely to have a cardiovascular disease benefit. The reduced risk of coronary heart disease for women starting HRT aged 50-59 should be reflected in the recommendations	Thank you for your comment. The reduced risk mentioned in your comment refers to a result in Evidence Review C for the comparison oestrogen-only versus placebo, outcome coronary heart disease (including MI) in current and past users (unknown recency) with 5-9 years duration of HRT use at 13 years cumulative follow-up, for the age at first use 50-59, which is part of a subgroup analysis that also includes results for age at first use 60-69 and 70-79. The data shows that there is a statistically significant difference in the individual subgroup 50-59 (RR 0.67 (0.46 to 0.98)), but no statistically significant differences for 60-69 (RR 1.01 (0.83 to 1.22) or 70-79 (RR 0.98 (0.79 to 1.23)). However, it is misleading to conclude that there is a difference in effect in different subgroups, because the test for subgroup differences was not statistically significant p=0.17 (please see forest plot figure 77 in Appendix E of Evidence Review C). Therefore, it is misleading to conclude that the reduced effect shown is specific to the age group 50-59. This methodology is in line with the NICE methods and processes and the Cochrane Handbook. As a result, the committee are unable to make a recommendation highlighting any reduced risk in coronary heart disease based on this result. This is further discussed in the committee's discussion of the evidence section in Evidence Review C which has been updated.

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					NICE commissioned an independent review of the breast cancer and cardiovascular evidence reviews and these checks support the conclusions reached by the committee (with changes made post consultation). With regards to the conclusion related to coronary heart disease the independent review concluded 'If considering each forest plot individually, there were subgroups where evidence suggests that HRT appears to be associated with cardiovascular benefits, which have been noted in the stakeholder comments. However, we agree with the committee's interpretation of the evidence, based on the limited power in these analyses to detect subgroup differences, and lack of interpretable trends of effects.' To address the issue of 'limited power' highlighted in this independent review a research recommendation was made to increase the evidence base. However, they highlighted that RCT, and observational study evidence should be discussed separately and given equal prominence throughout. The independent review also recommended that evidence from both study types should be added into the forest plots alongside each other where possible, so that a visual comparison of findings is easier. RCT and observational evidence is still analysed separately in accordance with NICE methodology. These and other evidence reviews have been revised to implement these changes accordingly.
Wellbeing of Women	Guideline	072 096	General Table 12	The recommendation presented by NICE refers to an increase in risk in women who first start HRT at the age of 65 and above. In our experience of what women tell us, few start it at that age. The vast majority of users would have started before 65 and these figures would	Thank you for your comment. For ages below 65 there was no clear evidence whether or not HRT increased risk of dementia. One study showed no difference whereas another study showed an increase in incidence of dementia. Given these discrepancies and potential for confounding in

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				therefore not apply to them and could be misleading to both the public and their GPs. Dementia is not a single entity and has a variety of causes. We'd suggest the recommendation should be less strong. As with all discussions of HRT, it should be clear that the significant positive impact can have on quality of life be balanced with risks.	observational data, the committee based this recommendation on the available RCT data with participants that started HRT over the age of 65 and decided not to comment on people initiating HRT earlier. Where data were divided by duration of use the pattern was unclear with one study showing no difference and the other an increase. The committee therefore decided not to comment on duration of HRT use beyond the age of 65. This is described in the rationale section. The committee decided to retain the 2015 research recommendation on the effects of HRT on dementia.
Wellbeing of Women	Guideline	074	017 - 019	It is concerning that no background reference is made to the adverse effect of early menopause on bone, cardiovascular and cognitive health and we would like to see some reference to this effect included here. We understand that there is a lot of evidence that shows an adverse effect on bone (including osteoporosis and fractures), cardiovascular disease and cognitive function in both these groups. This should be referred to in this section. GPs and their patients will want to know about all of the evidence in a simple summary. When NICE refers to '*early menopause being somewhere in between POI and menopause at and above* the age of 45', is not really helpful unless the adverse effects of POI are included.	Thank you for your comment. The aim of the evidence review carried out for the 2024 guideline update was assessing the impact of either taking HRT or not taking HRT on people with early menopause and the development of various health outcomes. The need to assess the impact of early menopause on health outcome has been acknowledged and will be passed onto the NICE surveillance teams for prioritised consideration during future updates.
Wellbeing of Women	Guideline	097	Table 16	This should clearly state the control group are women with early menopause who have a	Thank you for your comment. The comparison addressed in the related evidence review is women with early menopause taking HRT versus

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				significantly lower risk of breast cancer (not age matched premenstrual women). Table 17 showed that women aged 40 who took HRT for 10 years had a similar risk of breast cancer to women who did not take HRT. The recommendations should clearly reflect these findings.	women in early menopause not taking HRT. Whether or not women in early menopause have a lower risk of breast cancer to start with was not the focus of the question posed. In table 17 (related to oestrogen-only HRT) differences are statistically significant even if in one of them the difference is too small to show up as a difference per 1000. The committee reflected on this and decided that the limited evidence identified (only evidence for breast cancer incidence) was a reason for a research recommendation in this area and removed the reference to this from the recommendation. Topics related to early menopause that were mentioned as important by stakeholders and were not addressed in the 2024 guideline update were logged with surveillance so that they could be considered for future updates.
Wellbeing of Women	Guideline	088 – 099	All tables general comment	As GPs or patients reading this data may not have specific complex statistics knowledge, it should be made clear that these are single figures from 1 publication. Surely, there should be a range of some sort given. Women are likely to understand the need for this. The actual numbers themselves may be lower or higher and we believe this should be made clear to the reader. We also would like the data sources to be clear for all tables and figures.	Thank you for your comment. The appendix has been used to produce a discussion aid document including visualisation of the data. The purpose of this is to facilitate shared decision-making between the person and the healthcare professional. This provides details about the type of evidence data originated from, how to interpret the numbers and information about uncertainty. It also links to the relevant evidence reviews which contain details of the estimates from different study types as well as the confidence intervals. It also includes links to a separate supplement file which provides the details of each calculation. This discussion aid has undergone user-testing and was refined based on user feedback.
Women's Rights Network (WRN)	Equality impact assessment	General	General	The EIA has not properly considered whether "inclusive" language does in fact "promote [...] effective communication with everyone". It is	Thank you for your comment. Using inclusive language in healthcare is important for safety, and to promote equity, respect and effective

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				the view of the WRN that it actually makes the document more difficult and confusing for the majority of people to read and accurately understand. Research suggests using confusing language has a negative impact on healthcare of women (3). WRN considers that a further impact assessment on women's needs should be undertaken. This further assessment should specifically address the experience of women with learning disabilities, women with low literacy and women whose first language is not English. These women have specific communications needs as set out in the NHS England Accessible Information Standard (4). The implementation guidance for this Standard clearly states that people are at risk of even greater poor health outcomes if their additional communication needs are not met. Menopause information in simple language, including Easy Read, is available (5). The EIA has failed to consider that the language around "gender identity" is used by a tiny minority of people in the UK and many of those reading the NICE Guideline will not have a good understanding of its meaning. The EIA has also failed to consider those people for who English is not their first language or for those who have difficulty reading or for those who have little or no understanding of transgender ideological language. The other issue that the EIA has failed to consider is how using the language of "people" instead of "women" when referring to menopause is alienating and unwelcomed by	communication with everyone. The wording 'women, trans men and non-binary people registered female at birth' is used to be clear about all groups of people who can experience menopause and also be clear about people who do not experience menopause, such astrans women or non-binary people registered male at birth. In relation to people with learning disabilities or those with communication needs the committee agrees that people need to be heard and treated with dignity and respect. Further details on tailoring communication to people (including English not being the first language) is covered in the NICE guideline on patient experience in adult NHS services as well as in the NICE guideline on shared decision-making so this information is not repeated in all other NICE guidelines (they are cross referred to in recommendations 1.1.1 and 1.1.2). Based on the numbers in this appendix a discussion aid document has been developed which includes data visualisation of the numbers. The pictorial presentation would make this more accessible for people with English as a second language or those with verbal comprehension difficulties. This discussion aid has undergone user-testing and was refined based on user feedback. The word 'people' is only used in specific contexts where it is already clarified in the section who this would refer to.

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				many women. All women will experience the menopause at some point in their lives. Women account for 51 percent of the population and to refer to us as "people" when discussing issues relating to our health is offensive and inappropriate and attempts to separate the word woman from our being female. The removal of the word woman from women's health information is currently widely and strongly contested by numerous women's organisations including the Women's Rights Network. [3] https://www.frontiersin.org/articles/10.3389/fgwh.2022.818856/full [4] https://www.england.nhs.uk/about/equality/equality-hub/patient-equalities-programme/equality-frameworks-and-information-standards/accessibleinfo [5] https://www.balance-menopause.com/menopause-library/easy-read-guide-to-the-perimenopause-and-menopause/	We have added further information to the EIA form related to inclusive language so that the reasons for using it are clear.
Women's Rights Network (WRN)	Guideline	General	General	In the UK 51 percent of the population are born female and will, at some point in their lives, experience the menopause. We know from the most recent ONS Census 2021 that around one in 200 female people in England and Wales will identify as transgender (either as trans men or non-binary or another identity) (NB ONS have stated that this figure could either be an under-	Thank you for your comment. Using inclusive language in healthcare is important for safety, and to promote equity, respect and effective communication with everyone. The wording 'women, trans men and non-binary people registered female at birth' is used to be clear that this guideline does not cover trans women, who see themselves as women but do not go through the menopause.

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				estimate or over-estimate due to issues with how the question was asked in the Census (1)) The NICE Draft Guideline on menopause uses the phrase "women, trans men and non-binary people registered female at birth" throughout the document. It also uses the word "people" instead of the word women to describe those experiencing the menopause. The Women's Rights Network (WRN) understands from the Equality Impact Assessment (EIA) that NICE have carried out in relation to this Draft Guideline that the reason for the use of the word "people" and the phrase "women, trans men and non-binary people registered female at birth" is to be inclusive of the one in 200 women who identify as trans-men or non-binary or another identity. Further, the Draft Guideline states on page 5 that "using inclusive language in healthcare is important for safety, and to promote equity, respect and effective communication with everyone". WRN submits that the language used for promoting health messages should primarily be scientific, accurate and easy for the vast majority of its readers to understand. The "inclusive" language used in this Guideline is not accurate or scientific. it is ideological and only used by a small minority of individuals. [1]https://www.ons.gov.uk/peoplepopulationandcommunity/culturalidentity/genderidentity/articles/qualityofcensus2021genderidentitydata/2023-11-13	

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Women's Rights Network (WRN)	Guideline	General	General	There is evidence to demonstrate that menopause is associated with shame, embarrassment and difficulties discussing the experience (2). Whilst this is changing, using unclear language, or omitting the word 'women' adds to this shaming. WRN therefore submits that use of the word women should be promoted and supported. [2] https://pubmed.ncbi.nlm.nih.gov/37852008/	Thank you for your comment. The guideline's introduction states that women are covered by the recommendations. Where the groups of people covered by a recommendation (including women) need to be listed for clarity, all groups are stated. Elsewhere, the word 'people' is used to be inclusive and concise.

**None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.*