**Hypertension in adults**

**Consultation on draft scope**

**Stakeholder comments table**

**09/06/2017 to 07/07/2017**

<table>
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<tr>
<th>Stakeholder</th>
<th>Page no.</th>
<th>Line no.</th>
<th>Comments</th>
<th>Developer's response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Association of Anaesthetists of Great Britain and Ireland</td>
<td>General</td>
<td>General</td>
<td>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></td>
<td>Thank you for your comment and for providing this information.</td>
</tr>
<tr>
<td>Association of Anaesthetists of Great Britain and Ireland</td>
<td>General</td>
<td>General</td>
<td>The committee may wish to add the management of patients with hypertension undergoing elective surgery to the scope of the review</td>
<td>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.</td>
</tr>
<tr>
<td>British Acupuncture Council</td>
<td>6</td>
<td>10</td>
<td>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</td>
<td>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.</td>
</tr>
</tbody>
</table>
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| 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 | 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. The hypertension surveillance review recognised PATHWAY2 as new evidence that could impact current recommendations, and this will be assessed when reviewing the evidence. |
| British and Irish Hypertension Society | 7 | 1 - 8 | COST Saving - Low dose combinations as initial therapy rather than monotherapy better BP reduction - SBPM for assessing BP control on treatment. Current guidelines only seem to recommend ABPM/SBPM for initial diagnosis not for assessment of treatment control - 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. | Thank you for your comment. 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. |
| British and Irish Hypertension Society | 7-8 | 31 | 1 - 5 | It is important to address “Optimal timing” as a question | 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 |

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| 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. It was agreed that consideration of this area should not be addressed until this evidence is available. |
| 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. J Periop Crit Intensive Care Nursing 2016; 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. 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 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 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. |

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| British Dietetic Association | 5 | After line 12 (Table – ‘Lifestyle Interventions’) | 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. | that there was not enough evidence to recommend these procedures. Recognition will be given to resistant hypertension within the scope area of choosing hypertensive treatment and the questions around treatment sequencing. |

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<th>Commenter</th>
<th>ID</th>
<th>Page Range</th>
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<tbody>
<tr>
<td>CVRX</td>
<td>2</td>
<td>18 - 20</td>
</tr>
<tr>
<td>Diabetes UK</td>
<td>4</td>
<td>14</td>
</tr>
</tbody>
</table>

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.

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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<th>Diabetes UK</th>
<th>6</th>
<th>10</th>
<th>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.</th>
</tr>
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<tbody>
<tr>
<td></td>
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<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Diabetes UK</th>
<th>6</th>
<th>12</th>
<th>To be added to this list of related guidance are NG17 and NG28.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Diabetes UK</th>
<th>General</th>
<th>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</th>
</tr>
</thead>
</table>
|             |         | 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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<th>General Subject</th>
<th>Comment Text</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hull York Medical School</td>
<td>General</td>
<td>General</td>
<td>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.</td>
<td>Thank you for your comment. Resistant hypertension will be considered within the scope area of choosing hypertensive treatment and the questions around treatment sequencing.</td>
</tr>
<tr>
<td>Hull York Medical School</td>
<td>General</td>
<td>General</td>
<td>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.</td>
<td>Thank you for your comment. We will take this into consideration when reviewing the evidence and updating recommendations related to blood pressure targets.</td>
</tr>
<tr>
<td>Hull York Medical School</td>
<td>General</td>
<td>General</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>Hull York Medical School</td>
<td>Question 1</td>
<td>General</td>
<td>‘Physician inertia’ is a major problem and therefore a process lead approach should be considered.</td>
<td>Thank you for your comment.</td>
</tr>
<tr>
<td>Hull York Medical School</td>
<td>Question 2</td>
<td>General</td>
<td>Lifestyle interventions should not be covered.</td>
<td>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.</td>
</tr>
<tr>
<td>Hull York Medical School</td>
<td>Question 3</td>
<td>General</td>
<td>Malignant hypertension is now very rare and unlikely to benefit from consideration in a general population guideline.</td>
<td>Thank you for your comment. Based on stakeholder feedback the focus of the topic area around malignant hypertension has been updated.</td>
</tr>
</tbody>
</table>

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<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hull York Medical School</td>
<td>Question 4</td>
<td>General</td>
<td>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.</td>
</tr>
</tbody>
</table>
| Maharishi Foundation               | 5        | 12 (and table below) | 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.  

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). |

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. |

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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**Evidence for inclusion of Transcendental Meditation in recommendations for nonpharmacological measures for prevention and management of hypertension**

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## Summary of evidence for NICE Hypertension Guidelines Group

Roger Chalmers, sessional general practitioner (NHS England-East Anglia)

### Introduction

Nonpharmacological lifestyle measures, including diet, weight management, and physical activity, are well established aspects of optimal hypertension management.1-3 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.

### Transcendental Meditation

Transcendental Meditation® (TM), founded by Maharishi Mahesh Yogi, is a simple, effortless technique practised for 15-20 minutes twice daily. TM
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<tbody>
<tr>
<td><em>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.</em></td>
<td>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.</td>
</tr>
<tr>
<td><em>Research on TM, blood pressure and cardiovascular health</em></td>
<td>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</td>
</tr>
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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.

RCTs from this collaboration and other research groups have found that TM reduces BP in hypertensive and pre-hypertensive subjects,\textsuperscript{4-24} and improves cardiovascular outcomes, as indicated by reductions in major clinical events and mortality.\textsuperscript{9,10} 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.\textsuperscript{8,30,48,76-87,91-95,98}

Three well-conducted systematic reviews and meta-analyses of RCTs have concluded that TM reduces blood pressure.\textsuperscript{6,7,11}

American Heart Association Scientific Statement 2013

A Scientific Statement from the American Heart Association (AHA) in 2013 found that, based on RCTs and meta-analyses, "The overall evidence supports that TM modestly lowers BP", and states that "TM may..."
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| be considered in clinical practice to lower BP | 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 Class III, no benefit, Level of Evidence C recommendation. Thus, other meditation techniques are not recommended in clinical practice to lower BP at this time.’

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.

Indeed, a response to the AHA Scientific Statement observes that it ‘surveys 11 RCTs with >1200 subjects and 2 well-conducted meta-analyses on TM and BP.’ Moreover, there are multiple hard event outcome trials on TM that are not available for other nonpharmacologic approaches. 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. The 2012 cardiovascular disease event trial was analyzed independently. BP effects of TM have been

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confirmed by numerous investigators, in multiple populations, and with ambulatory monitoring. 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". 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". This conclusion is consistent with findings of hard event outcome trials on TM discussed below.

Recent systematic review and meta-analysis using Cochrane criteria

Since publication of the AHA statement, a further independent systematic review and meta-analysis of RCTs found that TM lowers blood pressure. This study employed rigorous Cochrane Collaboration criteria for assessing research quality. Regarding overall trial quality, the study concludes: "The quality of
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<th>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.</th>
<th>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.</th>
</tr>
</thead>
</table>
| 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. Another meta-analysis confirmed that TM leads to clinically important reductions in blood pressure. | ![](image)

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<th>Improved cardiovascular outcomes:</th>
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<tr>
<td>reduction of major clinical events;</td>
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<tr>
<td>and decreased mortality</td>
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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; $P=0.025$). 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%.9

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...
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| compared TM, other behavioural interventions, and usual therapy for elevated BP. | 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, \( P = 0.039 \)). Secondary analysis showed a 30% decrease in the rate of cardiovascular mortality with TM (relative risk 0.70, \( P = 0.045 \)).
| Other RCTs on TM and cardiovascular health have shown: |
| • decreased left ventricular mass in pre-hypertensive adolescents; |
| • reduced carotid atherosclerosis (intima-media thickness) in hypertensive subjects; |

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<td>• decreased insulin resistance and BP in patients with stable CHD. TM also increased stability of the cardiac autonomic nervous system;¹⁹</td>
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<tr>
<td></td>
<td>• improved functional capacity and quality of life in patients with chronic heart failure. TM subjects also showed reduced depression and had fewer hospitalizations.²⁵</td>
</tr>
<tr>
<td></td>
<td>• reduced use of antihypertensive medication compared to controls who practised progressive muscular relaxation or received health education.²²</td>
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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.²⁶

A controlled, non-randomized study on TM found improved exercise tolerance in angina patients with documented coronary lesions.²⁷ 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).²⁸

A narrative review of research on TM for prevention of cardiovascular disease notes that NIH-sponsored clinical

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Trials did not observe any adverse effects from TM, a finding consistent with other cardiovascular studies and wider TM research literature. The AHA Scientific Statement 2013, discussed above, observes that ‘TM (or meditation techniques in general) does not appear to pose significant health risks.’

**Effects on blood pressure in young adults and adolescents**

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.

In this connection, it is of interest that RCTs on younger populations have shown:

- In university students, TM reduced BP and also decreased total psychological distress, anxiety, depression, and anger/hostility; and improved coping.
- In pre-hypertensive adolescents, TM decreased BP at rest and during acute laboratory stress;

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<td>decreased ambulatory BP during normal daily activity.(^{16})</td>
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**Reduced smoking and alcohol consumption**  
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.\(^{30}\)  
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.\(^{30}\)
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. 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.

**Cholesterol**

An early matched-control study found reductions in serum cholesterol levels with TM in medication-free hypercholesterolaemic subjects over an 11-month period. In a more recent RCT, cholesterol did not
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<td>change significantly in patients with stable CHD in whom pre-test cholesterol levels were already reduced due to statin treatment in 83% of subjects.</td>
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**Stress reduction**

Substantial evidence indicates that psychosocial stress contributes to development and progression of hypertension and cardiovascular disease.\(^8,9,32-38\)

Attributable CHD risk associated with psychosocial stress factors across varied populations is similar to conventional cardiovascular risk factors.\(^39\)

Psychological distress, including depression, anger, hostility, and anxiety, predict cardiovascular clinical events,\(^40-42\) and may be related to death from cardiovascular disease in a dose-response manner.\(^32-33\)

As a BMJ editorial noted, the question remains as to how to intervene to reduce this risk.\(^32\)

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

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Physiological changes during TM
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.\textsuperscript{46-67} Findings include reduced respiration rate and minute ventilation;\textsuperscript{46-52} high and stable galvanic skin resistance;\textsuperscript{46-51} increased orderliness and integration of brain functioning;\textsuperscript{46,47,51,55-61} decreased peripheral vascular resistance;\textsuperscript{62} decreased plasma cortisol;\textsuperscript{53,54} reduced arterial blood lactate;\textsuperscript{46,49,63} other neuroendocrine changes;\textsuperscript{64-66} and decreased EMG activity.\textsuperscript{60,67} Overall, subjective experience during TM and its physiological correlates have been aptly described as a state of 'restful alertness'.\textsuperscript{46,47,49,55} Taken together, these findings distinguish the physiology of TM from

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| sleep, drowsiness, or simple eyes-closed rest.⁵⁶-⁵⁹,⁵¹,⁵⁵ |
| 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.⁵⁵ |

**Effects of regular practice of TM: sustained reductions in psychophysiological correlates of stress; improvements in physical, mental and social parameters**

In addition to the cardiovascular health findings discussed above, regular practice of TM is associated with sustained reductions in physiological correlates of stress⁸,⁴⁸ and longitudinal improvements in EEG markers of brain integration,⁵⁵,⁵⁹,⁶⁸-⁷¹ perceptual and cognitive functioning,¹³,⁷²-⁷⁵,⁸⁸-⁹⁰ psychological health (including reduced anxiety, depression, anger, and hostility, and increased well-being),⁷⁶-⁸⁷,⁹¹-⁹⁵,⁹⁸ and with improvements in education,⁷²,⁸⁵-⁹⁰ occupational health and performance,⁹¹-⁹⁵ and rehabilitation of offenders.⁹⁶-⁹⁸
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<td><strong>RCTs have shown improvements in quality of life and mental health with TM in patients with chronic physical disorders.</strong></td>
<td>25,76,77 Findings include: improvements in functional capacity and quality of life, and reduced depression levels, in patients with chronic heart failure;25 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).76 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).13</td>
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<td>Reduced anxiety</td>
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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.\(^7^8\) 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.\(^7^9\) TM was


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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.78,79

**Increased psychological well-being**

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.80

**Improvements in post-traumatic stress disorder**

An early RCT found that TM improved multiple features of post-traumatic stress disorder (PTSD) in American veterans of the Vietnam war, including

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| 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.\(^81\) 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;\(^82,83\) 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.\(^84\) |

### Health care needs and costs

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

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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.99-102

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

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Meaningful statistical analysis.\(^3\)

Conclusion

RCTs and meta-analyses of RCTs have found that TM reduces BP in hypertensive and pre-hypertensive subjects.\(^4-24\)

RCTs have shown that TM improves cardiovascular outcomes, notably marked reductions in major clinical events and mortality.\(^9,10\)

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.\(^8,30,48,76-87,91-95,98\)

The American Heart Association Scientific Statement (2013) found evidence that TM reduces BP and stated that ‘TM may be recommended in clinical practice to

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<td>lower BP; this was not the case for other methods of meditation and relaxation.</td>
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<td>NICE Hypertension Guideline CG127 (2011)¹ and US guidelines including JNC-8²,³ 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).¹⁰⁴ 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,</td>
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<td>Including pre-hypertensive young adults and adolescents, older subjects with mild hypertension, and secondary prevention patients with CHD.425</td>
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## References

   [https://www.nice.org.uk/guidance/cg127](https://www.nice.org.uk/guidance/cg127)


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| 12. Orme-Johnson D. Comment on 'Investigating the effect of transcendental meditation on blood pressure: a systematic review and meta-
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17. Barnes VA, Kapuku GK, Treiber FA. Impact of transcendental meditation on left ventricular mass in African American adolescents. |
### Hypertension in adults

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<td>American Journal of Managed Care 1996 2:427-437</td>
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<td>31. Cooper M, Aygen M. Transcendental Meditation in the management of...</td>
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| 42. Roest AM, Martens EJ, de Jonge P, Denollet J. Anxiety and risk of incident coronary heart disease.

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<td>48. Dillbeck MC, Orme-Johnson DW. Physiological differences between</td>
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<td>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. <em>Biological Psychology</em> 2002 61:293-319</td>
<td></td>
<td></td>
</tr>
<tr>
<td>72. So KT, Orme-Johnson DW. Three randomized experiments on the holistic longitudinal effects of the Transcendental Meditation technique on cognition. <em>Intelligence</em> 2001 29:419-440</td>
<td></td>
<td></td>
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<tr>
<td>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. Military Medicine 2016 181(1):56-63</td>
<td></td>
</tr>
<tr>
<td>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. Education 2013 133:495-501</td>
<td></td>
</tr>
</tbody>
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<td>95.</td>
<td>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. <em>Anxiety, Stress, and Coping</em> 1993 6:245-262</td>
</tr>
<tr>
<td>98.</td>
<td>Abrams AI, Siegel LM. The Transcendental Meditation program and rehabilitation at Folsom State Prison: a cross-validation study. <em>Criminal Justice and Behavior</em> 1978 5:3-20</td>
</tr>
<tr>
<td>99.</td>
<td>Herron R, Hillis S. The impact of the Transcendental Meditation program on government payments to physicians in</td>
</tr>
</tbody>
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<td>101.</td>
<td>erron R. Changes in physician costs among high-cost Transcendental Meditation practitioners compared with high-cost nonpractitioners over 5 years. <em>American Journal of Health Promotion</em> 2011 26(1):56-60</td>
<td></td>
<td></td>
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<tr>
<td>104.</td>
<td>Hypertension: Evidence Update 32, March</td>
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Competing interest statement:
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.

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## Hypertension in adults

### Consultation on draft scope

#### Stakeholder comments table

**09/06/2017 to 07/07/2017**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Rank</th>
<th>GPA</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicines and Healthcare products Regulatory Agency</td>
<td>General</td>
<td>General</td>
<td>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.</td>
</tr>
<tr>
<td>Medtronic Ltd</td>
<td>2</td>
<td>18 - 20</td>
<td>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.</td>
</tr>
<tr>
<td>Medtronic Ltd</td>
<td>6</td>
<td>18</td>
<td>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</td>
</tr>
<tr>
<td>Medtronic Ltd</td>
<td>General</td>
<td>General</td>
<td>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</td>
</tr>
</tbody>
</table>

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**Hypertension in adults**

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09/06/2017 to 07/07/2017

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<table>
<thead>
<tr>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obesity Group of the British Dietetic Association</td>
</tr>
<tr>
<td>Table under ‘Lifestyle interventions’</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

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**09/06/2017 to 07/07/2017**

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| RCGP | General | General | 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. 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 & exercise. Thank you for your comment. 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. 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... |

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## Hypertension in adults

### Consultation on draft scope
**Stakeholder comments table**

<table>
<thead>
<tr>
<th>Date</th>
<th>Number</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/06/2017</td>
<td>5</td>
<td>A key document that needs to be considered is the NICE multimorbidity guidance (nice.org.uk/guidance/ng56) as hypertension is the most common comorbid condition in the UK. (Dumbrek BMJ 2015 350:bmj.h949) 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. (Prosser 2017 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.</td>
</tr>
<tr>
<td>07/07/2017</td>
<td>12</td>
<td>I’m afraid we are unsure what this comment relates to and are unable to provide a specific response.</td>
</tr>
</tbody>
</table>

**RCGP General**

**Royal College of Anaesthetists**

Only if it is possible that they would reduce inequality.

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 evidence is available. 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.

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Hypertension in adults

Consultation on draft scope
Stakeholder comments table

09/06/2017 to 07/07/2017

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<table>
<thead>
<tr>
<th>Royal College of Anaesthetists</th>
<th>5</th>
<th>4</th>
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<tr>
<td></td>
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</table>

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

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.

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Hypertension in adults

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<table>
<thead>
<tr>
<th>Royal College of Anaesthetists</th>
<th>9</th>
<th>5</th>
<th>The RCoA notes the long time line until publication which is disappointing</th>
</tr>
</thead>
</table>
| Royal College of Physicians (RCP) | General | General | Reluctance to refer to epidemiology
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 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 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. |
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<tbody>
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<td></td>
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<td></td>
<td>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.</td>
</tr>
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<td></td>
<td></td>
<td>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.</td>
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**Hypertension in adults**

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<thead>
<tr>
<th>Royal College of Physicians (RCP)</th>
<th>General</th>
<th>General</th>
<th><strong>Reluctance to refer to dietary salt</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Royal College of Physicians (RCP)</th>
<th>General</th>
<th>General</th>
<th><strong>RCT trial data</strong></th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>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</td>
</tr>
</tbody>
</table>

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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Hypertension in adults

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<thead>
<tr>
<th>Royal College of Physicians (RCP)</th>
<th>General</th>
<th>General</th>
<th>Our experts note that there are two independent hypertension studies which are particularly important.</th>
</tr>
</thead>
</table>
|                                   |         |         | **MRC Hypertension Studies**  
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-smokers. |

Thank you for your comment and for sending this information.

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. 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).

outcome to be considered when searching for and assessing the evidence.

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.

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Royal College of Physicians (RCP)  General  General  ALLHAT trial
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.

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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<th>Royal College of Physicians (RCP)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td></td>
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<tr>
<td>taken account of through the health economics of the guideline.</td>
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<tr>
<td>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 hydrochlorothiazide. This is not consistent with the current BNF, which recommends for those under 55 to take an ACE inhibitor, AII 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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
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</tbody>
</table>

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<thead>
<tr>
<th>Royal College of Physicians (RCP)</th>
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<th>Treating CBBB as a class</th>
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<tbody>
<tr>
<td></td>
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<td>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>).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Royal College of Physicians (RCP)</th>
<th>General</th>
<th>General</th>
<th>Altering the measurement of blood pressure alters RCT interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Royal College of Physicians (RCP)</th>
<th>General</th>
<th>General</th>
<th>Spironolactone</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>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</td>
</tr>
</tbody>
</table>

Thank you for your comment. The available evidence for the use of spironolactone for hypertension will be considered by the guideline committee when refining the question and protocol for questions relating to antihypertensive drug treatment.

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<th>Royal College of Physicians (RCP)</th>
<th>General</th>
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<th>Cofactors</th>
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<tbody>
<tr>
<td></td>
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<td></td>
<td>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.</td>
<td>Committee when the systematic review is undertaken.</td>
</tr>
<tr>
<td>Royal College of Physicians (RCP)</td>
<td>General</td>
<td>General</td>
<td>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.</td>
<td>Thank you for your comments.</td>
</tr>
</tbody>
</table>

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.

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| Royal College of Physicians (RCP) | General | General | 1. What is the cause of primary high blood pressure (essential hypertension)? Is the cause avoidable? 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). | 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. |
| Royal College of Physicians (RCP) | General | General | 2. By how much does hypertension affect life expectancy? By how much does treatment reverse this? Treatment of mild to moderate hypertension does not significantly improve mortality. | 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. |
| Royal College of Physicians (RCP) | General | General | 3. By how much does hypertension affect the risk of MI? By how much does treatment reverse this? Treatment of mild to moderate hypertension shows a small, non-significant reduction in meta-analysis in CHD of 14% (95% CI 4-22%). | 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. |
| Royal College of Physicians (RCP) | General | General | 4. By how much does hypertension affect the risk of stroke? By how much does treatment reverse this? | Thank you for your comment. Stroke is listed as one of the main outcomes that will be considered |

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<th>Date Range</th>
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<tr>
<td>09/06/2017 to 07/07/2017</td>
<td>Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.</td>
<td>when undertaking the reviews, so the effect on reducing strokes will be considered.</td>
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<table>
<thead>
<tr>
<th>Royal College of Physicians (RCP)</th>
<th>General</th>
<th>General</th>
<th>5. Is the risk of hypertension linear?</th>
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<td></td>
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<td></td>
<td>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 5th April, 2017). This contrasts with the claim that a target of &lt;140/90 mm Hg is suitable for most patients (Kahan T. Lancet 5th April, 2017).</td>
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<tr>
<th>Royal College of Physicians (RCP)</th>
<th>General</th>
<th>General</th>
<th>6. How important is hypertension compared to risk of smoking?</th>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Smoking reduces life expectancy by 11-12 years. The average risk of a heart attack is 12-fold greater for the average American (AHA, 2017).</td>
</tr>
</tbody>
</table>

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# Hypertension in adults

## Consultation on draft scope

**Stakeholder comments table**

**09/06/2017 to 07/07/2017**

*Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.*

<table>
<thead>
<tr>
<th>St George’s University Hospitals NHS Foundation Trust</th>
<th>8</th>
<th>11</th>
<th>Under Main outcomes: Can I suggest Peripheral arterial disease and aortic disease (aneurysm, dissection)</th>
<th>Recommendation for smoking which states: offer advice and help to smokers to stop smoking.</th>
</tr>
</thead>
<tbody>
<tr>
<td>St George’s University Hospitals NHS Foundation Trust</td>
<td>8</td>
<td>6</td>
<td>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</td>
<td>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.</td>
</tr>
<tr>
<td>Stroke Association</td>
<td>1</td>
<td>20</td>
<td>With hypertension being a contributing factor in around half of strokes¹, the Stroke Association is concerned at the number of people with undiagnosed and untreated hypertension – more than 5.5 million in England alone.² Given the scale of this problem, we would like to see the estimated numbers of undiagnosed cases of malignant hypertension clarified.</td>
<td>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 accept comments on this.</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Comment No.</th>
<th>Comment Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke Association</td>
<td>2</td>
<td>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.</td>
</tr>
<tr>
<td>Stroke Association</td>
<td>21</td>
<td>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 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 thing that further emphasis is required on undiagnosed hypertension.</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th>Stakeholder</th>
<th>Comments</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke Association</td>
<td>3</td>
<td>23</td>
</tr>
</tbody>
</table>

|   |   | literature does not support the blood pressure goals set by…guidelines.3 |
|   |   | 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.4 |
|   |   | 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.5 |
|   |   | 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. |

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.

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| Stroke Association | 3   | 7   | After “providers of services” add “including those from the voluntary sector.”
|                   |     |     | 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.⁶ 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: [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) 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. |
| Stroke Association | 4   | 19  | Care homes should be explicitly mentioned here to ensure health professionals are working across health and social care when implementing the guideline. 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. |
## Hypertension in adults

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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. 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 Stroke Association | 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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Hypertension in adults

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<table>
<thead>
<tr>
<th>Association is looking to include pulse checks as part of our Know Your Blood Pressure events.</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
<tr>
<td>Stroke Association General General</td>
</tr>
<tr>
<td>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. 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.</td>
</tr>
<tr>
<td>Thank you for your comment and for highlighting this work.</td>
</tr>
</tbody>
</table>

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# Hypertension in adults

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<table>
<thead>
<tr>
<th>Stroke Association</th>
<th>General</th>
<th>General</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke Association</td>
<td>General</td>
<td>General</td>
<td>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.</td>
</tr>
</tbody>
</table>

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.

Thank you for your comment. We agree that lifestyle interventions programmes from Public Health England are an important part of managing hypertension.

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

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<table>
<thead>
<tr>
<th>The Dirac Foundation</th>
<th>General</th>
<th>General</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Which interventions or forms of practice might result in cost saving recommendations if included in the guideline?</td>
<td></td>
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<tr>
<td>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/M²) 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</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
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</tbody>
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| 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. P(type 2 diabetes) = 0.081. Circa 90% of type 2 diabetics are obese, i.e. P(obese | type 2 diabetes) = 0.9. Consequently P(obese & type 2 diabetes) = P(obese | type 2 diabetes) x P(type 2 diabetes) = 0.9 x 0.081 = 0.073 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 P(obesity if type 2 diabetes) = P(obesity | type 2 diabetes) = circa 0.1 to 0.2 (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 |

| The difference between association and causality is recognized and will be considered when any recommendations on related topics are made. |

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<tr>
<th>Remarks</th>
<th></th>
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<tbody>
<tr>
<td>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].</td>
<td></td>
</tr>
</tbody>
</table>

3. http://www.obesity.org/obesity/content/weight-diabetes
6. P. Costanzo et al. (2015) “The Obesity Paradox in Type 2 Diabetes Mellitus: Relationship of Body Mass Index to Prognosis:

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<tr>
<th>The Dirac Foundation</th>
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<th>General</th>
</tr>
</thead>
<tbody>
<tr>
<td>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 hypertension be considered by NICE?</td>
<td></td>
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</table>


“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.”

Chao Cao et al. (2012), Body Mass Index and Mortality in Chronic Obstructive Pulmonary Disease: A Meta-Analysis.

[http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0043892](http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0043892)

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.

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<thead>
<tr>
<th>The Dirac Foundation</th>
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<th>General</th>
<th>3. What aspects of the management of malignant hypertension in secondary care should the guideline focus on?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>

hypertension be considered for update within this guideline?
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.


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.

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| The Dirac Foundation | General | General | 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?**

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-

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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.

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<thead>
<tr>
<th>Registered stakeholders</th>
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</table>

Critical cases) of altering timing before changing dose or medication.