Familial Ovarian Cancer

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British Gynaecological Cancer Society	General	General	The BGCS commends the scope for its comprehensive coverage of the important issues including risk-reducing surgery, surveillance and the implications for menopause / HRT and fertility. These issues are crucial in women's decision-making on the timing of risk-reducing surgery and indeed whether to have such surgery.	Thank you.
British Gynaecological Cancer Society	General	General	Question 1 - Are there any cost saving interventions or examples of innovative approaches that should be considered for inclusion in this guideline? Yes, we are aware that a recently completed NHS pilot national study of ovarian cancer surveillance in BRCA-carriers (the ALDO Project https://www.nclcanceralliance.nhs.uk/our-work/diagnosis-and-treatment/aldo/) has been undertaken by the North Central London Cancer Alliance and the results (recently presented at the European Society of Gynaecological Oncology meeting) indicate likely cost-savings. The results will be submitted for publication early in 2022.	Thank you for your comment. The study will be considered for inclusion using the criteria of any relevant review protocol.
British Gynaecological Cancer Society	General	General	Question 2 - There were discussions about the terminology related to the title of the guideline. It has been suggested to change the title to: 'Ovarian Cancer: Identifying and managing genetic and familial risk' - Do you agree? Yes, we agree this is a more appropriate title.	Thank you for your comment. The title has been updated to 'Ovarian cancer: identifying and managing familial and genetic risk'.
British Gynaecological Cancer Society	002	022	In addition to failure to offering appropriate risk-reducing surgery, or it being offered inappropriately, we are aware of incorrect procedures being performed e.g. removal of ovaries	Thank you for your comment. The details of risk-reducing surgery for women at increased risk of familial ovarian cancer will be reviewed and discussed with the committee.

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			without concurrent removal of fallopian tubes, necessitating a second surgical procedure where one would have sufficed.	
British Gynaecological Cancer Society	003	024	Equality considerations: Whilst we commend the scope for its mention of accessing and providing information to people for whom English is not their first language, we feel there needs to be a more explicit acknowledgement of the dearth of research in relation to non-Caucasian populations and the limitation that this places on current risk-assessment. It is important to recognise that the prevalence of high-risk susceptibility genes in women of non-Caucasian, non-European ancestry with high-grade serous ovarian cancer is not widely researched (for example see https://academic.oup.com/pcm/article/1/2/75/5106037?login=true) and data on ovarian cancer penetrance in non-Caucasian germline mutation-carriers is limited. We are aware of additional data (currently in press) from the West Midlands genetics laboratory on outcomes from those considered at familial risk of Breast and ovarian cancer and this highlights the paucity of information on ethnic diverse women with variants in high risk susceptibility genes (we will be happy to provide this manuscript in confidence, but anticipate its publication prior to the current NICE deadline). Therefore, it is important to add 'ethnicity' both to the equality considerations and to the scope of the document. Most of the literature on ovarian cancer risk from high-risk susceptibility genes is derived from white European populations and may not	Thank you for your comments. We have added 'ethnicity' to the second bullet point of this section and updated the Equality Impact Assessment form accordingly. Equality groups highlighted in the Equality Impact Assessment form would be part of each of the review protocols so the committee will consider potential inequalities when drafting recommendations.

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			be entirely applicable without modification to diverse communities. In addition, there are cultural barriers to BRCA-testing that we encounter in populations that are diverse and this is important to include in the scope. Furthermore, risk-reducing interventions may be perceived differently in diverse populations - we simply do not know. It is important that the draft scope explicitly addresses these issues. Not only should there be provision of relevant information in different languages, but also there is a need to recognise that there may be cultural sensitivities around attitudes to risk-reducing surgery and hormone replacement therapy which could necessitate different approaches to how information is presented, and how women and their families are counselled.	
British Gynaecological Cancer Society	005	023	What will not be covered: The scope does not appear to include management of ovarian cancer specifically in those with a germline predisposing mutation. Presumably this is because this is already available in the NICE guidelines regarding use of specific targeted therapies in BRCA-carriers. Should this be pointed out under this section?	Thank you for your comment. Section 3.3 states that 'recognition and initial management of ovarian cancer' will not be covered, since this is currently covered in the NICE guideline on 'Ovarian cancer: recognition and initial management' (CG122)'.
British Gynaecological Cancer Society	009	020	Risk reducing surgery: There is no mention of whether the scope will or will not include the management of endometrial cancer risk in women with Lynch Syndrome. It would in our opinion make little clinical	Thank you for your comment. We have used the term 'risk-reducing surgery' to cover all types of surgical procedures which are relevant for women at increased risk of familial ovarian cancer. This key topic and draft review question was

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			sense to address only the ovarian cancer risk in this population, especially as risk-reducing surgery for this group needs to include hysterectomy along with removal of the ovaries. Therefore, a comment on inclusion of women with Lynch Syndrome and management of their ovarian AND endometrial cancer risk should be explicit. In addition, the guideline could be re-titled 'Familial Gynaecological Cancer: Identifying and Managing Risk' in order to make it more obvious that it will include management of endometrial cancer in women with Lynch Syndrome. If the decision is not to include management of endometrial cancer risk in women with Lynch Syndrome, then this needs to be explicitly mentioned in the section on 'Areas that will not be covered'. However, we believe that this would be a huge missed opportunity to improve the care of women with Lynch Syndrome (which has a similar prevalence to pathogenic germline BRCA-alterations) and we strongly recommend that management of their endometrial cancer risk is included in the guidance.	left intentionally broad to capture all 'risk reducing-surgery'. This is noted in the text in brackets within the draft review question stating 'extent of surgery'. This has now been amended to 'extent and type of surgery'. The details of this will be discussed with the committee when the evidence review protocol is finalised. We agree that in the context of women with Lynch Syndrome this could include a hysterectomy. As you have also highlighted this is not mentioned in the 'areas that will not be covered' specifically for this reason. Just as we have not specifically mentioned hysterectomy, we have also not specifically mentioned early salpingectomy. Covering all gynaecological cancers was considered too broad for the scope and it was therefore decided to focus on familial ovarian cancer. Hence, the term familial gynaecological cancer does not fit the remit of this guideline.
GO Girls	001 - 002	016 - 001	(page 2) Many women with ovarian cancer either do not currently have access to genetic testing nor is this systematically carried out in a timely way or tracked. Subsequent treatments are impacted by the need for this testing to be carried out. Guidance is required to ensure this is implemented uniformly across the UK, otherwise this will lead to health inequalities for women.	Thank you for your comment. We have reworded this background section to read 'The majority of women who carry a pathogenic variant for ovarian cancer do not have a family history suggestive of a genetic risk. This means many carriers have not sought testing for high risk ovarian cancer pathogenic variants. Current best estimates are that only 3% of pathogenic variant carriers know they are carriers.' To emphasise that

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				many carriers are not being tested to focus on this more explicitly. During the development of the guideline, the details of genetic testing for familial ovarian cancer will be reviewed and discussed with the committee. The guideline will look at inequalities relating to accessing genetic testing, and fertility and menopause services, including socioeconomic and geographical factors, and factors relating to age, ethnicity and disabilities as outlined in the 'equality considerations' section of the scope and the Equality Impact Assessment form. The draft review question 2.1 could consider retrospective tracking of women at risk. The details of this will be discussed with the committee.
GO Girls	002	020 - 025	Again this is correct. There is lack of uniformity on guidance relating to risk reducing surgery – again without an appropriate standard this will lead to health inequalities for women and a postcode lottery.	Thank you.
GO Girls	004	015 - 021	How will this impact on women with endometrial CA who have MMR/MSI deficiency. Does this impact vice versa for women with ovarian CA who are found to have MMR/MSI deficiency Lynch syndrome/follow up/planning/treatment.	Thank you for your comment. This guideline specifically relates to ovarian cancer and it was felt that adding endometrial cancer would broaden it too much. Syndromes, for example Lynch syndrome, are included when they are associated with an increased risk of ovarian cancer. This does not include all women with endometrial cancer.
GO Girls	007 - 008	025 – 002	There is an economic benefit and societal benefit to looking more effectively at managing risks associated with familial	Thank you for your comment. The details of risk-reducing surgery for women at increased risk of familial ovarian cancer

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			ovarian CA (impact on endometrial CA/dependent on MMR/MSI status). The costs to the individual and family are high in ovarian CA both in terms of costs of surgery/drug therapy and financial impact. Clear guidance on prophylactic surgery may offer many benefits and reduce the burden of ovarian/peritoneal cancers at all levels, both physically, psychologically, economically and reduce NHS costs considerably.	will be reviewed and discussed with the committee. This will include economic considerations and considerations of potential inequalities in access to services.
Royal College of Nursing	General	General	We do not have any comments from the RCN to add to this consultation.	Thank you.
Royal College of Pathologists	General	General	Removal of the tubes and ovaries in postmenopausal women who undergo hysterectomy for other reasons will significantly lower their risk of ovarian cancer. This guideline should look at this procedure as standard of care	Thank you for your comment. Surgery for other reasons than specifically aimed at risk reduction for women at a priori increased risk of ovarian cancer would not be the focus of this particular guideline because it is not specific to the aims of this topic.
Royal College of Pathologists	General	General	Tubal ligation is a common procedure in young women. Replacing this with tubectomy will significantly lower the risk of ovarian cancer. This guideline should look at this procedure as standard of care	Thank you for your comment. Surgery for other reasons than specifically aimed at risk reduction for women at a priori increased risk of ovarian cancer would not be the focus of this particular guideline because it is not specific to the aims of this topic.
Royal College of Pathologists	001	022	These sentences can be worded better. Presently they do not clearly convey the need for genetic testing in women without family history Over 50% of women with a pathogenic variant do not have any close family 22 members with cancer. Currently, only around 3% of women who carry a 23 pathogenic variant	Thank you for your comment. We have revised this to 'The majority of women who carry a pathogenic variant for ovarian cancer do not have a family history suggestive of a genetic risk. This means many carriers have not sought testing for high risk ovarian cancer pathogenic variants. Current best estimates are

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			which increases the risk of ovarian cancer have been 24 identified as a result of genetic testing.	that only 3% of pathogenic variant carriers know they are carriers.' This would more clearly indicate a greater need for testing awareness and access.
Royal College of Pathologists	002	024, 025	HRT is not in scope • Also, use of 24 hormone-replacement therapy after risk-reducing surgery varies.	Thank you for your comment. The issue of hormone-replacement therapy is covered in draft review question 8.3 in section 3.5 'What are the benefits and risks of hormone replacement therapy after risk-reducing surgery for women at increased risk of familial ovarian cancer?'
Royal College of Pathologists	002	027, 028	In situ lesions are always occult Please consider changing • occult in situ or invasive cancers to in situ or occult invasive cancers	Thank you for your comment. We have revised this accordingly.
Royal College of Pathologists	009	024	The term surgico-pathological is best replaced by surgical protocol and pathology protocol for handling specimens from risk reducing surgery	Thank you for your comment. We have amended this to: **'**8.2 What pathology protocol for handling specimens from risk-reducing surgery should be followed for risk-reducing surgery for women at increased risk of familial ovarian cancer?'. The surgical protocol would depend on the outcome of question 8.1 and be covered accordingly in that section.
Target Ovarian Cancer	General	General	Role of primary care is not clear – most women with a familial history but without a diagnosis of ovarian cancer will approach their GP for access to genetic testing making primary care one of the key drivers of access to genetic testing	Thank you for your comment. The details of configuration of ovarian cancer risk assessment and management services will be reviewed and discussed with the committee. The draft review question includes referral in this configuration of services and it is anticipated that this will include GP services. We have added 'referral' into the key area (heading) for this section and draft review question 2.1 in section 3.5 of the scope to make this clearer.

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Target Ovarian Cancer	General	General	Awareness of the role of genetics in ovarian cancer is low can the guideline look at how those without a direct link be made aware of their risk	Thank you for your comment. The details of information and support needs of women with familial ovarian cancer or who are at increased risk of ovarian cancer, and their families and carers will be reviewed and discussed with the committee. This would include women at increased risk without a direct link.
Target Ovarian Cancer	General	General	We would support the change of title	Thank you for your comment. The title has been updated to 'Ovarian cancer: identifying and managing familial and genetic risk'.
Target Ovarian Cancer	004	026	Can these populations be defined at this stage?	Thank you for your comment. We had considered providing an example during the development of the scope (for example the Ashkenazi Jewish population). However, we thought that this would be pre-empting the outcome of the evidence review. This would be the topic addressed by evidence review 4.3 in section 3.5 of the scope: '4.3 Which populations with a high prevalence of pathogenic variants would meet the risk threshold for genetic testing?'
Target Ovarian Cancer	010	011	'ovarian cancer' needs further definition – does it mean reduced incidence of ovarian cancer	Thank you for your comment. The outcome would be whether or not a women would develop 'ovarian cancer'. By using this outcome in a comparison between different groups of women it can then be concluded whether there is a reduction or not. We therefore have not given this a particular direction of effect in advance such as 'reduced incidence of ovarian cancer'.
The Eve Appeal	001 - 002	016 - 001	(page2) At Eve we hear from women who have not been offered genetic testing when diagnosed with ovarian cancer. These women having access in the internet are aware that genetic	Thank you for your comment. We have reworded this background section to read 'The majority of women who carry a pathogenic variant for ovarian cancer do not have a family history suggestive of a genetic risk. This means many carriers

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			testing could help their treatment pathways. We would hope that guidance for these women and their families could ameliorate these concerns.	have not sought testing for high risk ovarian cancer pathogenic variants. Current best estimates are that only 3% of pathogenic variant carriers know they are carriers.' To emphasise that many carriers are not being tested to focus on this more explicitly. During the development of the guideline, the details of genetic testing for familial ovarian cancer will be reviewed and discussed with the committee. The guideline will look at inequalities relating to accessing genetic testing, and fertility and menopause services, including socioeconomic and geographical factors, and factors relating to age, ethnicity and disabilities as outlined in the 'equality considerations' section of the scope and the Equality Impact Assessment form.
The Eve Appeal	002	020 - 025	The Ask Eve service hears from concerned from people about making choices to reduce risks of ovarian cancer. It has been noted this does not appear to be consistent across all regions..	Thank you for your comment. The details of risk-reducing surgery for women at increased risk of familial ovarian cancer will be reviewed and discussed with the committee. This would include consideration of geographical inequalities.
The Eve Appeal	004	015 - 021	Could we ask will this have an impact for women who may have a high grade serous endometrial CA due to Lynch syndrome.	Thank you for your comment. This guideline specifically relates to ovarian cancer and it was felt that adding endometrial cancer would broaden it too much. Syndromes, for example Lynch syndrome, are included when they are associated with an increased risk of ovarian cancer. This does not include all women with endometrial cancer or specifically serous endometrial cancer.

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The Eve Appeal	007 - 008	025 – 002	This is a hugely important topic. The Eve Appeal's mantra is about risk reduction. We would be keen to know what NHS methodology will be implemented to measure the economic health benefits.	Thank you for your comment. NICE considers economic aspects in relation to each topic. Measures related to the implementation may vary depending on the content of the recommendations related to risk reduction and NICE commonly develops implementation tools to facilitate this when the guideline nears publication. Therefore we are not able to say in advance which methodology will be implemented to measure the economic health benefits of the guideline's output.
UK Cancer Genetics Group	001	012	We commend the intent of this document to be inclusive to the trans community. We would suggest the term "female pelvic organs" would be better changed to "people who have ovaries/fallopian/uterus" for example to avoid gender-loaded language. Consideration of personalised risk for the non-binary/trans community is important not just in terms of barriers to health care etc but potential differences in risk levels.	Thank you for your comment. This has been revised to read 'This scope uses the term 'women' throughout, but this should be taken to include anyone born with some or all of the following organs: ovaries, fallopian tubes and uterus.' Whether or not trans people have a different risk level could feature as part of evidence searches related to draft review question 4.4 in section 3.5: 'At what carrier probability should women with ovarian cancer (with or without breast cancer) be offered genetic testing?' The details of this will be discussed with the committee.
UK Cancer Genetics Group	002	016	This line is confusing. Eligibility for germline genetic testing for individuals with ovarian cancer is clearly defined in the NHS England National Genomic Test Directory R207/R208: women with high grade non-mucinous ovarian cancer should be offered diagnostic germline genetic testing and at present this includes BRCA1, BRCA2, PALB2, but testing will soon be	Thank you for your comment. To clarify this, it has been reworded to: 'Germline genetic testing is defined in the NHS England National Genomic Test Directory. However not all eligible women are routinely offered this. In addition, women at increased risk could be missed because they do not fit the current criteria, for example on the basis of unaffected family history.'

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			extended to include the other genes mentioned , BRIP1, RAD51C, RAD51D, MLH1, MSH2, MSH6). Once a pathogenic variant is identified in the family, family members should be able to access a predictive genetic test for the identified variant. There is currently a gap in provision of genetic testing where patients with family members with ovarian cancer have died and genetic testing was not performed, as in this situation the unaffected relatives may not currently reach the eligibility criteria to be offered testing (e.g if only one relative was affected with ovarian cancer. This line needs to be clearer about the type of testing it is referring to, for example is it referring to predictive testing for known genes in relatives or testing unaffected individuals who meet unaffected testing criteria according to the NHSE Test Directory on the basis of their family history	
UK Cancer Genetics Group	004	005 - 006	This bullet point is not clear, I am not sure what is meant by "genetic testing risk reducing treatment". Does it mean risk reducing options available following genetic testing for gene carriers?	Thank you for your comment. This was an error and has now been amended to read '…..that could inform decisions about genetic testing and risk reducing options available following genetic testing for gene carriers'.
UK Cancer Genetics Group	004	024	We are wondering why Lynch syndrome has been singled out, over other hereditary ovarian cancer syndromes?	Thank you for your comment. Lynch syndrome is given as an example in this bullet rather than it being restricted to this alone. We have made this more explicit by replacing 'such as Lynch syndrome' with 'for example Lynch syndrome'.

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UK Cancer Genetics Group	005	005	Key areas to be covered should include provision of or access to menopausal services for women undergoing risk reducing surgery.	Thank you for your comment. This section provides the broad heading related to each topic. Section 3.5 includes details of the draft review questions. Menopause services are covered in the draft review question 2.1 'What is the most effective configuration of services for referral, risk assessment and risk management for women at increased risk of ovarian cancer (including fertility, menopause and psychological support services)?'.
UK Cancer Genetics Group	005	012 - 013	Any recommendations about risk thresholds for genetic testing should align/link up/be thought through with respect to the with recommendations in the National genomic Medicine Service and National Test Directory. It needs to be clear where recommendations pertain to risk thresholds for genetic testing, risk thresholds for risk reducing interventions, and the types of genetic testing and risk reducing interventions being considered.	Thank you for your comment. The committee will bear the National genomic medicine service and the directory in mind when discussing this topic.
UK Cancer Genetics Group	008	025	Need clarity about what is meant by carrier probability. There is a difference between the probability of a pathogenic variant being identified in an individual with either a diagnosis of ovarian cancer (diagnostic testing) or a significant family history (unaffected testing) and the probability of being a carrier of a known familial pathogenic mutation (predictive testing). The latter should not be within the remit of these guidelines	Thank you for your comment. The focus of our guideline will be on the identifying and managing familial and genetic risk of familial ovarian cancer. As such the committee may make statements about predictive testing such as cascade testing from an index case. Furthermore, the guideline may include statements that will help clinicians target genetic testing and empower patients to seek germline testing. Such matters will be discussed by the committee on the basis of evidence synthesis.

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UK Cancer Genetics Group	009	001	Not sure why Lynch syndrome singled out above other syndromes. Also, a bit confused by what is meant by this. Lynch Syndrome is diagnosed when a pathogenic variant is identified in one of the Lynch Genes, MLH1, MSH2, MSH6, PMS2 – in this instance, cascade screening for the familial mutation is available for relatives. We think 4.2 may refer to unaffected testing of individuals with a family history of Lynch Related cancers? In which case, clear criteria for this is already in the National Genomic Test Directory (R210) and it would be important to align with this or link to it.	Thank you for your comment. Lynch syndrome was meant to be used as an example in this draft review question. To clarify this we have reworded this to: 'At what carrier probability should a person with a family history of a syndrome associated with an increased risk of ovarian cancer, (for example Lynch syndrome) be offered genetic testing?'
UK Cancer Genetics Group	009	007	Genes of relevance may change and therefore NICE guidance quickly become outdated. There is a separate process in NHSE to select genes for panels for both germline and somatic testing assessing clinical utility. Does NICE need to decide which genes should be included above existing initiatives? Or just assess the cost effectiveness of a small NGS gene panel as decided to be clinically relevant.	Thank you for your comment. The committee will take the NHSE testing service into consideration. The details of the draft review question protocol will be discussed with the committee with the aim to avoid duplication of effort.
UK Cancer Genetics Group	009	008	Access to appropriate support prior to surgery in terms of information about potential side effects of early menopause, Support after surgery with protocol for HRT, access to specialist clinic for menopausal symptoms	Thank you for your comment. The details of this would be covered in draft review question 2.1 'What is the most effective configuration of services for referral, risk assessment and risk management for women at increased risk of ovarian cancer (including fertility, menopause and psychological support services)?'. This would include access to such services.
Wales Cancer Network	General	General	In response to the additional questions above, there are no cost saving interventions or examples of innovative approaches	Thank you for your comment. We will look for and consider any relevant economic evidence and carry out de novo economic analyses when detailed searches for evidence are conducted

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			that we aware of that should be considered for inclusion in this guideline	based on review protocols criteria agreed after discussions with the committee.
Wales Cancer Network	General	General	Regarding the change of name from 'Familial Ovarian Cancer' to 'Ovarian Cancer: Identifying and managing genetic and familial risk' – we are largely in favour but wonder if it may make it harder to find for those searching for the guidance?	Thank you for your comment. The title has been updated to 'Ovarian cancer: identifying and managing familial and genetic risk'. This still includes both the terms 'genetic' and 'familial' so we think that it would not negatively impact on finding this guideline.
Wales Cancer Network	General	General	We welcome the development of this guidance, it is much needed.	Thank you.
Wales Cancer Network	008	003	Should the requirement for additional workforce education and training on familial ovarian cancer be considered in this section? The development of an educational package for primary care, gynaecology, oncology, radiology, genetics etc would be useful to go alongside the guidance document.	Thank you for your comment. Medical education and continuous professional development are outside the scope because these are the responsibility of other bodies. There are already relevant resources available for example the work from NHS genomics in relation to this.
Wales Cancer Network	009	007	What impact will genetic testing for familial ovarian cancer have on clinical genetic services (in terms of testing numbers and turnaround times and access to geneticists)? This will be important for workforce planning and service development.	Thank you for your comment. After the evidence for this topic has been reviewed and presented, the committee has to consider the impact on practice and services when drafting recommendations.
Wales Cancer Network	009	011	What impact will familial ovarian cancer surveillance have on downstream services (e.g. access to gynaecology, radiology)? This will be important for workforce planning and service development.	Thank you for your comment. After the evidence for this topic has been reviewed and presented, the committee has to consider the impact on practice and services when drafting recommendations.