

## Hypertension in adults

### Consultation on draft scope Stakeholder comments table

09/06/2017 to 07/07/2017

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Association of Anaesthetists of Great Britain and Ireland	General	General	The committee drafting the guideline may wish to reference and refer to the joint AAGBI/BHS guideline 'The measurement of adult blood pressure and management of hypertension before elective surgery 2016' - <a href="http://www.aagbi.org/sites/default/files/The%20measurement%20of%20adult%20blood%20pressure%20and%20management%20of%20hypertension%20before%20elective%20surgery%202016(1).pdf">http://www.aagbi.org/sites/default/files/The%20measurement%20of%20adult%20blood%20pressure%20and%20management%20of%20hypertension%20before%20elective%20surgery%202016(1).pdf</a>	Thank you for your comment and for providing this information.
Association of Anaesthetists of Great Britain and Ireland	General	General	The committee may wish to add the management of patients with hypertension undergoing elective surgery to the scope of the review	Thank you for your comment. We agree that the primary care management of people with hypertension scheduled for urgent and elective surgery is an important issue. However we are not aware of evidence that would enable the committee would be able to make any more than consensus recommendations in this area and therefore this was not prioritised for inclusion in the guideline update.
British Acupuncture Council	6	10	The draft scope excludes non-pharmacological treatments. There is evidence from systematic reviews (Wang 2013, Li 2014, Zhao 2015) that acupuncture used adjunctively with anti-hypertensive drugs improves patient outcomes. More high quality studies, especially in countries other than China, are needed but this is how it stands at the moment. Given the potential harms associated with the drugs it would seem politic for the NHS, and NICE, to consider other options. Acupuncture can be delivered very cheaply in a group setting, is relatively very safe and is well	Thank you for your comment. We recognise that non-pharmacological interventions could have promising prospects for the treatment of hypertension. However, the surveillance review did not identify sufficient evidence to inform robust recommendations suggesting that non-pharmacological interventions such as supplements, acupuncture and herbal remedies should be added to the guideline. This area therefore has not been prioritised for inclusion in the guideline.

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			tolerated. Perhaps it could be used to reduce the need or the dose of pharmacological agents.	
British and Irish Hypertension Society	5	5 - 9	To consider PATHWAY2 and the use of spironolactone at low dose for preferred Step 4 in an updated algorithm	<p>Thank you for your comment. Sequencing of antihypertensive drug treatment will be covered by this guideline – please see question 4.2 on page 8, line 3 of the scope.</p> <p>The hypertension surveillance review recognised PATHWAY2 as new evidence that could impact current recommendations, and this will be assessed when reviewing the evidence.</p>
British and Irish Hypertension Society	7	1 - 8	<p>COST Saving</p> <ul style="list-style-type: none"> <li>- Low dose combinations as initial therapy rather than monotherapy better BP reduction</li> <li>- SBPM for assessing BP control on treatment. Current guidelines only seem to recommend ABPM/SBPM for initial diagnosis not for assessment of treatment control</li> <li>- Greater use of the hypertension nurse management and prescribing to Guidelines. Diabetes nurses already do all this. This would be of particular use as these really should be CV Risk guidelines so lipid and diabetes management vital as well.</li> </ul>	<p>Thank you for your comment.</p> <p>We will be assessing the economic evidence for all areas included in the guideline scope (which includes choosing antihypertensive drug treatment – question 4.1/4.2, and the best method of monitoring blood pressure to assess response to treatment – question 2.1) and conducting economic analysis where feasible. Hypertension nurse management is not within the scope of the guideline.</p>
British and Irish Hypertension Society	7-8	31 1 - 5	It is important to address “Optimal timing” as a question	<p>Thank you for your comment. We recognise that this is an important area in current research. The NICE hypertension surveillance review identified evidence related to optimal timing of antihypertensive drug treatment, however the largest trial in the area will not be published in time to inform the updated guidance and therefore</p>

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				it was agreed that consideration of this area should not be addressed until this evidence is available.
British and Irish Hypertension Society	8	6 - 8	Comments on Cause and diagnosis would be helpful. Not reducing BP too rapidly. Tried and tested safe treatment. Probably stroke physicians are the only ones who regularly rapidly reduce BP but in a non-malignant form for PICH or prior to and after thrombolysis. Little in stroke guidelines as to what to use.	Thank you for your comment. Based on stakeholder feedback the focus of the topic area around malignant hypertension has been updated to cover the identification of malignant hypertension, rather than management. The review question will be further refined in discussion with the guideline committee once we begin development.
British and Irish Hypertension Society	General	General	In view of recent consensus guidelines on management of hypertension prior to surgery, the mis-management of which results in many cancelled procedures, a comment in the new NICE guidelines would be appropriate. Hartle A, et al. Anaesthesia 2016; 71(3): 326-337 McCormack T. <a href="#">J Periop Crit Intensive Care Nursing 2016</a> ; 2: 130 McCormack T, et al. Br J Gen Pract 2016; 66: 230-231 Anderson Sg et al. Br J Cardiol 2017; 24: 11–12	Thank you for your comment. We agree that the primary care management of people with hypertension scheduled for urgent and elective surgery is an important issue. However we are not aware of evidence that would enable the committee would be able to make any more than consensus recommendations in this area and therefore this was not prioritised for inclusion in the guideline update.
British Cardiovascular Society	6	10 - 11	The draft scope includes the following exclusion: “Non-pharmacological interventions (e.g. supplements, acupuncture, herbal remedies)”.  It was not clear to BCS if other non-pharmacological interventions such as renal artery denervation, baroreceptor stimulation devices, and the ROX Coupler device to create an arteriovenous fistula, are to be excluded.	Thank you for your comment. We recognise that new devices could have promising prospects for the treatment of hypertension. However at this time, the hypertension surveillance review did not find enough current evidence to support the inclusion of these devices in the guideline. In addition, NICE IPG533 (interventional procedures guidance on implanting baroreceptor stimulation devices in resistant hypertension) in 2015 found

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			<p>The British Cardiovascular Society would welcome a review of the literature regarding the efficacy of these devices and guidance regarding their role in the management of (resistant) hypertension and encourage their inclusion in the final scope document. This would assist clinicians in managing patients with resistant hypertension.</p>	<p>that there was not enough evidence to recommend these procedures.</p> <p>Recognition will be given to resistant hypertension within the scope area of choosing hypertensive treatment and the questions around treatment sequencing.</p>
British Dietetic Association	5	After line 12 (Table – ‘Lifestyle Interventions’)	<p>Under ‘Lifestyle Interventions’, it states ‘No evidence review: retain recommendations from existing guideline’. This is very disappointing given the current climate and that lifestyle plays a significant role in prevention and treatment. There has been lots of research since 2004 looking at physical activity and also growing evidence to advocate a plant based diet to reduce blood pressure.</p>	<p>Thank you for your comment. We agree that lifestyle interventions are an important part of managing hypertension and we welcome any new evidence that could improve upon current recommendations. This is an area that was searched for in the surveillance process. New evidence was identified to support current recommendations, which already offer advice related to diet and exercise, alcohol, salt intake, smoking and caffeine. Some evidence was also identified that suggested the possibility of expanding upon these recommendations, particularly in the area of relaxation techniques. With the exception of relaxation therapies, stakeholders were in agreement that this evidence was not yet sufficient to lead to a change in the recommendations due to either being from a small sample size, short-term follow up only or focusing on change in blood pressure instead of direct patient important outcomes such as cardiovascular events. The research questions</p>

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				and protocols in the updated guidance will focus on patient important outcomes rather than blood pressure as this is a surrogate outcome that doesn't clearly identify what the measurable benefit of a treatment is, in terms of improvements to a persons' quality or length of life. Consequently it was agreed that lifestyle therapies as a whole should not be updated at this time, and existing recommendations will be carried forward into the updated guidance, but the evidence for relaxation therapies will be reviewed and has now been added to the scope.
CVRX	2	18 - 20	This paragraph declares that "resistant hypertension continues to be challenge" and yet resistant hypertension is not included anywhere within the draft scope in terms of being considered by the update to the guidelines. It is imperative that resistant hypertension is recognised (and properly defined) within the guideline, even if without specific strategy recommendation other than to refer to the European Society of Cardiology/European Society of Hypertension Guidelines, or to suggest referral to dedicated hypertension clinical specialists.	Thank you for your comment. The definition for resistant hypertension was established in the 2011 guideline and will be carried forward to the current update. Management of resistant hypertension will be considered within the guideline under the scope area of choosing hypertensive treatment and the questions around treatment sequencing.
Diabetes UK	4	14	Can the reasons behind excluding Type 1 diabetes (when Type 2 has been included), please be explained? The impact of hypertension in Type 1 diabetes is very similar to Type 2 diabetes when considering effects on risk of developing, and management of diabetes complications such as retinopathy, nephropathy, etc. A justification included	Thank you for your comment. Recommendations about the management of blood pressure in type 1 diabetes were addressed in the update of type I diabetes guideline in 2015 (NG17) specifically recommendations 1.13.8-1.13.13 and a reference to chronic kidney disease guideline (CG182). However, hypertension in

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			in the guideline document to make it clear for clinicians when they are accessing the guidelines in practice would be most helpful. This will also make it easier for us as an organisation when we get questions from clinicians regarding hypertension management in Type 1 diabetes.	people with type 2 diabetes has not been addressed in current NICE guidance.
Diabetes UK	6	10	Non-pharmacological interventions are described as being excluded from the scope of this guideline, yet above pg5 line 12, lifestyle interventions are listed as being set for inclusion (with no changes). This is inconsistent.	Thank you for your comment. Lifestyle interventions are not included within the scope for the update of the guideline (with the exception of relaxation therapies) as at the present time new evidence was not considered sufficient to alter the recommendations. However the existing recommendations from CG127 will still stand and will be carried forward into the update. The table on page 5 sets out the plan for each area in CG127 and therefore reflects this decision.
Diabetes UK	6	12	To be added to this list of related guidance are NG17 and NG28.	Thank you for your comment. We have added NG17 (Type 1 diabetes in adults: diagnosis and management) and NG28 (Type 2 diabetes in adults: management) to the related guidance in the scope.
Diabetes UK	General	General	Can it please be explained the reasons behind hypertension management information being taken out of the NG28 guideline, and put only into this one? We take into consideration that if health professionals are looking for management information for a patient with Type 2 diabetes they will first go to the NG28 guideline and search for the relevant comorbidity/condition. They would then need to go to	Thank you for your comment. This decision was made during the development of NG28; this area remains outstanding for update and therefore will be covered within this guidance. Although the recommendations will sit within this guidance, these will be presented on the NICE website so that there are clear links to related guidance, which is intended to make it easier for a health

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			the hypertension guideline, which would increase time spent researching best practice.	professional to find all of the relevant guidance linked to that area.
Hull York Medical School	General	General	Line 120 of the original draft scope stated “9. Approach to resistant hypertension”. This appears now to have been omitted. Resistant hypertension appears to be neither included nor excluded. It should be an important consideration in terms of new evidence available.	Thank you for your comment. Resistant hypertension will be considered within the scope area of choosing hypertensive treatment and the questions around treatment sequencing.
Hull York Medical School	General	General	At publication you should include a table of targets, which includes CKD and stroke, as well as adults with or without diabetes. This is something that primary care would cherish and value.	Thank you for your comment. We will take this into consideration when reviewing the evidence and updating recommendations related to blood pressure targets.
Hull York Medical School	General	General	A specific guidance on ‘who to refer to’ would be valuable. The term ‘a specialist with an interest in hypertension’ would seem suitable. If a lack of evidence prevents this, then that should be considered as an evidence question, exploring availability of specialist clinics and referral patterns.	Thank you for your comment. We agree that your suggested term sounds sensible. The committee will take your terminology suggestion under consideration when making recommendations.
Hull York Medical School	Question 1	General	‘Physician inertia’ is a major problem and therefore a process lead approach should be considered.	Thank you for your comment
Hull York Medical School	Question 2	General	Lifestyle interventions should not be covered.	Thank you for your comment. Following further consideration it has been decided that this area will not be updated with the exception of relaxation therapies. The existing recommendations for other lifestyle interventions will be kept in the updated guideline.
Hull York Medical School	Question 3	General	Malignant hypertension is now very rare and unlikely to benefit from consideration in a general population guideline.	Thank you for your comment. Based on stakeholder feedback the focus of the topic area around malignant hypertension has been updated

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				to cover the identification of malignant hypertension, rather than management. The review question will be further refined in discussion with the guideline committee once we begin development.
Hull York Medical School	Question 4	General	The team responsible for the large trial in optimal timing of medication should be consulted about their likely publication date, as it may occur before the end of the guideline process.	Thank you for your comment. As this study is currently still recruiting participants, we do not believe it will publish in time for consideration within the guideline. However, the investigators will be contacted to confirm.
Maharishi Foundation	5	12 (and table below)	<p>The draft scope does not include a review of lifestyle interventions but the current guidelines do not appear to have reviewed the research into Transcendental Meditation.</p> <p>Please find below a summary of the research supported by a list of research references. I would be happy to provide pdfs of some of the important papers discussed in the summary (see references 4-12).</p> <p style="text-align: center;"><b>Evidence for inclusion of Transcendental Meditation in recommendations for nonpharmacological measures for prevention and management of hypertension</b></p>	Thank you for your comment and for outlining this area of research. We agree that lifestyle interventions are an important part of hypertension management and have now added relaxation therapies to the scope as an area that will be considered within the guideline.

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			<p style="text-align: center;"><b>Summary of evidence for NICE Hypertension Guidelines Group</b></p> <p style="text-align: center;">Roger Chalmers, <i>sessional general practitioner (NHS England-East Anglia)</i></p> <p style="text-align: center;"><b>Introduction</b></p> <p>Nonpharmacological lifestyle measures, including diet, weight management, and physical activity, are well established aspects of optimal hypertension management.<sup>1-3</sup></p> <p>Evidence summarized below supports the inclusion of Transcendental Meditation among nonpharmacological methods recommended for the prevention and management of hypertension and for improving cardiovascular outcomes.</p> <p style="text-align: center;"><b>Transcendental Meditation</b></p> <p>Transcendental Meditation® (TM), founded by Maharishi Mahesh Yogi, is a simple, effortless technique practised for 15-20 minutes twice daily. TM</p>	
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		<p>is taught by qualified teachers who have completed an extensive and systematic training programme, ensuring quality and consistency in instruction worldwide. It requires no belief, nor any change in lifestyle or diet, and can be easily learned by anyone regardless of age, education, or culture. More than five million people have learned the technique worldwide.</p> <p>In the United Kingdom, courses in Transcendental Meditation are offered by Maharishi Foundation, which was established as an educational charity in 1975 [registered educational charity numbers 270157 (England &amp; Wales); XR20456 (Northern Ireland); and SC041919 (Scotland)]. Maharishi Foundation is the only official organisation to offer these courses in the UK; there are 60 teaching centres in UK.</p> <p><b>Research on TM, blood pressure and cardiovascular health</b></p> <p>Since 1970, hundreds of research studies on TM have been conducted at over 250 universities and research institutions in 33 countries. Many have been published in peer-reviewed journals. In recent years, a multicentre American team has attracted repeated</p>	
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		<p>grants from the US National Institutes of Health (NIH) for research on TM and cardiovascular health, focussing particularly on African-Americans, a high-risk group for vascular disease.</p> <p>RCTs from this collaboration and other research groups have found that TM reduces BP in hypertensive and pre-hypertensive subjects,<sup>4-24</sup> and improves cardiovascular outcomes, as indicated by reductions in major clinical events and mortality.<sup>9,10</sup> In addition, TM ameliorates other factors that contribute to cardiovascular disease and hypertension risk, including reductions in smoking, alcohol consumption, psychological distress, and physiological markers of stress.<sup>8,30,48,76-87,91-95,98</sup></p> <p>Three well-conducted systematic reviews and meta-analyses of RCTs have concluded that TM reduces blood pressure.<sup>6,7,11</sup></p> <p><b>American Heart Association Scientific Statement 2013</b></p> <p>A <a href="#">Scientific Statement from the American Heart Association (AHA) in 2013</a> found that, based on RCTs and meta-analyses, 'The overall evidence supports that TM modestly lowers BP', and states that 'TM may</p>	
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		<p>be considered in clinical practice to lower BP'.<sup>4</sup> In contrast, the AHA report found that there is not enough evidence to recommend other meditation techniques: 'Because of many negative studies or mixed results and a paucity of available trials, all other meditation techniques (including MBSR) [Mindfulness-Based Stress Reduction] received a <i>Class III, no benefit, Level of Evidence C</i> recommendation. Thus, other meditation techniques are not recommended in clinical practice to lower BP at this time.'<sup>4</sup></p> <p>The lack of evidence for other forms of meditation appears to be the principal reason for the report's cautiously-worded conclusion about meditation in general; however, this does not alter the evidence discussed in the report showing beneficial effects from TM.<sup>4,5</sup></p> <p>Indeed, a response to the AHA Scientific Statement observes that it 'surveys 11 RCTs with &gt;1200 subjects and 2 well-conducted meta-analyses on TM and BP'.<sup>6-8</sup> Moreover, there are multiple hard event outcome trials on TM that are not available for other nonpharmacologic approaches.<sup>9-10</sup> Most of the RCTs published in the past 20 years have been competitively reviewed and externally funded, rigorously conducted in collaboration with leading academic medical centers, blinded, independently monitored, published in peer-reviewed journals, and replicated.<sup>8</sup> The 2012 cardiovascular disease event trial was analyzed independently.<sup>9</sup> BP effects of TM have been</p>	
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		<p>confirmed by numerous investigators, in multiple populations, and with ambulatory monitoring'.<sup>5-8,10,16</sup> This response further notes that, in the AHA report, 'the summary states that TM "modestly lowers BP"; however, the effect is the same order of magnitude as aerobic exercise and other nonpharmacologic methods recommended by the Statement'.<sup>4,5</sup> A meta-analysis of studies on TM and BP cited by the AHA report concludes that 'Blood pressure reductions of this magnitude would be expected to be accompanied by significant reductions in risk for atherosclerotic cardiovascular disease'.<sup>6</sup> This conclusion is consistent with findings of hard event outcome trials on TM discussed below.<sup>9,10</sup></p> <p><b>Recent systematic review and meta-analysis using Cochrane criteria</b></p> <p>Since publication of the AHA statement, a further independent systematic review and meta-analysis of RCTs found that TM lowers blood pressure.<sup>11</sup> This study employed rigorous Cochrane Collaboration criteria for assessing research quality. Regarding overall trial quality, the study concludes: 'The quality of</p>	
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		<p>studies meeting inclusion criteria was acceptable overall, with all 12 studies indicating a low risk of reporting bias and most trials having a low risk of detection and other biases'.<sup>11,12-23</sup> The authors observe that some previous reviews have inappropriately excluded research on the grounds that it is not double blind when such a design is not possible for many behavioural interventions, including TM. A response to this study sheds light on the results of subgroup analyses through examination of individual trial data, noting that higher initial BP levels appear to be associated with larger reductions as a result of TM.<sup>12</sup></p> <p>An earlier systematic review and meta-analysis of stress-reduction programmes for elevated BP identified 107 studies, of which 17 trials with 23 treatment comparisons and 960 participants met criteria for well-designed RCTs and were replicated within intervention categories. TM significantly reduced both systolic and diastolic BP, while other methods of meditation, relaxation, biofeedback, and stress management did not produce significant effects.<sup>7</sup> Another meta-analysis confirmed that TM leads to clinically important reductions in blood pressure.<sup>6</sup></p>	
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		<p><b>Improved cardiovascular outcomes: reduction of major clinical events; and decreased mortality</b></p> <p>In an RCT of 201 black American men and women with coronary heart disease (CHD), funded by NIH National Heart, Lung and Blood Institute, TM was associated with a 48% risk reduction in major clinical events (all-cause mortality plus non-fatal myocardial infarction and stroke) over an average follow-up of 5.4 years, compared to controls who received health education (hazard ratio, 0.52; 95% confidence interval, 0.29–0.92; <math>P=0.025</math>). TM also significantly reduced systolic BP and anger expression. Analysis was by intention to treat. Secondary analysis found a significant association between regularity of practice and survival; the subgroup of subjects who were regular in their TM practice had a 66% risk reduction in major clinical events compared with the overall sample risk reduction of 48%.<sup>9</sup></p> <p>In another study evaluating long-term effects on all-cause and cause-specific mortality in older subjects, patient data were pooled from two published RCTs that</p>	
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		<p>compared TM, other behavioural interventions, and usual therapy for elevated BP.<sup>10,13,24</sup> Subjects were 202 men and women, including 77 whites (mean age 81 years) and 125 African-American (mean age 66 years). Average baseline BP was in the pre-hypertensive or stage 1 hypertension range. Follow-up of vital status and cause of death over a maximum of 18.8 years was determined from the National Death Index; mean follow-up was 7.6 years. Survival analysis was used to compare intervention groups on mortality rates after adjusting for study location. Compared with combined controls, the TM group showed a 23% decrease in the primary outcome of all-cause mortality after maximum follow-up (relative risk 0.77, <math>P = 0.039</math>). Secondary analysis showed a 30% decrease in the rate of cardiovascular mortality with TM (relative risk 0.70, <math>P = 0.045</math>).<sup>10</sup></p> <p>Other RCTs on TM and cardiovascular health have shown:</p> <ul style="list-style-type: none"> <li>• decreased left ventricular mass in pre-hypertensive adolescents;<sup>17</sup></li> <li>• reduced carotid atherosclerosis (intima-media thickness) in hypertensive subjects;<sup>18</sup></li> </ul>	
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		<ul style="list-style-type: none"> <li>• decreased insulin resistance and BP in patients with stable CHD. TM also increased stability of the cardiac autonomic nervous system;<sup>19</sup></li> <li>• improved functional capacity and quality of life in patients with chronic heart failure. TM subjects also showed reduced depression and had fewer hospitalizations.<sup>25</sup></li> <li>• reduced use of antihypertensive medication compared to controls who practised progressive muscular relaxation or received health education.<sup>22</sup></li> </ul> <p>An analysis of cost-effectiveness based on results of RCTs on TM and US cost data indicated that TM could compare favourably with pharmacological treatment for hypertension.<sup>26</sup></p> <p>A controlled, non-randomized study on TM found improved exercise tolerance in angina patients with documented coronary lesions.<sup>27</sup> An uncontrolled pilot study found improvements in clinical and ECG variables in patients with cardiac syndrome X (anginal pain, positive exercise ECG, and normal angiogram).<sup>28</sup></p> <p>A narrative review of research on TM for prevention of cardiovascular disease notes that NIH-sponsored clinica</p>	
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		<p>trials did not observe any adverse effects from TM, a finding consistent with other cardiovascular studies and wider TM research literature.<sup>8</sup> The AHA Scientific Statement 2013, discussed above, observes that ‘TM (or meditation techniques in general) does not appear to pose significant health risks.’<sup>4</sup></p> <p><b>Effects on blood pressure in young adults and adolescents</b></p> <p>Adult essential hypertension has its origins in youth, BP levels ‘track’ relative to peers from late childhood onward and are predictive of future hypertension risk. The incidence of essential hypertension among young people has risen sharply in recent years. The need for early intervention to reduce BP is increasingly recognized.<sup>8,29</sup></p> <p>In this connection, it is of interest that RCTs on younger populations have shown:</p> <ul style="list-style-type: none"> <li>• In university students, TM reduced BP and also decreased total psychological distress, anxiety, depression, and anger/hostility; and improved coping.<sup>23</sup></li> <li>• In pre-hypertensive adolescents, TM decreased BP at rest and during acute laboratory stress;<sup>21</sup> and</li> </ul>	
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			<p>decreased ambulatory BP during normal daily activity.<sup>16</sup></p> <p><b>Reduced smoking and alcohol consumption</b></p> <p>A systematic review and meta-analysis of 198 studies (including 19 on TM) found that Transcendental Meditation was associated with marked, sustained, and highly significant reductions in smoking, alcohol consumption, and illicit drug use, with larger effects than other treatments, including standard therapies, other forms of meditation, relaxation training, educational programmes, anxiety management, counselling to counteract peer pressure, biofeedback, hypnosis, acupuncture and sensory deprivation.<sup>30</sup></p> <p>Over an 18-24 month period, abstinence ranged from 51% to 89% for people practising Transcendental Meditation, compared to 21% for good conventional substance abuse programmes. In contrast to high early relapse rates with standard programmes, reductions in smoking and alcohol consumption with TM increased gradually over time, while initial marked reductions in illicit drug use were sustained.<sup>30</sup></p>	
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		<p>These findings are notable in that practice of TM is not specifically directed towards changing substance use, unlike the other treatments analysed. Reductions in substance use with TM appear to develop as a consequence of reduced stress levels, increased psychological health and well-being, and associated reduced need for stimulation.<sup>30</sup></p> <p>Such effects could have important implications for many aspects of health, including prevention of cardiovascular disorders. However, in the RCT by Schneider et al. showing reduced risk of major clinical events with TM in CHD patients (discussed above), changes in smoking and alcohol consumption were not significant between groups. Thus the marked improvement in outcomes could not attributed to reduced substance use in this sample.<sup>9</sup></p> <p style="text-align: center;"><b>Cholesterol</b></p> <p>An early matched-control study found reductions in serum cholesterol levels with TM in medication-free hypercholesterolaemic subjects over an 11-month period.<sup>31</sup> In a more recent RCT, cholesterol did not</p>	
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		<p>change significantly in patients with stable CHD in whom pre-test cholesterol levels were already reduced due to statin treatment in 83% of subjects.<sup>19</sup></p> <p style="text-align: center;"><b>Stress reduction</b></p> <p>Substantial evidence indicates that psychosocial stress contributes to development and progression of hypertension and cardiovascular disease.<sup>8,9,32-38</sup> Attributable CHD risk associated with psychosocial stress factors across varied populations is similar to conventional cardiovascular risk factors.<sup>39</sup> Psychological distress, including depression, anger, hostility, and anxiety, predict cardiovascular clinical events,<sup>40-42</sup> and may be related to death from cardiovascular disease in a dose-response manner.<sup>32-33</sup> As a BMJ editorial noted, the question remains as to how to intervene to reduce this risk.<sup>32</sup> Research on TM has documented multiple short- and long-term physiological and psychological effects indicative of stress reduction and reduced psychological distress (discussed below). Reduction of stress through TM has been proposed as a rationale for cardiovascular research on this technique and as a</p>	
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		<p>possible mechanism underlying empirically-observed improvements in BP and cardiovascular outcomes with TM.<sup>8,9,43-45</sup></p> <p style="text-align: center;"><b>Physiological changes during TM</b></p> <p>Physiological changes during TM have been investigated over more than 40 years, showing a distinct physiological state characterized by increased integration in brain functioning and by metabolic, electrophysiological and biochemical markers indicative of deep rest and changes opposite to the physiological correlates of stress.<sup>46-67</sup> Findings include reduced respiration rate and minute ventilation;<sup>46-52</sup> high and stable galvanic skin resistance;<sup>46-51</sup> increased orderliness and integration of brain functioning;<sup>46,47,51,55-61</sup> decreased peripheral vascular resistance;<sup>62</sup> decreased plasma cortisol;<sup>53,54</sup> reduced arterial blood lactate;<sup>46-49,63</sup> other neuroendocrine changes;<sup>64-66</sup> and decreased EMG activity.<sup>60,67</sup> Overall, subjective experience during TM and its physiological correlates have been aptly described as a state of 'restful alertness'.<sup>46,47,49,55</sup> Taken together, these findings distinguish the physiology of TM from</p>	
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		<p>sleep, drowsiness, or simple eyes-closed rest.<sup>46-49,51,55</sup></p> <p>A review of different forms of meditation identified characteristics of practice and EEG patterns that distinguish TM from other methods. TM was the only technique for which EEG correlates had been documented in RCTs.<sup>55</sup></p> <p><b>Effects of regular practice of TM: sustained reductions in psychophysiological correlates of stress; improvements in physical, mental and social parameters</b></p> <p>In addition to the cardiovascular health findings discussed above, regular practice of TM is associated with sustained reductions in physiological correlates of stress<sup>8,48</sup> and longitudinal improvements in EEG markers of brain integration,<sup>55,59,68-71</sup> perceptual and cognitive functioning,<sup>13,72-75,88-90</sup> psychological health (including reduced anxiety, depression, anger, and hostility, and increased well-being),<sup>76-87,91-95,98</sup> and with improvements in education,<sup>72,85-90</sup> occupational health and performance,<sup>91-95</sup> and rehabilitation of offenders.<sup>96-98</sup></p>	
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			<p><b>Improved quality of life and well-being in patients with chronic disorders, and in the elderly</b></p> <p>RCTs have shown improvements in quality of life and mental health with TM in patients with chronic physical disorders.<sup>25,76,77</sup> Findings include: improvements in functional capacity and quality of life, and reduced depression levels, in patients with chronic heart failure;<sup>25</sup> and improvements in overall quality of life, emotional well-being, social well-being, and mental health in women with breast cancer (stage II to IV).<sup>76</sup></p> <p>Another RCT found that elderly people (mean age 81 years) who learned TM showed greater improvement on measures of mental health, cognitive flexibility, systolic BP, and well-being, and lower mortality than three comparison groups from the same residential institutions (who learned either a relaxation technique, a mindfulness procedure, or received no treatment).<sup>13</sup></p> <p><b>Reduced anxiety</b></p>	
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		<p>A systematic review and meta-analysis of 146 independent outcomes found that Transcendental Meditation was more than twice as effective in reducing trait anxiety as other techniques (including progressive muscular relaxation, methods claimed to induce a 'relaxation response', and other forms of meditation). Only TM showed a positive correlation between duration of regular practice and reduction of anxiety. Results remained robust when only the most rigorous studies were included and when other potentially confounding factors were controlled.<sup>78</sup> These findings are supported and extended by a recent systematic review and meta-analysis of RCTs which confirmed that TM was effective in reducing trait anxiety, with greater effects seen in subjects with high anxiety levels before starting the technique. Studies using repeated measures showed substantial reductions in anxiety within two weeks of learning TM, and sustained improvements after one and three years. No other alternative active treatment was more effective than TM. Moreover, TM had a greater effect in decreasing anxiety than was observed with mindfulness in a previous meta-analysis.<sup>79</sup> TM was</p>	
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		<p>also exceptional in the breadth and depth of beneficial effects associated with anxiety reduction. The analysis found no evidence that author affiliation influenced outcomes: effect sizes of studies conducted by researchers from Maharishi University of Management were not greater than those of studies from independent universities, consistent with previous findings.<sup>78,79</sup></p> <p style="text-align: center;"><b>Increased psychological well-being</b></p> <p>Another meta-analysis of 42 independent research results found that Transcendental Meditation was three times as effective as other meditation and relaxation procedures in increasing self-actualization, an overall measure of positive mental health and personal development. Further analysis revealed that the technique is exceptionally effective in developing three independent components of this dimension: emotional maturity, a resilient sense of self, and a positive, integrated perspective of self and the world.<sup>80</sup></p> <p style="text-align: center;"><b>Improvements in post-traumatic stress disorder</b></p> <p>An early RCT found that TM improved multiple features of post-traumatic stress disorder (PTSD) in American veterans of the Vietnam war, including</p>	
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		<p>reductions in depression, anxiety, insomnia, severity of delayed stress syndrome, emotional numbness, alcohol consumption, family problems, and difficulty in obtaining employment, compared to controls who received psychotherapy.<sup>81</sup></p> <p>These results are consistent with more recent controlled, non-randomized studies on TM showing: marked, rapid, and sustained reductions in PTSD symptom scores in civilian refugees of the Congo war with severe PTSD;<sup>82,83</sup> and reduced medication usage and an overall decrease in the severity of psychological symptoms in American active duty military service members with PTSD or anxiety.<sup>84</sup></p> <p style="text-align: center;"><b>Health care needs and costs</b></p> <p>A 14-year controlled retrospective study of 2836 people enrolled in the Quebec provincial health insurance scheme found that, after beginning TM, subjects showed a progressive decline in payments to physicians compared to controls. The average annual difference was 13%, leading to a cumulative cost reduction of 55% after six years. These</p>	
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		<p>findings are supported by further analyses of two important subgroups whose costs contribute strongly to overall health care expenditure: for the highest-cost 10% of subjects, the TM group's payments decreased by 11% over one year, with a cumulative reduction of 28% after five years compared to controls; and for subjects over 65 years, the TM group showed a five-year cumulative cost reduction of 70% compared to controls.<sup>99-102</sup></p> <p>An earlier study of data from major US health insurer Blue Cross/Blue Shield examined medical care utilization over five consecutive years among 2,000 subscribers practising Transcendental Meditation, as compared to norms and control groups matched by age, gender, occupation, and health insurance terms (drawn from a total sample of 600,000). Both hospital admissions and outpatient consultations were over 50% fewer for subjects practising TM compared to norms and controls. In the over-40 age group, the reduction was over 70%. Hospital admission rates were reduced in all 17 disease categories studied (including cardiovascular disorders, although sample size for specific disease categories was too small for</p>	
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		<p>meaningful statistical analysis).<sup>103</sup></p> <p style="text-align: center;"><b>Conclusion</b></p> <p>RCTs and meta-analyses of RCTs have found that TM reduces BP in hypertensive and pre-hypertensive subjects.<sup>4-24</sup></p> <p>RCTs have shown that TM improves cardiovascular outcomes, notably marked reductions in major clinical events and mortality.<sup>9,10</sup></p> <p>Research has also found that TM ameliorates other factors that contribute to cardiovascular disease and hypertension risk, including reductions in smoking, alcohol consumption, psychological distress, and physiological markers of stress.<sup>8,30,48,76-87,91-95,98</sup></p> <p>The American Heart Association Scientific Statement (2013) found evidence that TM reduces BP and stated that 'TM may be recommended in clinical practice to</p>	
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		<p>lower BP'; this was not the case for other methods of meditation and relaxation.<sup>4</sup></p> <p>NICE Hypertension Guideline CG127 (2011)<sup>1</sup> and US guidelines including JNC-8<sup>2,3</sup> emphasize nonpharmacological lifestyle measures, including healthy diet, weight control, and regular exercise, for all stages of hypertension. NICE guidelines also appropriately recognize the wider health implications of such measures, for example the multiple benefits of smoking cessation and reduced alcohol consumption. Moreover, lifestyle measures are recommended as the primary approach to management of pre-hypertension and stage 1 hypertension, for which longer term benefits of drug treatment are uncertain in patients without target organ damage, existing cardiovascular disease or at low risk of cardiovascular disease, as reported in NICE Evidence Update 32 (2013).<sup>104</sup></p> <p>In this context, TM offers a valuable addition to nonpharmacological measures for hypertension, with supporting evidence documenting beneficial effects on BP, cardiovascular outcomes, and other aspects of health and well-being in varied subject populations,</p>	
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			<p>including pre-hypertensive young adults and adolescents, older subjects with mild hypertension, and secondary prevention patients with CHD.<sup>4-25</sup></p> <p><b>References</b></p> <ol style="list-style-type: none"> <li>1. Hypertension in adults: diagnosis and management. NICE clinical guideline CG127 (2011). <a href="https://www.nice.org.uk/guidance/cg127">https://www.nice.org.uk/guidance/cg127</a></li> <li>2. Eckel RH, Jakicic JM, Ard JD, Houston Miller N, Hubbard VS, Nonas CA, <i>et al.</i> AHA/ACC guideline on lifestyle management to reduce cardiovascular risk: a report of the American College of Cardiology/American Heart Association task force on practice guidelines. <i>Circulation</i> 2013. doi:10.1161/01.cir.0000437740.48606.d1</li> <li>3. James PA, Oparil S, Carter BL, Cushman WC, Dennison-Himmelfarb C, Handler J, <i>et al.</i> 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults. Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC 8). <i>Journal of the American Medical Association</i> 2014 311(5):507-520. doi:10.1001/jama.2013.284427</li> </ol>	
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			<ol style="list-style-type: none"> <li>4. Brook RD, Appel LJ, Rubenfire M, Ogedegbe G, Bisognano JD, Elliott WJ, <i>et al.</i> Beyond medications and diet: alternative approaches to lowering blood pressure. A Scientific Statement from the American Heart Association. <i>Hypertension</i> 2013 61(6):1360-1383. doi:10.1161/HYP.0b013e318293645f</li> <li>5. Schneider RH. Response to AHA scientific statement on alternative methods and BP: evidence for upgrading the ratings for Transcendental Meditation. <i>Hypertension</i> 2013 62(6):e42. doi:10.1161/HYPERTENSIONAHA.113.02115</li> <li>6. Anderson JW, Liu C, Kryscio RJ. Blood pressure response to Transcendental Meditation: a meta-analysis. <i>American Journal of Hypertension</i> 2008 21:310-316. doi: 10.1038/ajh.2007.65</li> <li>7. Rainforth MV, Schneider RH, Nidich SI, Gaylord-King C, Salerno JW, Anderson JW. Stress reduction programs in patients with elevated blood pressure: a systematic review and meta-analysis. <i>Current Hypertension Reports</i> 2007 9:520-528. PMID: PMC2268875</li> <li>8. Barnes VA, Orme-Johnson DW. Prevention and treatment of cardiovascular disease in adolescents and adults through the Transcendental Meditation® Program: a</li> </ol>	
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			<p>research review update. <i>Current Hypertension Reviews</i> 2012 8(3):227-242. doi:<a href="https://doi.org/10.2174/157340206778132545">10.2174/157340206778132545</a></p> <p>9. Schneider RH, Grim CE, Rainforth MV, Kotchen T, Nidich SI, Gaylord-King C, Salerno JW, Kotchen JM, Alexander CN. Stress reduction in the secondary prevention of cardiovascular disease: randomized, controlled trial of Transcendental Meditation and health education in blacks. <i>Circulation: Cardiovascular Quality and Outcomes</i> 2012 5(6):750-758. doi: <a href="https://doi.org/10.1161/CIRCOUTCOMES.112.967406">10.1161/CIRCOUTCOMES.112.967406</a></p> <p>10. Schneider RH, Alexander CN, Staggars F, Rainforth M, Salerno JW, Hartz A, <i>et al.</i> Long-term effects of stress reduction on mortality in persons <math>\geq 55</math> years of age with systemic hypertension. <i>American Journal of Cardiology</i> 2005 95(9):1060-1064. doi:<a href="https://doi.org/10.1016/j.amjcard.2004.12.058">10.1016/j.amjcard.2004.12.058</a></p> <p>11. Bai Z, Chang J, Chen C, Li P, Yang K, Chi I. Investigating the effect of transcendental meditation on blood pressure: a systematic review and meta-analysis. <i>Journal of Human Hypertension</i> 2015 29: 653-662. doi:<a href="https://doi.org/10.1038/jhh.2015.6">10.1038/jhh.2015.6</a></p> <p>12. Orme-Johnson D. Comment on 'Investigating the effect of transcendental meditation on blood pressure: a systematic review and meta-</p>	
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			<p>analysis'. <i>Journal of Human Hypertension</i> 2015 Nov 5. doi:10.1038/jhh.2015.111</p> <p>13. Alexander CN, Langer EJ, Newman RI, Chandler HM, Davies JL. Transcendental meditation, mindfulness, and longevity: an experimental study with the elderly. <i>Journal of Personality and Social Psychology</i> 1989 57:950-964</p> <p>14. Schneider RH, Staggars F, Alexander CN, Sheppard W, Rainforth M, Kondwani K <i>et al.</i> A randomized controlled trial of stress reduction for hypertension in older African Americans. <i>Hypertension</i> 1995 26:820-827</p> <p>15. Alexander CN, Schneider RH, Staggars F, Sheppard W, Clayborne BM, Rainforth M <i>et al.</i> Trial of stress reduction for hypertension in older African Americans: II. Sex and risk subgroup analysis. <i>Hypertension</i> 1996 28:228-237</p> <p>16. Barnes VA, Treiber FA, Johnson MH. Impact of transcendental meditation on ambulatory blood pressure in African-American adolescents. <i>American Journal of Hypertension</i> 2004 17:366-369</p> <p>17. Barnes VA, Kapuku GK, Treiber FA. Impact of transcendental meditation on left ventricular mass in African American adolescents.</p>	
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			<p><i>Evidence-Based Complementary and Alternative Medicine</i> 2012;923153, 1-6</p> <p>18. Castillo-Richmond A, Schneider RH, Alexander CN, Cook R, Myers H, Nidich S <i>et al.</i> Effects of stress reduction on carotid atherosclerosis in hypertensive African Americans. <i>Stroke</i> 2000 31:568-573</p> <p>19. Paul-Labrador M, Polk D, Dwyer JH, Velasquez I, Nidich S, Rainforth M <i>et al.</i> Effects of a randomized controlled trial of transcendental meditation on components of the metabolic syndrome in subjects with coronary heart disease. <i>Archives Internal Medicine</i> 2006 166(11):1218-1224</p> <p>20. Wenneberg SR, Schneider RH, Walton KG, Maclean CR, Levitsky DK, Salerno JW <i>et al.</i> A controlled study of the effects of the transcendental meditation program on cardiovascular reactivity and ambulatory blood pressure. <i>International Journal of Neuroscience</i> 1997 89:15-28</p> <p>21. Barnes VA, Treiber FA, Davis H. Impact of Transcendental Meditation on cardiovascular function at rest and during acute stress in adolescents with high normal blood pressure. <i>Journal of Psychosomatic Research</i> 2001 51(4):597-605</p>	
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			<p>22. Schneider RH, Alexander CN, Stagers F, Orme-Johnson DW, Rainforth M, Salerno JW <i>et al.</i> A randomized controlled trial of stress reduction in African Americans treated for hypertension for over one year. <i>American Journal of Hypertension</i> 2005 18:88-98</p> <p>23. Nidich SI, Rainforth MV, Haaga DAF, Hagelin J, Salerno JW, Travis F <i>et al.</i> A randomized controlled trial on effects of the transcendental meditation program on blood pressure, psychological distress, and coping in young adults. <i>American Journal of Hypertension</i> 2009 22:1326-1331</p> <p>24. Alexander C, Barnes V, Schneider R <i>et al.</i> Randomized controlled trial of stress reduction on cardiovascular and all-cause mortality in the elderly: results of 8-year and 15-year follow-ups. <i>Circulation</i> 1996 93:629</p> <p>25. Jayadevappa R, Johnson JC, Bloom BS, Nidich S, Desai S, Chhatre S, <i>et al.</i> Effectiveness of Transcendental Meditation on functional capacity and quality of life of African Americans with congestive heart failure: a randomized control study. <i>Ethnicity and Disease</i> 2007 17:72-77</p> <p>26. Herron R, Schneider RH, Mandarino JV, Alexander CN, Walton KG. Cost-effective hypertension management: comparison of drug therapies with an alternative program.</p>	
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			<p><i>American Journal of Managed Care</i> 1996 2:427-437</p> <p>27. Zamarra JW, Schneider RH, Besseghini I, Robinson DK, Salerno JW. Usefulness of the Transcendental Meditation program in the treatment of patients with coronary artery disease. <i>American Journal of Cardiology</i> 1996 77(10):867-870</p> <p>28. Cunningham CH, Brown S, Kaski JC. The effects of Transcendental Meditation on symptoms and electrocardiographic changes in patients with cardiac syndrome X: a pilot study. <i>American Journal of Cardiology</i> 2000 85(5):653-655</p> <p>29. Muntner P, He J, Cutler JA, Wildman RP, Whelton PK. Trends in blood pressure among children and adolescents. <i>Journal of the American Medical Association</i> 2004; 291: 2107-2113</p> <p>30. Alexander CN, Robinson P, Rainforth MV. Treating and preventing alcohol, nicotine, and drug abuse through Transcendental Meditation: a review and statistical meta-analysis. <i>Alcoholism Treatment Quarterly</i> 1994 11(1/2):13-87</p> <p>31. Cooper M, Aygen M. Transcendental Meditation in the management of</p>	
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## Hypertension in adults

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			<p>hypercholesterolemia. <i>Journal of Human Stress</i> 1979 5(4):24-27</p> <p>32. Lewis G. Psychological distress and death from cardiovascular disease (<i>editorial</i>). <i>British Medical Journal</i> 2012 345:e5177</p> <p>33. Russ TC, Stamatakis E, Hamer M, Starr JM, Kivimaki M, Batty GD. Association between psychological distress and mortality: individual participant pooled analysis of prospective cohort studies. <i>British Medical Journal</i> 2012 354:e4933</p> <p>34. Dimsdale JE. Psychological stress and cardiovascular disease. <i>Journal of the American College of Cardiology</i> 2008 51:1237-1246</p> <p>35. Rozanski A, Blumenthal JA, Davidson KW, Saab PG, Kubzansky L. The epidemiology, pathophysiology, and management of psychosocial risk factors in cardiac practice: the emerging field of behavioral cardiology. <i>Journal of the American College of Cardiology</i> 2005 45:637-651</p> <p>36. Snieder H, Harshfield G, Barbeau P, Pollock D, Pollock J, Treiber F. Dissecting the genetic architecture of the cardiovascular and renal stress response. <i>Biological Psychology</i> 2002; 61: 73-95</p>	
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**09/06/2017 to 07/07/2017**

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			<p>37. Brotman DJ, Golden SH, Wittstein IS. The cardiovascular toll of stress. <i>Lancet</i> 2007 370:1089-1100</p> <p>38. Bairey Merz CN, Dwyer J, Nordstrom CK, Walton KG, Salerno JW, Schneider RH. Psychosocial stress and cardiovascular disease: pathophysiological links. <i>Behavioral Medicine</i> 2002 27:141-147</p> <p>39. Yusuf S, Hawken S, Ounpuu S, Dans T, Avezum A, Lanas F, <i>et al.</i> INTERHEART Study Investigators. Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART study): case-control study. <i>Lancet</i> 2004 364:937-952</p> <p>40. Barth J, Schumacher M, Herrmann-Lingen C. Depression as a risk factor for mortality in patients with coronary heart disease: a meta-analysis. <i>Psychosomatic Medicine</i> 2004 66:802-813</p> <p>41. Chida Y, Steptoe A. The association of anger and hostility with future coronary heart disease: a meta-analytic review of prospective evidence. <i>Journal of the American College of Cardiology</i> 2009 53:936-946</p> <p>42. Roest AM, Martens EJ, de Jonge P, Denollet J. Anxiety and risk of incident coronary heart</p>	
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			<p>disease: a meta-analysis. <i>Journal of the American College of Cardiology</i> 2010 56:38-46</p> <p>43. Walton KG, Schneider RH, Nidich SI, Salerno JW, Nordstrom CK, Merz CN. Psychosocial stress and cardiovascular disease. Part 2: effectiveness of the Transcendental Meditation program in treatment and prevention. <i>Behavioral Medicine</i> 2002 28(3):106-123</p> <p>44. Walton KG, Schneider RH, Salerno JW, Nidich SI. Psychosocial stress and cardiovascular disease. Part 3: clinical and policy implications of research on the Transcendental Meditation program. <i>Behavioral Medicine</i> 2005 30(4):173-183</p> <p>45. Schneider RH, Carr T. Transcendental Meditation in the prevention and treatment of cardiovascular disease and pathophysiological mechanisms: an evidence-based review. <i>Advances in Integrative Medicine</i> (online) 2014. doi: 10.1016/j.aimed.2014.08.003</p> <p>46. Wallace RK. Physiological effects of Transcendental Meditation. <i>Science</i> 1970 167:1751-1754</p> <p>47. Wallace RK, Benson H, Wilson AF. A wakeful hypometabolic physiologic state. <i>American Journal of Physiology</i> 1971 221:795-799</p> <p>48. Dillbeck MC, Orme-Johnson DW. Physiological differences between</p>	
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			<p>Transcendental Meditation and rest. <i>American Psychologist</i> 1987 42:879-881</p> <p>49. Jevning R, Wallace RK, Beidebach M. The physiology of meditation: a review. A wakeful hypometabolic integrated response. <i>Neuroscience and Biobehavioral Reviews</i> 1992 16(3):415-424</p> <p>50. Wolkove N, Kreisman H, Darragh D, Cohen C, Frank H. Effect of Transcendental Meditation on breathing and respiratory control. <i>Journal of Applied Physiology: Respiratory, Environmental and Exercise Physiology</i> 1984 56:607-612</p> <p>51. Gallois P. Modifications neurophysiologiques et respiratoires lors de la pratique des techniques de relaxation. <i>L'Encephale</i> 1984 10:139-144</p> <p>52. Garnier D, Cazabat A, Thébault P, Gauge P. Pulmonary ventilation during the Transcendental Meditation technique: applications in preventive medicine. <i>Est-Médecine</i> 1984 4(76):867-870</p> <p>53. Jevning R, Wilson AF, Davidson JM. Adrenocortical activity during meditation. <i>Hormones and Behavior</i> 1978 10(1):54-60</p> <p>54. MacLean CR, Walton KG, Wenneberg SR, Levitsky DK, Mandarino JV, Waziri R, <i>et al.</i> Effects of the Transcendental Meditation</p>	
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			<p>program on adaptive mechanisms: changes in hormone levels and responses to stress after four months of practice. <i>Psychoneuroendocrinology</i> 1997 22(4):277-295</p> <p>55. Travis F, Shear J. Focused attention, open monitoring and automatic self-transcending: categories to organize meditations from Vedic, Buddhist and Chinese traditions. <i>Consciousness and Cognition</i> 2010 19:1110-1118</p> <p>56. Travis FT, Haaga DH, Hagelin JS, Tanner M, Arenander A, Nidich S, <i>et al.</i> A self-referential default brain state: patterns of coherence, power, and eLORETA sources during eyes-closed rest and the Transcendental Meditation practice. <i>Cognitive Processing</i> 2010 11:21-30</p> <p>57. Yamamoto S, Kitamura Y, Yamada N, Nakashima Y, Kuroda S. Medial prefrontal cortex and anterior cingulate cortex in the generation of alpha activity induced by Transcendental Meditation: a magnetoencephalographic study. <i>Acta Medica Okayama</i> 2006 60(1):51-58</p> <p>58. Hebert JR, Lehmann D, Tan G, Travis FT, Arenander A. Enhanced EEG alpha time-domain phase synchrony during Transcendental Meditation: implications for</p>	
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			<p>cortical integration theory. <i>Signal Processing</i> 2005 85(11):2213-2232</p> <p>59. Travis FT, Arenander A. Cross-sectional and longitudinal study of effects of Transcendental Meditation practice on interhemispheric frontal asymmetry and frontal coherence. <i>International Journal of Neuroscience</i> 2006 116:1519-1538</p> <p>60. Banquet JP. Spectral analysis of the EEG in meditation. <i>Electroencephalography and Clinical Neurophysiology</i> 1973 35:143-151</p> <p>61. Travis F. Transcendental experiences during meditation practice. <i>Annals of the New York Academy of Sciences</i> 2014 1307:1-8</p> <p>62. Barnes VA, Treiber FA, Turner JR, Davis H, Strong WB. Acute effects of Transcendental Meditation on hemodynamic functioning in middle-aged adults. <i>Psychosomatic Medicine</i> 1999 61(4):525-531</p> <p>63. Jevning R, Wilson AF, O'Halloran JP, Walsh RN. Forearm blood flow and metabolism during stylized and unstylized states of decreased activation. <i>American Journal of Physiology</i> 1983 245 (Regulatory Integrative Comp. Physiol.14):R110-R116</p> <p>64. Infante JR, Torres-Avisbal M, Pinel P, Vallejo JA, Peran F, Gonzalez F, <i>et al.</i> Catecholamine levels in practitioners of the Transcendental</p>	
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			<p>Meditation technique. <i>Physiology and Behavior</i> 2001 72(2):141-146</p> <p>65. Infante JR, Peran F, Martinez M, Roldan A, Poyatos R, Ruiz C, <i>et al.</i> ACTH and beta-endorphin in Transcendental Meditation. <i>Physiology and Behavior</i> 1998 64(3):311-315</p> <p>66. Tooley GA, Armstrong SM, Norman TR, Sali A. Acute increases in night-time plasma melatonin levels following a period of meditation. <i>Biological Psychology</i> 2000 53(1):69-78</p> <p>67. Kemmerling T. Wirkung der Transzendentalen Meditation auf den Muskeltonus. <i>Psychopathometrie</i> 1978 4:437-438</p> <p>68. Travis F, Haaga DA, Hagelin J, Tanner M, Nidich S, Gaylord-King C, <i>et al.</i> Effects of Transcendental Meditation practice on brain functioning and stress reactivity in college students. <i>International Journal of Psychophysiology</i> 2009 71(2):170-176</p> <p>69. Travis F Grosswald S, Stixrud W. ADHD, brain functioning, and Transcendental Meditation practice. <i>Mind &amp; Brain, The Journal of Psychiatry</i> 2011 2:73-81</p> <p>70. Orme-Johnson DW, Schneider RH, Son YD, Nidich S, Cho Z-H. Neuroimaging of meditation's effect on brain reactivity to pain. <i>NeuroReport</i> 2006 17:1359-1363</p>	
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			<p>71. Travis FT, Tecce J, Arenander A, Wallace RK. Patterns of EEG coherence, power and contingent negative variation characterize the integration of transcendental and waking states. <i>Biological Psychology</i> 2002 61:293-319</p> <p>72. So KT, Orme-Johnson DW. Three randomized experiments on the holistic longitudinal effects of the Transcendental Meditation technique on cognition. <i>Intelligence</i> 2001 29:419-440</p> <p>73. Fergusson LC. Field independence, transcendental meditation, and achievement in college art: a re-examination. <i>Perceptual and Motor Skills</i> 1993 77:1104-1106</p> <p>74. Chandler HM, Alexander CN, Heaton DP, Grant J. Transcendental Meditation and postconventional self-development: a 10-year longitudinal study. <i>Journal of Social Behavior and Personality</i> 2005 17:93-122</p> <p>75. Sridevi K, Krishna Rao PV. Temporal effects of meditation on cognitive style. <i>Journal of Indian Psychology</i> 2003 21:38-51</p> <p>76. Nidich SI, Fields JZ, Rainforth MV, Pomerantz R, Cella D, Kristeller J, <i>et al.</i> A randomized controlled trial of the effects of Transcendental Meditation on quality of life in older breast cancer patients. <i>Integrative Cancer Therapies</i> 2009 8:228-234</p>	
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			<p>77. Chhatre S, Metzger DS, Frank I, Boyer J, Thompson E, Nidich S, <i>et al.</i> Effects of behavioral stress reduction Transcendental Meditation intervention in persons with HIV. <i>AIDS Care: Psychological and Socio-medical Aspects of AIDS/HIV</i> 2013 25:1291-1297</p> <p>78. Eppley K, Abrams A, Shear J. Differential effects of relaxation techniques on trait anxiety: a meta-analysis. <i>Journal of Clinical Psychology</i> 1989 45:957-974</p> <p>79. Orme-Johnson DW, Barnes VA. Effects of the Transcendental Meditation Technique on trait anxiety: a meta-analysis of randomized controlled trials. <i>Journal of Alternative and Complementary Medicine</i> 2013 19:1-12</p> <p>80. Alexander CN, Rainforth MV, Gelderloos P. Transcendental Meditation, self-actualization, and psychological health: a conceptual overview and statistical meta-analysis. <i>Journal of Social Behavior and Personality</i> 1991 6:189-247</p> <p>81. Brooks JS, Scarano T. Transcendental Meditation in the treatment of post-Vietnam adjustment. <i>Journal of Counseling and Development</i> 1985 64:212-215</p> <p>82. Rees B, Travis F, Shapiro D, Chant R. Reduction in posttraumatic stress symptoms in Congolese refugees practicing Transcendental</p>	
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			<p>Meditation. <i>Journal of Traumatic Stress</i> 2013 26:295-298</p> <p>83. Rees B, Travis F, Shapiro D, Chant R. Significant reductions in posttraumatic stress symptoms in Congolese refugees within 10 days of Transcendental Meditation practice. <i>Journal of Traumatic Stress</i> 2014 27:112-115</p> <p>84. Barnes VA, Monto A, Williams JJ, Rigg JL. Transcendental Meditation® and psychotropic medication use among active duty military service members with anxiety and PTSD. <i>Military Medicine</i> 2016 181(1):56-63</p> <p>85. Colbert RD, Nidich S. Effect of the Transcendental Meditation Program on graduation, college acceptance and dropout rates for students attending an urban public high school. <i>Education</i> 2013 133:495-501</p> <p>86. Elder C, Nidich S, Colbert R, Hagelin J, Grayshield L, Oviedo-Lim D, <i>et al.</i> Reduced psychological distress in racial and ethnic minority students practicing the Transcendental Meditation Program. <i>Journal of Instructional Psychology</i> 2011 38:109-116</p> <p>87. Barnes VA, Bauza LB, Treiber FA. Impact of stress reduction on negative school behavior in adolescents. <i>Health and Quality of Life Outcomes</i> 2003 1:10</p>	
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			<p>88. Kember P. The Transcendental Meditation technique and postgraduate academic performance. <i>British Journal of Educational Psychology</i> 1985 55:164-166</p> <p>89. Nidich S, Mjasiri S, Nidich R, Rainforth M, Grant J, Valosek L, <i>et al.</i> Academic achievement and Transcendental Meditation: a study with at-risk urban middle school students. <i>Education</i> 2011 131:556-564</p> <p>90. Cranson RW, Orme-Johnson DW, Dillbeck MC, Jones CH, Alexander CN, Gackenbach J. Transcendental Meditation and improved performance on intelligence-related measures: a longitudinal study. <i>Journal of Personality and Individual Differences</i> 1991 12:1105-1116</p> <p>91. Elder C, Nidich S, Moriarty F, Nidich R. Effect of Transcendental Meditation on employee stress, depression, and burnout: a randomized controlled study. <i>The Permanente Journal</i> 2014 18:19-23</p> <p>92. Sheppard DH, Staggars F, John L. The effects of a stress management program in a high security government agency. <i>Anxiety, Stress and Coping</i> 1997 10:341-350</p> <p>93. Haratani T, Hemmi T. Effects of Transcendental Meditation on mental health of industrial workers. <i>Japanese Journal of Industrial Health</i> 1990 32:656</p>	
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			<p>94. Haratani T, Hemmi T. Effects of Transcendental Meditation on health behavior of industrial workers. <i>Japanese Journal of Public Health</i> 1990 37:729</p> <p>95. Alexander CN, Swanson GC, Rainforth MV, Carlisle TW, Todd CC, Oates RM. Effects of the Transcendental Meditation program on stress reduction, health, and employee development: a prospective study in two occupational settings. <i>Anxiety, Stress, and Coping</i> 1993 6:245-262</p> <p>96. Bleick CR, Abrams AI. The Transcendental Meditation program and criminal recidivism in California. <i>Journal of Criminal Justice</i> 1987 15:211-230</p> <p>97. Rainforth M, Alexander CN, Cavanaugh KL. Effects of the Transcendental Meditation program on recidivism of former inmates of Folsom Prison: survival analysis of 15-year follow-up data. <i>Journal of Offender Rehabilitation</i> 2003 35:181-204</p> <p>98. Abrams AI, Siegel LM. The Transcendental Meditation program and rehabilitation at Folsom State Prison: a cross-validation study. <i>Criminal Justice and Behavior</i> 1978 5:3-20</p> <p>99. Herron R, Hillis S. The impact of the Transcendental Meditation program on government payments to physicians in</p>	
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			<p>Quebec: an update. <i>American Journal of Health Promotion</i> 2000 14:284-291</p> <p>100. erron RE, Hillis SL, Mandarinino JV, Orme-Johnson DW, Walton KG. The impact of the Transcendental Meditation program on government payments to physicians in Quebec. <i>American Journal of Health Promotion</i> 1996 10:208-216</p> <p>101. erron R. Changes in physician costs among high-cost Transcendental Meditation practitioners compared with high-cost nonpractitioners over 5 years. <i>American Journal of Health Promotion</i> 2011 26(1):56-60</p> <p>102. erron RE, Cavanaugh KL. Can the Transcendental Meditation program reduce medical expenditures of older people? A longitudinal cost-reduction study in Canada. <i>Journal of Social Behavior and Personality</i> 2005 17:415-442</p> <p>103. rme-Johnson DW. Medical care utilization and the Transcendental Meditation program. <i>Psychosomatic Medicine</i> 1987 49:493-507</p> <p>104. ypertension: Evidence Update 32, March</p>	
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			<p>2013. A summary of selected new evidence relevant to NICE clinical guideline 127 'Clinical management of primary hypertension in adults' (2011). <a href="https://www.nice.org.uk/guidance/cg127/evidence/evidence-update-248584429">https://www.nice.org.uk/guidance/cg127/evidence/evidence-update-248584429</a></p> <p><b>Competing interest statement:</b> Roger Chalmers became a teacher of Transcendental Meditation (TM) in 1975 and qualified in medicine from Cambridge University in 1979. He has maintained an interest in research on TM and its medical applications for more than 40 years. From 1982-1987, he worked directly with institutions established to further the teaching of TM, promote research into its effects, and educate the public, scientists, professions, and government about its benefits. During this period he co-edited three volumes of collected research on TM. From 1987-1991, he was engaged in private medical practice, utilizing a complementary health system which includes TM, alongside modern medicine. Dr Chalmers returned to NHS practice in 1996, completing training as a general practitioner in 1998. For the past 18 years, he has worked in UK general practice and is currently a part-time sessional GP on the NHS England-East Anglia medical performers list. He has derived more than 99% of his earnings over the past 20 years from NHS clinical work.</p>	
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Medicines and Healthcare products Regulatory Agency	General	General	The MHRA recommends using scientific terminology in identifying patient groups for treatment in preference to terms such as “blacks/ Orientals”. It is recognised such terms were previously used and there might be some carryover but the terms might not describe genetically / pharmacogenetically distinct groups.	Thank you for your comment and for the information you have provided. This will be considered by the guideline committee when discussing the population and subgroups for our review questions and protocols to ensure the terms used are appropriate.
Medtronic Ltd	2	18 - 20	We support NICE in recognising the challenge associated with resistant hypertension and would like to draw your attention to our ongoing SPYRAL HTN Global Clinical Trials; SPYRAL HTN-OFF MED and SPYRAL HTN-ON MED which NICE may wish to consider in future updates of the clinical guideline.	Thank you for your comment. While the current update will not cover non-pharmacological interventions, this area may be covered in future updates when these trials may be assessed for inclusion.
Medtronic Ltd	6	18	Although renal denervation is not in scope of the guideline, the intervention is of direct relevance and therefore Medtronic respectfully request that the following IPG is added to the list of related NICE guidance:  Percutaneous transluminal radiofrequency sympathetic denervation of the renal artery for resistant hypertension (2012) NICE Guideline IPG418	Thank you for your comment. We have added IPG418 to the list of related NICE guidance.
Medtronic Ltd	General	General	Thank you for the opportunity to comment on the draft scope.  As a registered stakeholder, Medtronic received the committee recruitment emails for the clinical guideline. We support the recruitment of 2 physicians with	Thank you for your comment. The composition of the guideline committee is intended to provide expertise to inform all areas included in the guideline and this will be considered during the recruitment process.

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			interest in hypertension and strongly recommend that these are secondary care consultants who have experience in renal denervation for the treatment of resistant hypertension. It is important that the expert opinions communicated and decisions made are representative of both primary and secondary care.	
Obesity Group of the British Dietetic Association	5	Table under 'Lifestyle interventions'	We note that the recommendations from the existing guidance are to be retained which we welcome. However we also note that a number of new papers relating to lifestyle intervention have been identified. In view of this we think that a limited review of the new papers to ascertain whether they change existing guidance or not should be undertaken, including the use of more intensive interventions such as meal replacements.	Thank you for your comment. A surveillance review was conducted before determining whether a guideline should be updated. Lifestyle interventions were searched for in the surveillance process. New evidence was identified to support current recommendations, which already offer advice related to diet and exercise, alcohol, salt intake, smoking and caffeine. However no evidence was identified relating specifically to meal replacement strategies. Some new evidence was identified that suggested the possibility of expanding upon the existing recommendations in the area of relaxation therapies. However, with the exception of relaxation therapies, stakeholders were in agreement that this evidence was not yet sufficient to lead to a change in the recommendations due to either being from a small sample size, short-term follow up only or focusing on change in blood pressure instead of direct patient important outcomes such as cardiovascular events. The research questions and protocols in the updated guidance will focus on patient important outcomes rather than blood

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## Hypertension in adults

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				<p>pressure as this is a surrogate outcome that doesn't clearly identify what the measurable benefit of a treatment is, in terms of improvements to a persons' quality or length of life. Consequently it was agreed that lifestyle therapies as a whole should not be updated at this time, and existing recommendations will be carried forward into the updated guidance, but the evidence for relaxation therapies will be reviewed and has now been added to the scope.</p>
RCGP	General	General	<p>Men are at 25% higher risk of having a stroke and at a younger age compared to women (Stroke Association State of the Nation Stroke Statistics accessed 22/6/2017). This is not mentioned the "equality considerations" section. It is surprising that the equality impact assessment has not raised this as an issue. Interventions concerning hypertension targeted towards men may result in cost savings and reduction in morbidity and mortality.</p> <p>This seems like a pretty sensible guideline. My only thought would be to ask NICE why they have not kept up with the times. We are now advised to take a view of the overall cardiovascular risk of patients. I would argue that we should not see hypertension as a separate entity, but simply as one element in a bigger picture. A suggestion would be a single guideline on cardiovascular risk, and incorporate within it guidance about raised blood pressure, smoking, lipids &amp; exercise.</p>	<p>Thank you for your comment.</p> <p>There are a number of sources of epidemiological data for the risk factor prevalence in a variety of groups for stroke. The risk of stroke arises from an interaction between multiple risk factors some of which may correlate with basic epidemiological data such as age and gender. Therefore we do not think it is necessary to look at men as a separate subgroup, but we have added gender as a factor in the equalities impact form as suggested.</p> <p>We agree that NG56, the NICE multimorbidity guideline, is a key document related to the current update and have noted this on page 6 under the section on related NICE guidance. The guideline will be developed with other existing guidance in mind, including updating the database of treatment effects from the multimorbidities guideline where</p>

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			<p>A key document that needs to be considered is the NICE multimorbidity guidance (<a href="http://nice.org.uk/guidance/ng56">nice.org.uk/guidance/ng56</a>) as hypertension is the most common comorbid condition in the UK. (Dumbrek BMJ 2015 350:bmj.h949)</p> <p>Specifically that guidance talks about treatment burden experienced by multimorbid patients (including clinic time, drug burden and side effects) and hypertension accounts for a lot of this treatment burden. Looking at treatment targets that the risk / benefits of polypharmacy for hypertension is explored particularly the evidence for adding 3 or even 4th line drugs. (Prosser2017 DOI: 10.1007/s11906-017-0728-z ) The equality statement suggests looking at the over 80s as specific group but an arbitrary age cut off is unhelpful and a multi-morbid/ frailty perspective would be more clinically useful.</p>	<p>evidence is available.</p> <p>Whilst we recognise that there can be varying opinions as to an age cut off for older people, this was discussed at the stakeholder workshop, and in the absence of a clear definition for frailty, it was agreed that using an age that was considered to be consistent with the trial data available, was the best approach for the guideline.</p>
RCGP	General	General	Only if it is possible that they would reduce inequality.	I'm afraid we are unsure what this comment relates to and are unable to provide a specific response.
Royal College of Anaesthetists	5	12	Lifestyle intentions; The RCoA considers that the guidance around the preventative and societal benefit and economic advantages of lifestyle interventions, should be strengthened.	Thank you for your comment. We agree that lifestyle interventions are an important part of managing hypertension and we welcome any new evidence that could improve upon current recommendations. This is an area that was searched for in the surveillance process. New evidence was identified to support current

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				<p>recommendations, which already offer advice related to diet and exercise, alcohol, salt intake, smoking and caffeine. Some evidence was also identified that suggested the possibility of expanding upon these recommendations particularly for relaxation therapies. With the exception of relaxation therapies, stakeholders were in agreement that this evidence was not yet sufficient to lead to a change in the recommendations due to either being from a small sample size, short-term follow up only or focusing on change in blood pressure instead of direct patient important outcomes such as cardiovascular events. The research questions and protocols in the updated guidance will focus on patient important outcomes rather than blood pressure as this is a surrogate outcome that doesn't clearly identify what the measurable benefit of a treatment is, in terms of improvements to a persons' quality or length of life. Consequently it was agreed that lifestyle therapies as a whole should not be updated at this time, and existing recommendations will be carried forward into the updated guidance, but the evidence for relaxation therapies will be reviewed and has now been added to the scope.</p>
Royal College of Anaesthetists	5	4	The RCoA feel the scope should include the primary care management of newly diagnosed and known hypertensives scheduled for urgent and elective surgery.	Thank you for your comment. We agree that the primary care management of people with hypertension scheduled for urgent and elective surgery is an important issue. However we are not

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				aware of evidence that would enable the committee would be able to make any more than consensus recommendations in this area and therefore this was not prioritised for inclusion in the guideline update.
Royal College of Anaesthetists	9	5	The RCoA notes the long time line until publication which is disappointing	Thank you for your comment. The 3-year timeframe is standard for NICE guidelines, due to the large amount of time and resources required for the development of a guideline.
Royal College of Physicians (RCP)	General	General	<u>Reluctance to refer to epidemiology</u> The links between blood pressure and cardiovascular disease have important implications. The epidemiology of the high salt Japanese diet, and many other populations, shows that hypertension is a particular risk for stroke. Though hypertension is a contributing factor to myocardial infarction, (MI) the epidemiology of MI most closely relates to smoking. This pattern explains why trials have in general have shown an impact on stroke incidence, rather than MI, even though MI is approximately 4-5 times more frequent than stroke. The risk of blood pressure is not fully defined, such as discussions on the J-shaped curve. A small lowering of the national target systolic or diastolic blood pressure has huge commercial implications in terms of the number of people treated. The relationship between blood pressure and mortality suggests that over-treatment should be avoided. (J Gen Intern Med 2011;26:685-690; Rev Esp Cardiol 2013;66:464-471; Lancet 2000;355:175-180). These data do not support	Thank you for your comment. Some detail on epidemiology which sets out why this guidance is important has been included within the relevant section of the scope. . The statement regarding risk is informed by the Prospective Studies collaboration in 2002. The risk associated with increasing blood pressure is continuous. At ages 40–69 years, each difference of 20 mm Hg usual SBP (or, approximately equivalently, 10 mm Hg usual DBP) is associated with more than a twofold difference in the stroke death rate, and with twofold differences in the death rates from ischaemic heart disease and from other vascular causes. The introduction has been updated with this information. We believe the statement for those over 60 is accurate, and is important to note.

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			the statement in the NICE briefing document that 'The risk associated with increasing blood pressure is continuous, with each 2 mm Hg rise in systolic blood pressure associated with a 7% increased risk of mortality from ischaemic heart disease and a 10% increased risk of mortality from stroke'. The statement by NICE that more than half of those older than 60 have high blood pressure is misleading with major public health implications.	
Royal College of Physicians (RCP)	General	General	<p><u>Reluctance to refer to dietary salt</u></p> <p>The epidemiology of blood pressure shows that essential hypertension is caused by excess dietary salt despite considerable pressure from the food industry to say otherwise (Webster J et al. Understanding the science that supports population-wide salt reduction programs. J Clin Hypertens 2017). This has significant public health implications for a national hypertension guideline. Graham McGregor, with his lobbying through the charity Consensus Action on Salt and Health, was given a Life Scientific slot on Radio 4, 25 April 2017, but much more action is needed. Our experts believe that NICE is in an excellent position to help.</p>	Thank you for your comment. We identified through the surveillance review a number of additional papers relating to lifestyle interventions including salt reduction. However, it was considered that this evidence will not lead to substantive changes to the recommendation which already encourages people to keep their dietary sodium intake low, either by reducing or substituting sodium salt and therefore this area was not prioritised for inclusion within the update, but the existing recommendations will be carried forward
Royal College of Physicians (RCP)	General	General	<p><u>RCT trial data</u></p> <p>Our experts note that good quality RCTs are the mainstay of medical prescribing, but most hypertension trials have commercial sponsors. There is commercial justification for funding a trial only if a positive outcome</p>	Thank you for your comment. We agree that the efficacy of treatment as well as adverse events should be taken into account within decision making. We will be including adverse events as an

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			<p>is likely. The chances of a positive outcome can be greatly enhanced by the design of the protocol. The one sided use of cardiovascular composites for efficacy, without a corresponding composite for safety, has generated many positive opinions for data sets where there is no benefit on mortality.</p> <p>Sponsorship can be associated with bias; for example smoking is protective for Alzheimer's disease in studies with tobacco industry affiliation, yet harmful in studies without this affiliation (J Alzheimer's Disease 2010;19:465-80).</p>	<p>outcome to be considered when searching for and assessing the evidence.</p> <p>We are also aware of the contentious issues around industry sponsored drug trials and this is not something that will be overlooked. All of the evidence is critically appraised and assessed for risk of bias, and this is one of the factors that will be taken into account when assessing the evidence.</p>
Royal College of Physicians (RCP)	General	General	<p>Our experts note that there are two independent hypertension studies which are particularly important.</p> <p><i>MRC Hypertension Studies</i> In patients aged 35-64 with a diastolic of 90-109, a diuretic or a beta-blocker reduced the stroke rate from 2.6 to 1.4 per thousand years of observation. The mortality rate and rate of MI was not affected significantly. This is consistent with smoking being the major risk of MI, rather than hypertension. This trial defined that large numbers of patients need to be treated for small gains in benefit such that only low cost medication can be justified for the national treatment of mild hypertension (BMJ 1985;29:97-104). The effect of either treatment on cardiovascular events was minimal compared to the benefit of being a non-smoker. The mortality rate of the smokers was approximately double the mortality rate of the non-</p>	<p>Thank you for your comment and for sending this information.</p>

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			<p>smokers. Being a smoker had a far bigger effect on the rates of stroke and MI than the effect of treatment. In the MRC trial of elderly patients, (BMJ 1992;304:405-412) mortality was slightly higher with a beta blocker and slightly lower with a diuretic despite significant falls in blood pressure starting from a mean pre-treatment systolic pressure in the range of 160-209 mm Hg. The main benefit was the reduction in stroke and MI with a low dose diuretic. The effect of either treatment on cardiovascular events was minimal compared to the benefit of being a non-smoker. The results from the MRC trials led to the widespread adoption of thiazide diuretics at low doses so as to minimise adverse events with treatment that is cost effective.</p>	
Royal College of Physicians (RCP)	General	General	<p><u>ALLHAT trial</u></p> <p>This was sponsored by the NIH and compared chlortalidone, lisinopril and amlodipine (JAMA 2002;288:2981-97). The doxazosin arm was discontinued because of harm. This concluded that thiazide-type diuretics are superior in preventing one or more major forms of CVS and less expensive. They should be preferred for first-step antihypertensive therapy.</p>	Thank you for this information. Question 4.1 is intended to address first line hypertensive treatment where this study may be considered.
Royal College of Physicians (RCP)	General	General	The recommendation of both the MRC and ALLHAT trials for cheap, generic thiazide or thiazide-type	Thank you for your comment. Both cost and effectiveness in terms of risks and benefits are

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			<p>diuretics is a considerable commercial challenge. Multiple industry sponsored trials have tried to address this issue. In general, as a medicine becomes available as a cheaper generic, the support for a favourable risk-benefit erodes with time and studies are published that favour more expensive new treatments. This has occurred with propranolol, atenolol, nifedipine, amlodipine and ACE inhibitors. The RCT data for a product can only be interpreted in full by understanding the state of the data in relation to the life cycle of the product.</p>	<p>taken account of through the health economics of the guideline.</p>
Royal College of Physicians (RCP)	General	General	<p>Though the ALLHAT trial used chlortalidone, there is little doubt that the risk-benefit is reproducible with other thiazides like drugs, though chlortalidone is longer acting. There is little point recommending chlortalidone in the UK because of lack of availability. Benefit is just as likely with the cheapest members of the class, such as bendroflumethiazide or hydrochlorthiazide. This is not consistent with the current BNF, which recommends for those under 55 to take an ACE inhibitor, All inhibitor, beta-blocker, or CCB. Only chlortalidone and indapamide are mentioned as thiazide related diuretics. For those &gt;55 CBB are mentioned as first choice. The BNF also recommends using spironolactone in an unlicensed indication for resistant hypertension, which is seems not evidence based.</p>	<p>Thank you for your comment. We will keep this information in mind during guideline development. The guideline however is not associated with the BNF, and we will not be involved in updating this.</p>

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Royal College of Physicians (RCP)	General	General	<p><u>Treating CBBB as a class</u>  Numerous trials have confirmed the usefulness of amlodipine as an antihypertensive that can reduce CV events, though there is a significant risk of heart failure. Amlodipine has not been shown to decrease or increase total mortality. In contrast, short acting nifedipine has been associated with an increase in mortality in trials, several of which were terminated early because of this (Lau NEJM 1992; 327:248-254). For this reason CBB should not be referred to as a class. Nifedipine is still referenced as a treatment of hypertension in the current BNF despite no RCT evidence of any benefit on mortality. The BNF currently is not consistent with NIH trial results, see: (<a href="https://www.nhlbi.nih.gov/health/allhat/qckref.htm">https://www.nhlbi.nih.gov/health/allhat/qckref.htm</a>).</p>	<p>Thank you for your comment. This will be considered by the guideline committee when refining the question and protocol for questions relating to antihypertensive drug treatment.</p>
Royal College of Physicians (RCP)	General	General	<p><u>Altering the measurement of blood pressure alters RCT interpretation</u>  Though blood pressure measurement techniques have advanced, it should be borne in mind that the results of RCTs are only valid for the conditions and populations of each trial. Altering the methodology may restrict the interpretation of RCT results.</p>	<p>Thank you for your comment. We agree and directness and generalisability of the evidence will be taken into account when the systematic reviews are undertaken.</p>
Royal College of Physicians (RCP)	General	General	<p><u>Spirolactone</u>  There is no RCT database to support the use of spironolactone for hypertension. It is a useful drug in heart failure, where most patients can expect some</p>	<p>Thank you for your comment. The available evidence for the use of spironolactone for hypertension will be considered by the guideline</p>

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			benefit and monitoring is likely to detect hyperkalaemia. It can lower BP. It is an unproven drug for hypertension, where only a small minority may expect to have a cardiovascular event prevented. The incidence of hyperkalaemia and other adverse events becomes significant in the hypertensive population, particularly as adequate monitoring of electrolytes is unlikely.	committee when the systematic review is undertaken.
Royal College of Physicians (RCP)	General	General	<u>Cofactors</u> The main determinant of MI worldwide is cigarette smoking. Even in the hypertension trials that show the most favourable outcomes with treatment, the efficacy size effect is small compared to the benefit of being a non-smoker. It is a significant risk for stroke. It decreases the life expectancy of the average smoker by 11-12 years. Weight reduction for the majority of the population is relatively unimportant, huge gains in weight are necessary to double mortality. The main target for hypertension is stroke reduction of the whole population by reducing excess dietary salt intake.	Thank you for your comment. We agree that both smoking and obesity are contributors to cardiovascular risk. Obesity seems to have a direct relationship to blood pressure. Epidemiologically salt intake is a significant contributor to cardiovascular risk and blood pressure. The recommendations from the previous guideline regarding lifestyle interventions will be carried forward in the current update. There is a specific recommendation for smoking which states: offer advice and help to smokers to stop smoking. There is a specific recommendation for salt reduction which states: encourage people to keep their dietary sodium intake low, either by reducing or substituting sodium salt, as this can reduce blood pressure.
Royal College of Physicians (RCP)	General	General	Our experts note that one way to look at the issue is to consider what needs to be known. Our experts address these issues below.	Thank you for your comments.

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Royal College of Physicians (RCP)	General	General	<p><i>1. What is the cause of primary high blood pressure (essential hypertension)? Is the cause avoidable?</i></p> <p>Considerable epidemiology implicates dietary salt. National daily salt intake should be reduced from a current almost 10 gm/day. For summary, see Webster J et. Understanding the science that supports population-wide salt reduction programs. J Clin Hypertens 2017;1-8 (authors include Franco Cappucio).</p>	<p>Thank you for your comment. The recommendations from the previous guideline regarding lifestyle interventions will be carried forward in the current update. There is a specific recommendation for salt reduction which states: encourage people to keep their dietary sodium intake low, either by reducing or substituting sodium salt, as this can reduce blood pressure.</p>
Royal College of Physicians (RCP)	General	General	<p><i>2. By how much does hypertension affect life expectancy? By how much does treatment reverse this?</i></p> <p>Treatment of mild to moderate hypertension does not significantly improve mortality.</p>	<p>Thank you for your comment. Mortality is listed as one of the main outcomes that will be considered when undertaking the reviews, so the effect on reducing mortality will be considered.</p>
Royal College of Physicians (RCP)	General	General	<p><i>3. By how much does hypertension affect the risk of MI? By how much does treatment reverse this?</i></p> <p>Treatment of mild to moderate hypertension shows a small, non-significant reduction in meta-analysis in CHD of 14% (95% CI 4-22%).</p>	<p>Thank you for your comment. Myocardial infarction and heart disease are listed within the main outcomes that will be considered when undertaking the reviews, so the effect on reducing these will be considered.</p>
Royal College of Physicians (RCP)	General	General	<p><i>4. By how much does hypertension affect the risk of stroke? By how much does treatment reverse this?</i></p>	<p>Thank you for your comment. Stroke is listed as one of the main outcomes that will be considered</p>

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			Treatment of mild to moderate hypertension causes an important and significant reduction in the risk of stroke, 42% (95% CI 33-50%).	when undertaking the reviews, so the effect on reducing strokes will be considered.
Royal College of Physicians (RCP)	General	General	<p><i>5. Is the risk of hypertension linear?</i></p> <p>The statement by NICE that risk associated with increasing blood pressure is continuous, with each 2 mm Hg rise in systolic associated with a 7% increased mortality from IHD and a 10% increased risk of mortality from stroke obviously does not extend down to low pressures. There is a considerable debate about the J shaped curve. When treating malignant hypertension a rapid fall in BP is detrimental. A diastolic of 70 mm Hg or less has been reported as the highest risk for most outcomes compared with all diastolic categories &gt;70 mm Hg; risk of &lt;70 mm Hg 1.16 (1.06-1.28) compared to a diastolic of 70-80 mm Hg. The risk of all-cause mortality was 1.28 (1.15-1.42) for patients with a systolic &lt;120 mm Hg compared to systolic of 120-140 mm Hg (Bohm M et al, Lancet 5<sup>th</sup> April, 2017). This contrasts with the claim that a target of &lt;140/90 mm Hg is suitable for most patients (Kahan T. Lancet 5<sup>th</sup> April, 2017).</p>	Thank you for your comment. The statement regarding risk is informed by the Prospective Studies collaboration in 2002. The risk associated with increasing blood pressure is continuous. At ages 40–69 years, each difference of 20 mm Hg usual SBP (or, approximately equivalently, 10 mm Hg usual DBP) is associated with more than a twofold difference in the stroke death rate, and with twofold differences in the death rates from ischaemic heart disease and from other vascular causes. The introduction has been updated with this information.
Royal College of Physicians (RCP)	General	General	<p><i>6. How important is hypertension compared to risk of smoking?</i></p> <p>Smoking reduces life expectancy by 11-12 years. The average risk of a heart attack is 12-fold greater for</p>	Thank you for your comment. The recommendations from the previous guideline regarding lifestyle interventions will be carried forward in the current update. There is a specific

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			those who smoke 40/day. (INTERHEART studies, see also Lancet 2017;389:1885). The treatment of mild to moderate hypertension is far less important compared to the importance of being a non-smoker.	recommendation for smoking which states: offer advice and help to smokers to stop smoking.
St George's University Hospitals NHS Foundation Trust	8	11	Under Main outcomes: Can I suggest Peripheral arterial disease and aortic disease (aneurysm, dissection)	Thank you for your comment. These are the main outcomes that are expected to be of relevance for the majority of questions covered within the guideline. Additional outcomes may be added as relevant when the protocols are agreed by the committee and we will take these suggestions into consideration.
St George's University Hospitals NHS Foundation Trust	8	6	Under managing malignant hypertension, I would suggest adding "How to diagnose malignant hypertension". Examining the fundus using an ophthalmoscope is essential, but ophthalmoscopes are not usually available	Thank you for your comment. Based on stakeholder feedback the focus of the topic area around malignant hypertension has been updated to cover the identification of malignant hypertension, rather than management. The review question will be further refined in discussion with the guideline committee once development begins.
Stroke Association	1	20	With hypertension being a contributing factor in around half of strokes <sup>1</sup> , the Stroke Association is concerned at the number of people with undiagnosed and untreated hypertension – more than 5.5 million in England alone. <sup>2</sup> Given the scale of this problem, we would like to see the estimated numbers of undiagnosed cases of	Thank you for your comment. We believe that the key reasons outlining why this guidance is needed are adequately conveyed with the current wording. Screening for hypertension is not within the remit of the guidance and therefore we do not

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			hypertension quantified within the scope to better set the context and need for action. We would also like to see more emphasis placed on hypertension not just as 'a' risk factor but the single largest modifiable risk factor.	thing that further emphasis is required on undiagnosed hypertension.
Stroke Association	2	14	We welcome the mention of variable access to ambulatory blood pressure monitoring. Millions of people are living with undiagnosed and usually symptomless hypertension, partly because of this variability. Over and above our Know Your Blood Pressure events, we encourage people to have their blood pressure checked regularly by a medical professional, trained volunteer or, increasingly, by themselves at home using a home blood pressure monitoring tool.	Thank you for your comment; we agree this is an important area to address.
Stroke Association	2	21	We welcome the review of the existing evidence around hypertension, particularly as it is six years since the 2011 guideline was published. There may be important new evidence around not only the pharmacological management of hypertension, but the efficacy and availability of home monitoring equipment. There may also be evidence which contradicts of challenges previously accepted norms. For example, Makridakis, S and DiNicolantonio, JJ (2014) suggested in Open Heart that "there are significant conflicts in the conclusions of hypertension studies that cannot be explained statistically" and "the current evidence in the	Thank you for your comment. A surveillance review was undertaken to inform the decision to update the guideline which did identify new evidence in a number of areas and will be considered in the updated guidance.

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			literature does not support the blood pressure goals set by...guidelines". <sup>3</sup>	
Stroke Association	3	23	<p>We welcome consideration being given to the inequalities currently set out in the draft scope, particularly around ethnicity. We know that black people are twice as likely to have high blood pressure as white people and, as a result, their risk of stroke is higher.<sup>4</sup></p> <p>However, we strongly encourage the consideration in this guideline of socioeconomic inequality. In general, people from more deprived areas have an increased risk of stroke and people from more deprived areas are likely to experience more severe strokes.<sup>5</sup></p> <p>Related to this, those from poorer areas tend to have strokes at a younger age than those from wealthier areas and that is why we would recommend that equality considerations are given not just to people aged over 80 but those in at-risk groups over the age of 55. The Stroke Association actively targets men, in particular, over 55 years old who tend to be of higher risk and less likely to visit their GP.</p>	<p>Thank you for your comment. We acknowledge and recognise that socioeconomic inequality is an issue. Inherent barriers to accessing treatment are taken under consideration when making recommendations. We believe that some of your concerns will be addressed through public health guidance, rather than specific clinical guidance, and it is unlikely we will be able to make specific recommendations based on socioeconomic status. However we have specified this as a consideration in the Equality Impact Assessment form.</p>

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Stroke Association	3	7	<p>After “providers of services” add “including those from the voluntary sector.”</p> <p>We would like the role of the voluntary sector in identifying hypertension, monitoring blood pressure and raising awareness clearly set out in this guideline. Public Health England is clear that the voluntary sector has an important role to play and, through channels such as its Blood Pressure System Leadership Board, seeks to raise performance in England when it comes to the prevention, detection and management of hypertension, as well as reducing inequalities. PHE is clear that the voluntary sector has a role to play in preventing hypertension in particular.<sup>6</sup> We have jointly developed information packs on blood pressure for commissioners and providers which have been warmly welcomed. This shows there is a clear need for the voluntary sector to play an important role in upskilling professionals and give them the tools they need to manage hypertension at a local level. These packs can be accessed here: <a href="https://www.bhf.org.uk/healthcare-professionals/bp-how-can-we-do-better">https://www.bhf.org.uk/healthcare-professionals/bp-how-can-we-do-better</a></p>	<p>Thank you for your comment. Although we agree that the voluntary sector plays a very important role the intention of this statement is to keep the description broad to encompass any provider of NHS services, rather than mentioning specific providers or sectors.</p>
Stroke Association	4	19	<p>Care homes should be explicitly mentioned here to ensure health professionals are working across health and social care when implementing the guideline.</p>	<p>Thank you for your comment. The scope states that the guideline will cover all settings in which NHS commissioned care is provided. Care homes have not been mentioned specifically as not all care homes are NHS funded.</p>

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Stroke Association	4	6	The draft makes clear that “no specific subgroups of people have been identified as needing specific considerations.” However, we would suggest that women on the combined oral contraceptive pill or HRT, which increase risk of stroke by affecting and often raising a woman’s blood pressure, should be included as a specific subgroup. These women should have blood pressure checks every year but we know that this does not always happen and we know many women are unaware of the risks associated with stroke and the pill.	Thank you for your comment. We believe that the advice you suggest relating to annual checks is already covered under the prescribing guidance for the oral contraceptive pill and relates to the implementation of the current drug surveillance guidance from prescribing authorities and therefore will not be addressed as a specific subgroup within the guidance.
Stroke Association	6	8	We would like to see included stronger references to those conditions strongly linked to hypertension, such as atrial fibrillation, particularly as they are both so central to stroke. Along with hypertension, atrial fibrillation (AF) is a key stroke risk factor, with around 1 in 5 strokes in the UK attributed to AF. <sup>78</sup> Adults with hypertension and type 2 diabetes are a group which this guideline focuses on. Given the link between AF and the most devastating strokes, we would like to see this focus widened to include adults at risk of AF. AF is chronically under-diagnosed and mismanaged as a condition and AF is linked to hypertension. AF can be detected through opportunistic pulse checking done while blood pressure is being taken. New technology is now enabling blood pressure and screening for AF to be done concurrently. Indeed, the Stroke	Thank you for your comment. We have added CG180 (Atrial fibrillation: management) to the list of related NICE guidance. People at risk of AF will not be excluded from the guideline if they are hypertensive. However the assessment and management of AF is covered in the above guidance.

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			<p>Association is looking to include pulse checks as part of our Know Your Blood Pressure events.</p> <p>Those with other long-term conditions such as hypertension and diabetes are more likely to have AF and this guideline should therefore link to the AF guidance and promote opportunistic pulse testing for AF to make every health professional contact count.</p>	
Stroke Association	General	General	<p>We welcome NICE's plans to update its hypertension in adults guideline. Given the strong link between hypertension and stroke, we are obviously interested in any proposals to improve guidance around the diagnosis and management of high blood pressure.</p> <p>The Stroke Association works to help people understand the link between high blood pressure and stroke, and what they can do to reduce their risk of having a stroke. Our Know Your Blood Pressure campaign gets to the heart of communities by holding events across the UK offering free blood pressure testing, stroke prevention information and friendly advice. Know Your Blood Pressure events are free to anyone wanting to have their blood pressure checked and learn more about stroke prevention. In 2016/17, we took over 54,000 blood pressures and year on year we strive to improve our reach to those from groups at increased risk of stroke such as BME communities and older people.</p>	Thank you for your comment and for highlighting this work.

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Stroke Association	General	General	Although screening for hypertension is outside of the scope of this guideline, we would like NICE to promote opportunistic blood pressure checking for higher risk groups to help make every contact count and therefore make better use of under-pressure NHS resources.	Thank you for your comment. Risk factors for hypertension are beyond the scope of this guideline and therefore we will be unable to make specific comments on high risk groups.
Stroke Association	General	General	In response to question 2, we would say yes. NICE should be updating the recommendations to ensure health professionals are encouraged to make the best use of the programmes on offer from PHE, for example One You, Couch to 5K, and campaigns from the third sector, which are not included in the guideline.	<p>Thank you for your comment. We agree that lifestyle interventions programmes from Public Health England are an important part of managing hypertension.</p> <p>This is an area that was searched for in the surveillance process. New evidence was identified to support current recommendations, which already offer advice related to diet and exercise, alcohol, salt intake, smoking and caffeine. Some evidence was also identified that suggested the possibility of expanding upon these recommendations particularly in the area of relaxation therapies. However, with the exception of relaxation therapies, stakeholders were in agreement that this evidence was not yet sufficient to lead to a change in the recommendations due to either being from a small sample size, short-term follow up only or focusing on change in blood pressure instead of direct patient important outcomes such as cardiovascular events. The research questions and protocols in the updated guidance will focus on patient important outcomes rather than blood pressure as this is a surrogate outcome that</p>

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				<p>doesn't clearly identify what the measurable benefit of a treatment is, in terms of improvements to a persons' quality or length of life. Consequently it was agreed that lifestyle therapies as a whole should not be updated at this time, and existing recommendations will be carried forward into the updated guidance, but the evidence for relaxation therapies will be reviewed and has now been added to the scope.</p>
The Dirac Foundation	General	General	<p><b>1. Which interventions or forms of practice might result in cost saving recommendations if included in the guideline?</b></p> <p>Care should be taken before rushing to conclusions about the universality of clinical and financial benefits of non-pharmacological weight reduction, and certainly treatments should be "personalized". See also here my response to question (2) below. This is important because I suspect that more and more physicians and medical personal are finding it easier to treat guidelines as comprehensive clinical pathways and even a matter of compliance, without adjustment case by case, and this seems likely in this domain. On the whole, reduction of BMI by lifestyle changes does of course at first seem likely to be of value. An example from the Caribbean community is that Kaufman et al [1] found systolic BP (mmHg) increasing regression with BMI (Kg/M<sup>2</sup>) at a slope of circa 2.0 in 1997 for African and Caribbean subjects while in a recent survey for the Cayman heart fund I found a slope of 1.33 for a survey in the Cayman</p>	<p>Thank you for your interesting points and statistics on prevalence, and if non-pharmacological interventions were being updated then health economics would weigh up the costs alongside the benefits and risks (which would be obtained from the clinical review) to help inform decision making. On balance the majority of evidence that exists in this area points to the benefits of weight loss, and therefore other areas in the guideline were felt to have more conflicting evidence since the last guideline that would benefit from evaluation and add value to the guideline. Populations with hypertension and type 2 diabetes are being covered in the guideline.</p> <p>The previous guideline, along with CG181, Cardiovascular disease: risk assessment and reduction have both identified that exercise improves outcomes for people with hypertension or other cardiovascular risk factors, such as obesity.</p>

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		<p>Islands, falling to circa 1.0 above BMI 3.0. However, it is also important to consider aetiology and what causes what. Notably, we cannot divorce this entirely from type 2 diabetes and very roughly one in ten people are obese, and significant more obese or overweight, and at the same time have type 2 diabetes. This rough estimate is derived as follows. 9% over 16 years old have diabetes [2] and 90% are type 2, indicating a prevalence of 8.1% type two diabetes [2]., i.e. <math>P(\text{type 2 diabetes}) = 0.081</math>. Circa 90% of type 2 diabetics are obese, i.e. <math>P(\text{obese} \mid \text{type 2 diabetes}) = 0.9</math>. Consequently <math>P(\text{obese} \ \&amp; \ \text{type 2 diabetes}) = P(\text{obese} \mid \text{type 2 diabetes}) \times P(\text{type 2 diabetes}) = 0.9 \times 0.081 = 0.073</math> approx., or 7.3%. We can significantly expect more to have type 2 diabetes or prediabetes or undetected prediabetes or diabetes, which is also affected by the following consideration. "In England, 12.4% of people aged 18 years and over with obesity have diagnosed diabetes, five times that of people with a healthy weight" [4]. Disturbing, but we can deduce from that (and other studies) that <math>P(\text{obesity if type 2 diabetes}) = P(\text{obesity} \mid \text{type 2 diabetes}) = \text{circa } 0.1 \text{ to } 0.2</math> (10-20%), a much smaller probability that raises issues as to what most often causes what (does obesity cause type 2 diabetes, or type 2 diabetes cause obesity?) . Although traditional frequentist statistics of the school of Sir Ronald Fisher emphasizes that "correlation does not imply causation" and that we should not deduce mechanism, this radical difference is suggestive that type 2 diabetes causes obesity and</p>	<p>The difference between association and causality is recognized and will be considered when any recommendations on related topics are made.</p>
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			<p>remains consistent with our understanding of metabolic processes. Treating the diabetes appropriately may be more effective. Moreover, one should not be too quick to assume that reducing patient's weight will reduce morbidity and fatality without more research. There is the and the issue of the "obesity paradox" that obese patients may live longer than non-obese patients [5]. In view of the fact that the risk factor due to not being obese or overweight roughly doubles or more in some studies cited (see that by Chao Cao et al. (2012)), the clinical and hence financial consequences could be significant without deeper understanding. While this long-standing issue has been in the balance, it is at least recently indicated that there is an "overweight paradox" [6].</p> <ol style="list-style-type: none"> <li>1. J. S. Kaufman et al.,(1997), Relationship between blood pressure and body mass index in lean populations, Hypertension. 1997 Dec;30(6):1511-6.</li> <li>2. <a href="https://www.gov.uk/government/news/38-million-people-in-england-now-have-diabetes">https://www.gov.uk/government/news/38-million-people-in-england-now-have-diabetes</a></li> <li>3. <a href="http://www.obesity.org/obesity/content/weight-diabetes">http://www.obesity.org/obesity/content/weight-diabetes</a></li> <li>4. <a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/338934/Adult_obesity_and_type_2_diabetes_.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/338934/Adult_obesity_and_type_2_diabetes_.pdf</a>,</li> <li>5. <a href="https://en.wikipedia.org/wiki/Obesity_paradox">https://en.wikipedia.org/wiki/Obesity_paradox</a></li> <li>6. P. Costanzo et al. (2015) "The Obesity Paradox in Type 2 Diabetes Mellitus: Relationship of Body Mass Index to Prognosis:</li> </ol>	
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			<p>A Cohort Study” Ann Intern Med.  <a href="http://annals.org/aim/article/2288519/obesity-paradox-type-2-diabetes-mellitus-relationship-body-mass-index">http://annals.org/aim/article/2288519/obesity-paradox-type-2-diabetes-mellitus-relationship-body-mass-index</a></p> <p>“Compared with patients having a normal BMI, underweight individuals were associated with higher mortality (RR = 1.34, 95% CI = 1.01–1.78), whereas overweight (RR = 0.47, 95% CI = 0.33–0.68) and obese (RR = 0.59, 95% CI = 0.38–0.91) patients were associated with lower mortality.”</p> <p><b>Chao Cao et al. (2012)</b>, Body Mass Index and Mortality in Chronic Obstructive Pulmonary Disease: A Meta-Analysis.</p> <p><a href="http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0043892">http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0043892</a></p> <p>7.</p>	
The Dirac Foundation	General	General	<p><b>2. We have identified through surveillance review a number of additional papers relating to lifestyle intervention in the management of hypertension. However, we think it unlikely that this will lead to substantive changes to recommendations. Should lifestyle interventions for the management of</b></p>	<p>Thank you for your comment. We agree that lifestyle interventions are an important part of managing hypertension and we welcome any new evidence that could improve upon current recommendations. This is an area that was searched for in the surveillance process. New evidence was identified to support current recommendations, which already offer advice</p>

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			<p><b>hypertension be considered for update within this guideline?</b></p> <p>Yes. It is of course important to include Current Best Evidence. A statement can't really be made here on confirming that the new work would have no impact without reading the papers referred to in significant depth and performing systematic Review/meta-analysis. In those that I have examined, I do see that recent papers tend to be more fine grained in analysis in fat distribution, type of exercise, and nature of the diet. For example, one 2017 study [1] noted that the nature of the diet, not the calories or simply exercise, can have a role. "Nutrition parameters can be addressed through therapeutic diet models, among which predominant seem to be the DASH diet and the Mediterranean diet." [1] My response to question 1 is also relevant here.</p> <p>1. A.Vamvakis et al. (2017) Beneficial effects of nonpharmacological interventions in the management of essential hypertension, <i>JRSM Cardiovasc Dis.</i> 2017 Jan-Dec; 6: 2048004016683891</p>	<p>related to diet and exercise, alcohol, salt intake, smoking and caffeine. Some evidence was also identified that suggested the possibility of expanding upon these recommendations particularly in the area of relaxation therapies. However, with the exception of relaxation therapies, stakeholders were in agreement that this evidence was not yet sufficient to lead to a change in the recommendations due to either being from a small sample size, short-term follow up only or focusing on change in blood pressure instead of direct patient important outcomes such as cardiovascular events. The research questions and protocols in the updated guidance will focus on patient important outcomes rather than blood pressure as this is a surrogate outcome that doesn't clearly identify what the measurable benefit of a treatment is, in terms of improvements to a persons' quality or length of life. Consequently it was agreed that lifestyle therapies as a whole should not be updated at this time, and existing recommendations will be carried forward into the updated guidance, but the evidence for relaxation therapies will be reviewed and has now been added to the scope.</p>
The Dirac Foundation	General	General	<p><b>3. What aspects of the management of malignant hypertension in secondary care should the guideline focus on?</b></p>	<p>Thank you for your comment. Based on stakeholder feedback the focus of the topic area around malignant hypertension has been updated to cover the identification of malignant</p>

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			<p>In my opinion this can't be done without serious consideration for treatment or amelioration of the effects of diverse aetiologies (e.g. Collagen vascular disease, kidney disease, spinal cord injuries, adrenal tumor, use of certain medications, e.g. birth control pills and MAOIs, and use of certain illegal drugs, such as cocaine) on a case by case basis. Of course some causes are more prevalent than others, but one should not give blanket recommendations.</p>	<p>hypertension rather than management. The review question will be further refined in discussion with the guideline committee once we begin development.</p>
The Dirac Foundation	General	General	<p><b>4. The surveillance identified evidence relating to the optimal timing of antihypertensive medication and suggested that this could be included as a question within the guideline. However, stakeholders at the workshop disagreed that this evidence would lead to clear recommendations. They were also aware of a large trial that is in progress but won't publish in the lifetime of the guideline. Should we include a question about the optimal timing of mediation in the guideline?</b></p> <p>Again, it is of course important to include Current Best Evidence. A statement can't really be made here on whether the new work would have no impact without reading the papers and information about the study referred to in significant depth. However, matters of timing could be explored for individual patients, seeing the effects (in non-</p>	<p>Thank you for your comment. We recognise that this is an important area in current research. The NICE hypertension surveillance review identified evidence related to optimal timing of antihypertensive drug treatment however the largest trial in the area will not be published in time to inform the updated guidance and therefore it was agreed that consideration of this area should not be done until this evidence is available.</p>

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			critical cases) of altering timing before changing dose or medication.	
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#### [Registered stakeholders](#)

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