NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

CENTRE FOR CLINICAL PRACTICE

QUALITY STANDARDS PROGRAMME

Quality standard topic: Hypertension

Output: Briefing paper

Introduction

This briefing paper presents a structured evidence review to help determine the suitability of recommendations from the key development sources listed below, to be developed into a NICE quality standard. The draft quality statements and measures presented in this paper are based on published recommendations from these key development sources:

Hypertension. NICE clinical guideline 127 (2011).

Lipid modification. NICE clinical guideline 67 (2008)

Structure of the briefing paper

The body of the paper presents supporting evidence for the draft quality standard reviewed against the three dimensions of quality: clinical effectiveness, patient experience and safety. Information is also provided on available cost-effectiveness evidence and current clinical practice for the proposed standard. Where possible, evidence from the clinical guideline is presented. When this is not available, other evidence sources have been used.

1 Diagnosis: considering a diagnosis of hypertension

1.1 NICE CG127 recommendation 1.21

1.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

Guideline recommendations	1.2.1 When considering a diagnosis of hypertension, measure blood pressure in both arms. - If the difference in readings between arms is more than 20 mmHg, repeat the measurements. - If the difference in readings between arms remains more than 20 mmHg on the second measurement, measure subsequent blood pressures in the arm with the higher reading. **[new 2011].**
Proposed quality statement	People with a clinic blood pressure of 140/90 or higher and no confirmed diagnosis of hypertension, and a difference in blood pressure readings between arms of more than 20 mmHg, have all subsequent blood pressure taken in the arm with the highest reading.
Draft quality measure	**Process:** a) Proportion of people with a difference in blood pressure readings between arms of more than 20 mmHg, for whom there is a record of the arm with the highest pressure to be used for all subsequent blood pressure measurements. Numerator – the number of people in the denominator for whom there is a record of the arm with the highest pressure recorded to be used for all subsequent blood pressure measurements. Denominator – the number of people with a difference in blood pressure readings between arms of more than 20 mmHg. b) Proportion of people with a difference in blood pressure readings between arms of more than 20 mmHg who use the arm with the higher reading for all subsequent ambulatory blood pressure monitoring blood pressure measurements. Numerator – the number of people in the denominator who use the arm with the highest blood pressure reading for all subsequent ambulatory blood pressure monitoring blood pressure measurements. Denominator – the number of people with a difference in blood pressure readings between arms of more than 20 mmHg who are using ambulatory blood pressure monitoring.
Questions for the TEG	Would ‘subsequent’ blood pressure measurements be solely the measurements taken to confirm diagnosis, or would this extend to measurements in people with a confirmation of diagnosis to monitor response to treatment?

1.1.2 Clinical and cost-effectiveness evidence

The GDG for the NICE clinical guideline on Hypertension (CG127) noted that a difference of <10mmHg in blood pressure measurements between arms can be considered normal, however, a difference of more than 20mmHg is unusual, occurring in <4% of people and is usually associated with underlying vascular disease. Clinicians are advised to take readings in both of the patient's arms initially, and use the arm with the higher reading for subsequent measurements of blood pressure. Consistent inter-arm differences of over 20/10 mmHg may suggest pathology warranting specialist referral.

When using ambulatory blood pressure monitoring, patients should be advised that if one arm gives a higher reading at baseline then this should be used subsequently.

1.1.3 Patient experience

No patient experience evidence was identified.

1.1.4 Patient safety

Some people have higher blood pressures away from the clinic (masked hypertension) and ambulatory blood pressure monitoring could reveal much worse blood pressure control levels than apparent in the clinic, therefore the higher clinic reading should be used.

1.1.5 Current practice

No current practice evidence was identified.

1.1.6 Current indicators

No current indicators were identified.

2 Diagnosis: ambulatory blood pressure monitoring

2.1 NICE CG127 recommendation 1.2.3 (KPI)

2.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

Guideline recommendations	1.2.3 If the clinic blood pressure is 140/90 mmHg or higher, offer ambulatory blood pressure monitoring (ABPM) to confirm the diagnosis of hypertension. **[new 2011]**
Proposed quality statement	People with a clinic blood pressure of 140/90 mmHg or higher are offered ambulatory blood pressure monitoring (ABPM) to confirm a diagnosis of hypertension.
Draft quality measure	**Structure:** a) Evidence of local arrangements to ensure people with a clinic blood pressure of 140/90 mmHg or higher receive ambulatory blood pressure monitoring to confirm a diagnosis of hypertension. **Process:** a) Proportion of people with a clinic blood pressure of 140/90 mmHg or higher who receive ambulatory blood pressure monitoring to confirm a diagnosis of hypertension. Numerator – the number of people in the denominator who received ambulatory blood pressure monitoring to confirm a diagnosis of hypertension. Denominator – the number of people with clinic blood pressure of 140/90 mmHg or higher.

2.1.2 Clinical and cost-effectiveness evidence

The GDG compared evidence on the predictive value for clinical outcomes of blood pressure measurement (mortality, stroke, MI, heart failure, diabetes, vascular procedures, hospitalisation for angina, and other major adverse cardiac and cerebrovascular events) based on clinic blood pressure measurement (CBPM), home blood pressure measurement (HBPM) and ABPM. In 8 out of 9 prognostic studies comparing CBPM with ABPM, ABPM was found to be superior to CBPM at predicting clinical events.

In two prognostic studies comparing all three blood pressure measurement methods, one showed that ABPM and HBPM were similar to each other but superior to CBPM at predicting clinical outcomes. The other study showed no difference in their predictive value.

Based on these prognostic studies, the GDG concluded that CBPM was never superior to ABPM or HBPM at predicting clinical outcomes. Furthermore, ABPM was never inferior to other methods and was most often the best predictor of clinical outcomes. HBPM also appeared superior to CBPM at predicting clinical outcomes but there was less data with HBPM when

compared ABPM. The GDG therefore concluded that multiple blood pressure measurements away from the clinic setting are the best predictor of blood pressure-related clinical outcomes and that to date, studies with ABPM provided the most robust evidence.

The GDG also reviewed a meta-analysis which compared the sensitivity and specificity of CBPM and HBPM measurements against the reference standard ABPM. The analysis found that compared with ABPM, CBPM had a mean sensitivity of 74.6% (95% CI, 60.7 to 84.8) and specificity of 74.6% (47.9 to 90.4) and HBPM had a mean sensitivity of 85.7% (78.0 to 91.0) and specificity of 62.4% (48.0 to 75.0). CBPM was therefore found to misdiagnose hypertension in 25% of people without hypertension (38% with HBPM) and not diagnose hypertension in 25% of people with hypertension (14% with HBPM).

It was however noted that the studies included in the meta-analysis for CBPM were in a range of populations. Sensitivity analysis using results from only studies with a mean BP close to or above the diagnostic threshold, found that CBPM and HBPM are virtually identical in terms of sensitivity, but HBPM is more specific than CBPM. This analysis was considered more relevant to the guideline as screening in the general population is outside of its scope.

Taking into account the prognostic data and the meta-analysis of sensitivity and specificity, the GDG agreed that ABPM appeared to provide the best method of confirming a diagnosis of hypertension.

The GDG noted that despite the clear effectiveness of ABPM in improving the specificity and sensitivity of diagnosis for hypertension, ABPM devices are more expensive than desk top blood pressure monitors. The GDG considered that a significant change in practice such as this required clear evidence that ABPM would not only be a more effective means of diagnosis but also, a more cost-effective means of establishing a diagnosis of hypertension.

A cost-utility analysis was undertaken to assess different blood pressure monitoring methods for confirming a diagnosis of hypertension. A Markov model was used to estimate lifetime quality-adjusted life years (QALYs) and costs from a current UK NHS and personal social services perspective. Uncertainty was explored through probabilistic analysis and extensive sensitivity analyses.

The GDG considered cost-effectiveness analysis comparing CBPM, HBPM and ABPM for confirming a diagnosis in people with suspected hypertension (CBPM ≥140/90 mmHg) in ten gender and age (40, 50, 60, 70, 75 years) stratified subgroups. The analysis found that ABPM was the most cost-effective option in all age groups in both men and women and was, in fact, cost saving compared to CBPM when long term costs were taken into

account. The key driver of cost savings was hypertension treatment costs avoided due to more accurate diagnosis. In most groups ABPM was found to improve health (increased QALYs), as well as reduce costs. The GDG noted this conclusion was robust to a wide range of sensitivity analyses including those varying the cost of ABPM, the failure rate for ABPM, the level of CVD risk and the prevalence of true hypertension in the population.

The GDG noted that the analysis was probably conservative in terms of ABPM in a number of factors and that where sensitivity analysis impacted the conclusions these should not change the overall conclusion.

2.1.3 Patient experience

No patient experience evidence has been identified.

2.1.4 Patient safety

The NICE guideline notes that there is currently insufficient evidence of benefit for initiating treatment below the currently recommended thresholds for diagnosing hypertension. Whilst the GDG noted that the results of the cost effectiveness sensitivity analysis suggest the health benefits of misdiagnosing people with hypertension are worth the additional cost of treatment, there may be some potential negative effects of treatment (in people without hypertension), in terms of reducing people's quality of life.

2.1.5 Current practice

For many years elevated blood pressure readings of greater than 140/90 on three separate occasions have generally been used to confirm sustained high blood pressure.

The GDG of the clinical guideline noted that few practices presently have sufficient numbers of ABPM devices to increase their use as required by guideline recommendation 1.2.3. Currently, some but not all primary care practices have access to ABPM devices with some practices accessing ABPM through referral to secondary care. The GDG considered it likely that alternative models of service provision would emerge over time to meet local demand and that the costs of ABPM devices would fall as demand for their use increases.

2.1.6 Current indicators (Please refer to Appendix B)

Indicator in development for the QOF: The percentage of patients with a new diagnosis of hypertension after 1 April 2012 whose diagnosis was confirmed following ABPM.

3 Diagnosis: investigations prior to confirmation of diagnosis

3.1 NICE CG127 recommendation 1.2.6; NICE CG67 recommendation 1.4.2 (KPI)

3.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

Guideline recommendations	CG127 – recommendation 1.2.6: While waiting for confirmation of a diagnosis of hypertension, carry out investigations for target organ damage (such as left ventricular hypertrophy, chronic kidney disease and hypertensive retinopathy) (see recommendation 1.3.3) and a formal assessment of cardiovascular risk using a cardiovascular risk assessment tool (see recommendation 1.3.2). **[new 2011]** CG67 – recommendation 1.4.2: Before offering lipid modification therapy for primary prevention, all other modifiable CVD risk factors should be considered and their management optimised if possible. Baseline blood tests and clinical assessment should be performed, and comorbidities and secondary causes of dyslipidaemia should be treated. Assessment should include: - smoking status - alcohol consumption - blood pressure (see 'Hypertension', NICE clinical guideline 34) - body mass index or other measure of obesity (see 'Obesity', NICE clinical guideline 43) - fasting total cholesterol, LDL cholesterol, HDL cholesterol and triglycerides (if fasting levels are not already available) - fasting blood glucose - renal function - liver function (transaminases) - thyroid-stimulating hormone (TSH) if dyslipidaemia is present.
Proposed quality statement	People with a clinic blood pressure of 140/90 or higher have a formal estimation of CVD risk while waiting for confirmation of a diagnosis of hypertension. OR People with a clinic blood pressure of 140/90 or higher have investigations for target organ damage while waiting for confirmation of a diagnosis of hypertension. OR People (with hypertension) who have a 20% or higher risk of developing CVD, are offered statin therapy.

Draft quality measure	**Structure:** a) Evidence of local arrangements to ensure that investigations for target organ damage and formal assessment of CVD risk are carried out for people with a clinic blood pressure of 140/90 or higher (who are awaiting a confirmed diagnosis of hypertension). **Process:** a) Proportion of people with a clinic blood pressure of 140/90 or higher for whom formal estimation of CVD risk and investigations for target organ damage are carried out while awaiting a confirmed diagnosis of hypertension. Numerator – the number of people in the denominator for whom formal CVD risk and investigations for target organ damage are carried out. Denominator – the number of people with a clinic blood pressure of 140/90 or higher awaiting confirmation of diagnosis.
Questions for the TEG	• Is there one particular element that is the key quality issue here? • If this is about consideration of target organ damage we will need to consider a definition of investigations (e.g. left ventricular hypertrophy, hypertensive retinopathy, increased albumin:creatinine ratio). • Can we apply a timescale to this statement?

3.1.2 Clinical and cost-effectiveness evidence

The GDG for the NICE clinical guideline on Hypertension (CG127) considered evidence from 61 prospective observational studies which explored the relationship between blood pressure level and strokes and ischaemic heart disease events. Across age bands from 40 to 89, reduction in usual diastolic blood pressure of 20 mmHg systolic or 10 mmHg diastolic blood pressure was associated with reductions in death from stroke and ischemic heart disease of about one half. Findings were consistent across the range of blood pressure (down to 115/75 mmHg). An earlier analysis of nine observational studies found that the relationship between blood pressure and disease was constant over a wide range, suggesting there is no clear threshold below which further reduction in blood pressure becomes unbeneficial or harmful. A systematic review of 14 antihypertensive randomised drugs found that a mean reduction in diastolic blood pressure of 5–6 mmHg over 5 years achieved a relative reduction in stroke of 42% (95% CI: 33–50%) and CHD of 14% (95%CI: 4–22%).

The GDG noted that a person's risk of clinical events associated with hypertension is not only determined by their blood pressure but also by:

- the presence of target organ damage
- the presence of established cardiovascular disease (iscahemic heart disease or heart failure, cerebrovascular disease, peripheral vascular disease) or concomitant disease associated with high cardiovascular disease risk, e.g. diabetes or CKD
- the calculated cardiovascular risk (estimated from factors such as age, gender, smoking history, etc.)

The assessment of a person when contemplating a clinical diagnosis of hypertension must take account of these additional factors. The GDG considered that target organ damage may not always be due to hypertension, even when the two appear to co-exist. For example, the presence of ECG LVH in a patient subsequently shown not to be hypertensive would prompt consideration of alternative causes for the ECG abnormality.

The GDG noted that there is no firm evidence from which to define the exact composition of a full cardiovascular risk assessment, therefore recommendations are consensus-based.

The GDG identified the following tests as necessary to obtain an accurate profile of cardiovascular risk. These tests may help identify diabetes, evidence of hypertensive damage to the heart and kidneys, and secondary causes of hypertension such as kidney disease:

- Urine strip test for blood and protein
- Blood electrolytes and creatinine, and eGFR
- Blood glucose
- Serum total and HDL cholesterol
- 12 lead electrocardiogram.

No cost-effectiveness evidence was identified regarding the choice of CVD risk assessment tool.

The GDG for the NICE clinical guideline on Lipid Modification (CG67) concluded that for primary prevention, statins are effective in reducing fatal and nonfatal MI and the composite outcome CHD death or nonfatal MI, fatal and nonfatal stroke and revascularisation. The GDG reviewed evidence from a meta-analysis containing three randomised controlled trials and another that included data from six randomised controlled trials. Trials predominantly comprising primary prevention but including a minority of people with established CVD, meta-analysis found that statin therapy was associated with a reduction in the risk of all cause mortality, fatal and nonfatal MI and the composite outcomes of CHD death, nonfatal MI, fatal or nonfatal stroke and coronary revascularization.

Results from a primary prevention study of 10,305 people, which compared

atorvastatin with placebo over approximately 3 years, indicated that the number needed to treat (NNT) to avoid either a death from CHD or a nonfatal MI, in people without existing CHD, was 95 (95% CI 60 to 216).

NICE guideline CG67 concludes that statin treatment in patients with CVD is cost effective compared with no statin treatment. The GDG considered a cost effectiveness analysis which indicated that simvastatin 40 mg and pravastatin 40 mg are both cost effective options for the primary prevention of CVD. The GDG concluded that these were the most effective preparations at the lowest acquisition cost.

3.1.3 Patient experience

No patient experience evidence was found.

3.1.4 Patient safety

Testing may detect diabetes and identify signs of developing target organ damage such as left ventricular hypertrophy and angina. The clinical history, examination and routine blood and urine tests will also alert the clinician to possible secondary causes of hypertension. It was noted that target organ damage may not always be due to hypertension, even when the two appear to co-exist, which would warrant consideration of alternative causes.

3.1.5 Current practice

CG67 reported that in current clinical practice, formal assessment of cardiovascular risk is done opportunistically. Underlying achievement of PP01, which relates to face to face CVD risk assessment for patients at the outset of hypertension was 80.2% for England in 2010-2011. This has dropped from 81.7% in 2009/10. The exception rate was 15.9% in 2010/11, and 17.82% in 2009/10.

3.1.6 Current indicators (Please refer to Appendix B)

Indicator in the QOF: PP1 - In those patients with a new diagnosis of hypertension (excluding those with pre-existing CHD, diabetes, stroke and/or TIA) recorded between the preceding 1 April to 31 March: the percentage of patients who have had a face to face cardiovascular risk assessment at the outset of diagnosis (within 3 months of the initial diagnosis) using an agreed risk assessment tool.

Indicator on the NICE menu of indicators: In those patients with a new diagnosis of hypertension aged 30-74 years, recorded between the preceding 1 April to 31 March (excluding those with pre-existing CHD, diabetes, stroke and/or TIA), who have a recorded CVD risk assessment score (using an agreed risk assessment tool) of>20% in the preceding 15 months: the

percentage who are currently treated with statins (unless there is a contraindication).

4 Referral to a specialist in hypertension for: people with suspected secondary causes of hypertension

4.1 NICE CG127 recommendation 1.2.12

4.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

Guideline recommendations	1.2.12 Consider the need for specialist investigations in people with signs and symptoms suggesting a secondary cause of hypertension. **[2004, amended 2011]**
Proposed quality statement	People with suspected secondary causes of hypertension are referred for specialist investigations.
Draft quality measure	**Structure:** a) Evidence of local arrangements to refer people with suspected secondary causes of hypertension for specialist investigations. **Process:** a) Proportion of people with suspected secondary causes of hypertension who are referred for specialist investigations Numerator – the number of the denominator who are referred for specialist investigations. Denominator – the number of people with suspected secondary causes of hypertension.
Questions for the TEG	• The underpinning recommendation is a 'consider' recommendation. Is a statement on referral appropriate? • The foundation of recommendation 1.2.12 of the clinical guideline is the need for awareness of signs and symptoms, and referral on the basis of a high index of suspicion, and where the findings are likely to necessitate specialist management. Is it possible to define a 'high index of suspicion'? • The current wording of the statement may be too strong given the above, which is about the level of suspicion?

4.1.2 Clinical and cost-effectiveness evidence

Secondary hypertension refers to high blood pressure from an identifiable underlying cause. It may occur in up to 10% of hypertension cases, the most common cause being chronic renal disease. Other principal identifiable causes are renovascular hypertension, pheochromocytoma, Cushing syndrome, and primary aldosteronism.

The GDG for the NICE clinical guideline on Hypertension (CG127) noted that an identifiable cause of hypertension is more likely when hypertension occurs in younger patients (less than 40 years of age), worsens suddenly, presents as accelerated hypertension (BP more than 180/110 mmHg with signs of papilloedema and/or retinal haemorrhage) or responds poorly to treatment.

The GDG noted that clinical history, examination and routine blood and urine tests can alert the clinician to possible secondary causes of hypertension, some of which are potentially life threatening (e.g. phaeochromocytoma), and others which might be amenable to potentially curative interventions (e.g. Conn's adenoma, fibromuscular dysplasia). Many diagnostic techniques are accessed through specialist referral. If the initial clinical evaluation suggests the possibility of secondary hypertension, the patient should be referred for specialist review (for example, renal disease may be diagnosed by elevated serum levels of urea or creatinine (found by a blood test) or reduced eGFR. Specialist investigation includes magnetic resonance angiography for imaging of the kidneys, and duplex ultrasound scanning directly measuring the size of the kidneys).

The GDG retrieved no useful diagnostic studies which might establish primary care screening characteristics for secondary causes of hypertension as a basis for referral. The foundation for this recommendation is therefore the need for awareness of signs and symptoms, and referral on the basis of a high index of suspicion, and where the findings are likely to necessitate specialist management.

4.1.3 Patient experience

No patient experience evidence was identified.

4.1.4 Patient safety

Some secondary causes of hypertension are potentially life threatening (e.g. phaeochromocytoma). Patients with signs and symptoms of pheochromocytoma need immediate specialist investigation given the seriousness of the condition and risk to the patient. The definitive treatment of pheochromocytoma is surgical removal of the tumour.

4.1.5 Current practice

No current practice evidence has been identified.

4.1.6 Current indicators

No current indicators have been identified.

5 Referral to a specialist in hypertension for: younger adults (aged 18 to 40)

5.1 NICE CG127 recommendation 1.5.3 (KPI)

5.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

Guideline recommendations	1.5.3 For people aged under 40 years with stage 1 hypertension and no evidence of target organ damage, cardiovascular disease, renal disease or diabetes, consider seeking specialist evaluation of secondary causes of hypertension and a more detailed assessment of potential target organ damage. This is because 10-year cardiovascular risk assessments can underestimate the lifetime risk of cardiovascular events in these people. **[new 2011]**
Proposed quality statement	People with stage 1 hypertension aged under 40 years and with no evidence of target organ damage, CVD, renal disease or diabetes, are offered referral for specialist assessment.
Draft quality measure	**Structure:** a) Evidence of local arrangements to refer people aged under 40 years with stage 1 hypertension and no evidence of target organ damage, cardiovascular disease, renal disease or diabetes for specialist evaluation and assessment. **Process:** a) Proportion of people aged under 40 years with stage 1 hypertension and no evidence of target organ damage, cardiovascular disease, renal disease or diabetes who are referred for specialist evaluation and assessment. Numerator – the number of people in the denominator who are referred for specialist evaluation and assessment. Denominator – the number of people aged under 40 years with stage 1 hypertension and no evidence of target organ damage, cardiovascular disease, renal disease or diabetes. **Outcome:** a) Incidence of cardiovascular events in people aged under 40 years with stage 1 hypertension and no evidence of target organ damage, cardiovascular disease, renal disease or diabetes.

5.1.2 Clinical and cost-effectiveness evidence

The GDG discussed the fact that most people who would not be offered pharmacological treatment in accordance with the current recommendations would be younger, i.e. ≤ 40 years. This is because of their lower 10 year CVD risk and lower likelihood that they will have developed target organ damage or have established CVD. The GDG considered that 10 year CVD risk estimates

are strongly age dependent and as such, in younger people will rarely provide an indication for treatment of uncomplicated stage 1 hypertension.

The GDG considered that younger people with stage 1 hypertension are less likely to have overt evidence of target organ damage or vascular disease, and assessment of their CVD risk over a relatively short duration of 10 years is unlikely to adequately reflect their lifetime risk of CVD. The GDG noted that there is much less epidemiological data linking uncomplicated stage 1 hypertension in younger people with adverse clinical outcomes. In addition, younger people have not been included in clinical outcome trials in sufficient numbers to evaluate the impact of the pharmacological treatment of stage 1 hypertension on clinical outcomes.

The GDG discussed the need to develop more accurate estimates of the lifetime risk of younger people with uncomplicated stage 1 hypertension and the cost-effectiveness of treatment. In this regard, the GDG recognised the importance of thorough assessment of target organ damage to exclude its presence before deciding not to offer pharmacological treatment of hypertension for younger people with seemingly uncomplicated stage 1 hypertension. The GDG recommended that for younger people (i.e. <40years) with uncomplicated stage 1 hypertension, specialist referral for exclusion of secondary causes of hypertension and detailed evaluation of target organ damage e.g. by echocardiography to exclude LVH and dysfunction, should be considered before concluding not to offer treatment..

5.1.3 Patient experience

No patient experience evidence has been identified.

5.1.4 Patient safety

The GDG concluded that uncomplicated stage 1 hypertension in younger people is unlikely to be benign, blood pressure will most likely rise over time, and that there is uncertainty surrounding whether delayed pharmacological treatment will necessarily reverse any accumulated target organ or cardiovascular damage.

5.1.5 Current practice

The GDG identified that current guidance around treatment for hypertension would mean that most people with stage 1 hypertension will be offered pharmacological treatment because the majority of people with hypertension are older rather than younger and age is a major determinant of CVD risk.

The GDG discussed the fact that most of the people with stage 1 hypertension who would not be offered treatment according to this guidance will be younger (i.e. <40 years) because of their lower 10 year risk and lesser likelihood that

they will have developed target organ damage or have established cardiovascular disease. Furthermore, there maybe greater uncertainty about the diagnosis of hypertension when blood pressure is close to the threshold for stage 1 hypertension.

5.1.6 Current indicators

No current indicators have been identified.

6 Monitoring of treatment efficacy and adherence: targeting treatment and monitoring

6.1 NICE CG127 recommendations 1.5.5 and 1.5.6

6.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

Guideline recommendations	1.5.5 Aim for a target clinic blood pressure below 140/90 mmHg in people aged under 80 years with treated hypertension. [new 2011] 1.5.6 Aim for a target clinic blood pressure below 150/90 mmHg in people aged 80 years and over, with treated hypertension. [new 2011]
Proposed quality statement	People with treated hypertension have a target clinical blood pressure below 140/90 if aged under 80 years, or below 150/90 if aged 80 years and over.
Draft quality measure	**Structure:** a) Evidence of local arrangements to ensure people with treated hypertension who are aged under 80 years are targeted to a clinic blood pressure below 140/90 mmHg. b) Evidence of local arrangements to ensure people with treated hypertension who are aged 80 years and over are targeted to a clinic blood pressure below 150/90 mmHg. **Outcome:** a) Achievement of blood pressure target.

6.1.2 Clinical and cost-effectiveness evidence

The GDG assessed a series of studies including meta-analyses/systematic reviews examining more intense versus less intense blood pressure lowering to define optimal treatment targets for people receiving antihypertensive therapy. One study did show a benefit of more intensive lowering on cardiovascular morbidity and mortality; however overall there was no consistent benefit of the lower blood pressure target on clinical outcomes. The studies did however find that more intensive blood pressure lowering, was associated with a lower final blood pressure, and that relative risk reduction was related to the extent of blood pressure lowering across the range.

The GDG noted that in studies randomising patients to less intensive blood pressure lowering, more patients achieved the lower target reflecting the fact that lower blood pressure targets are more difficult to achieve and generally required more medications.

The GDG noted that in studies examining the impact of achieved blood pressure on treatment versus clinical outcomes, a higher achieved blood pressure was associated with a higher risk of cardiovascular events. Blood pressure of <140/90mmHg in people receiving antihypertensive therapy was associated with a lower risk of cardiovascular events. In contrast, in one systematic review, the achieved systolic blood pressure did not correlate with the risk of cardiovascular events.

The GDG noted that the risk of stroke was particularly sensitive to achieved blood pressure on treatment with the risk of stroke lowest in people with the lowest on-treatment blood pressure, down to a value of 115/75 mmHg. One study which stratified outcomes in people on treatment according to baseline blood pressure, showed that in patients with a baseline systolic blood pressure <130mmHg, further blood pressure lowering appeared to be associated with an increased risk of cardiovascular events. The GDG noted that this finding from a large clinical trial of patients at high cardiovascular risk does not support the uncritical adoption of lowering blood pressure in all patients at high risk of cardiovascular disease, irrespective of their baseline blood pressure.

The GDG noted evidence from one potentially applicable study, with potentially serious limitations which found that lower blood pressure targets were associated with higher costs (due to the requirement for more treatment) and no significant difference in clinical outcomes.

The GDG concluded that most clinical trials adopted a treatment target of <140/90 mmHg and that there was no convincing evidence supporting a lower treatment target for the pharmacological treatment of hypertension.

Blood pressure targets for people over the age of 80 years

The GDG considered one systematic review (meta-analysis) which compared the development of clinical outcomes in people aged ≥80 years who had been randomised to antihypertensive treatment versus placebo. The results of the analysis showed that in people with hypertension ≥80 years, pharmacological treatment was significantly better than placebo for reducing the risk of stroke, cardiovascular events and heart failure.

The GDG noted that the evidence supports initiation of treatment at stage 2 hypertension in people aged ≥80 years and treating to a CBPM target of <150/90mmHg. The GDG highlighted that this is not to say that people reaching this age who have been previously treated at lower levels of blood pressure and/or to a lower treatment target of <140/90mmHg should have their treatment back-titrated.

The GDG noted that lower thresholds and targets for this age group might be appropriate, however, the balance if safety and efficacy for a more aggressive treatment strategy has not been established.

6.1.3 Patient experience

No patient experience evidence was identified.

6.1.4 Patient safety

The GDG noted that there is an important distinction between continuing long-term and well-tolerated treatment in people over the age of 80 years and the initiation of blood pressure lowering therapy at that age.

The GDG noted that before the emergence of recent evidence there was uncertainty about the balance of efficacy versus harm (such as syncope and falls) with regard to initiating blood pressure treatment in people aged 80 years or over.

The GDG noted that the key studies supporting this recommendation generally included older people who were fit and active and had low levels of comorbidities.

The GDG recommended that treatment decisions in those aged ≥80 years should be based on the realistic expectations of clinical benefit from treatment in the context of other comorbidities which might limit life expectancy.

6.1.5 Current practice

Underlying achievement of QOF indicator BP05: The percentage of patients with hypertension in whom the last blood pressure (measured in the last 9 months) is 150/90 or less was 79.3%. This has risen from 78.7% in 2009/10.

Current indicators (Please refer to Appendix B)

Indicator in the QOF: BP05 - The percentage of patients with hypertension in whom the last blood pressure (measured in the last 9 months) is 150/90 or less.

Indicator on the NICE menu of indicators: The percentage of patients under 80 years old with hypertension in whom the last recorded blood pressure (measured in the preceding 9 months) is 140/90 or less.

Indicator on the NICE menu of indicators: The percentage of patients aged 80 years and over with hypertension in whom the last recorded blood pressure (measured in the preceding 9 months) is 150/90 or less.

7 Monitoring of treatment efficacy and adherence: annual review of care

7.1 NICE CG127 recommendation 1.7.3

7.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

Guideline recommendations	CG127 Recommendation 1.7.3 Provide an annual review of care to monitor blood pressure, provide people with support and discuss their lifestyle, symptoms and medication. **[2004]**
Proposed quality statement	People with hypertension are offered review of care at least annually, which includes a review of CVD risk factors
Draft quality measure	**Structure:** a) Evidence of local arrangements to ensure people receiving treatment for hypertension have an annual review of care. **Process:** a) Proportion of people receiving treatment for hypertension who receive an annual review of care Numerator – the number of people in the denominator who receive an annual review of care. Denominator – the number of people receiving treatment for hypertension.

7.1.2 Clinical and cost-effectiveness evidence

The GDG noted that people with hypertension who are not eligible for pharmacological treatment should receive lifestyle advice and an annual check-up as their blood pressure and cardiovascular disease risk will increase over time. The GDG noted that this would include people with stage 1 hypertension without any additional higher cardiovascular factors (target organ damage, established cardiovascular disease, the presence of concomitant disease that increases cardiovascular disease risk such as diabetes or CKD, 10 year cardiovascular risk estimated to be 20% or more). The GDG considered that an annual review would enable re-evaluation of the patient's condition and an opportunity to offer pharmacological treatment if they develop more severe hypertension, i.e. stage 2 hypertension, or they develop additional higher cardiovascular factors.

The GDG recommended that people with a clinic blood pressure ≥140/90mmHg but ABPM daytime average <135/85mmHg should also be offered annual review.

The GDG considered evidence from a systematic review of 18 trials examining the effects of multiple risk factor interventions (stopping smoking,

exercise, dietary control, weight control, antihypertensive drugs and cholesterol lowering drugs) in the primary prevention of coronary heart disease in middle aged adults and noted that there was little overall effect on mortality. However, the GDG noted that hypertensive 'high risk' patients were more likely to benefit from counselling, education and effective drugs and thus targeting health education to this group might be of some value.

The GDG noted that lifestyle interventions such as weight reducing diets, lowering salt intake, exercise, alcohol reduction and relaxation therapy can reduce blood pressure and recommended that patients are given advice to promote such lifestyle changes. The GDG recognised that lifestyle changes are difficult to adopt and their effectiveness is often limited. The GDG considered that a number of factors influence adherence including age, sex, education, understanding and disease perspectives, the mode of delivering advice and the type of health system. The GDG considered that adherence may be improved by good communication between patients and health professionals addressing knowledge about disease, active involvement of patients in decisions, setting achievable goals and good family and community support.

The GDG noted that advice alone is less effective than specifically adapted programmes supported by written and audiovisual material. The GDG also noted that material tailored to meet the educational and cultural needs of the population it is targeting has also been shown to be effective.

The GDG considered that targeting of advice to higher risk populations is thought to be more clinically and cost effective.

7.1.3 Patient experience

The GDG considered evidence from a published survey that examined the views of 452 hypertensive patients in one urban GP practice. Four in every five people taking part in the study said they had reservations about taking antihypertensives. Over a third of patients reported experiencing current or previous side effects from blood pressure lowering medication and nearly 40% were concerned by the potential harm caused by the long term use of such drugs. Thirty-six percent of responders wondered if they still needed blood pressure lowering medication and two-thirds would prefer non-drug therapy.

The GDG also considered information from transcribed interviews from 40–50 people who have experienced hypertension and found that compliance to medication was an issue for people. A number of people reported that they found it difficult to remember to take tablets. In attempts to avoid or delay drug therapy, a proportion of patients wanted to try lifestyle measures or complementary therapies as an initial alternative to blood pressure lowering drugs.

The survey found that patients often felt they wanted advice from health care professionals to avoid 'self-harm' and reported feelings of guilt and frustration if targets were not achieved. In general, patients welcomed information provided by general practitioners; some felt doctors did not provide enough information. A minority of patients felt that the greater their understanding about high blood pressure, the more that they had to worry about.

7.1.4 Patient safety

No patient safety evidence was identified (see full report from the patient safety function at the NHS Commissioning Board Special Health Authority for broader themes).

7.1.5 Current practice

The GDG noted that adherence with lifestyle modifications, especially dietary changes, is lower than with antihypertensive drug therapy by between 13% and 76%. The GDG considered that in many instances, lifestyle advice is given by nurses who manage clinics for the secondary prevention of coronary heart disease. These nurse-led initiatives have been shown to be effective at modifying lifestyle behaviours, reducing blood pressure, monitoring medication and ultimately in reducing mortality.

Underlying achievement of PP02 (provision of lifestyle advice in the last 15 months) was 81.9% for England in 2010-2011. This has dropped from 84.5% in 2009/10.

Underlying achievement of SMOKE03 (patients with any or any combination of certain conditions, including hypertension whose notes record smoking status in the previous 15 months) was 95.4% for England in 2010-2011. This has risen slightly from 95.2% in 2009/10.

7.1.6 Current indicators (Please refer to Appendix B)

Indicator in the QOF: PP2 - The percentage of people diagnosed with hypertension after 1 April 2009 who are given lifestyle advice in the last 15 months for: increasing physical activity, smoking cessation, safe alcohol consumption and healthy diet.

Indicator in the QOF: SMOKE03 - Patients with any or any combination of the following conditions: coronary heart disease, stroke or TIA, hypertension, diabetes, COPD, CKD, asthma, schizophrenia, bipolar affective disorder or other psychoses whose notes record smoking status in the previous 15 months.

8 Referral to a specialist in hypertension for: people with resistant hypertension

8.1 NICE CG127 recommendations 1.6.18 and 1.6.22

8.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

Guideline recommendations	1.6.18: Regard clinic blood pressure that remains higher than 140/90 mmHg after treatment with the optimal or best tolerated doses of an ACE inhibitor or an ARB plus a CCB plus a diuretic as resistant hypertension, and consider adding a fourth antihypertensive drug and/or seeking expert advice. **[new 2011]** 1.6.22: If blood pressure remains uncontrolled with the optimal or maximum tolerated doses of four drugs, seek expert advice if it has not yet been obtained. **[new 2011]**
Proposed quality statement	People with resistant hypertension are offered a fourth hypertensive drug and/or referral for specialist advice
Draft quality measure	**Structure:** a) Evidence of local arrangements to ensure people with clinic blood pressure that is not controlled to <140/90mmHg, despite optimal or best tolerated doses of third line treatment (optimal or best tolerated doses of an ACE inhibitor or an ARB plus a CCB plus a diuretic) are offered a fourth hypertensive drug and/or referral for specialist advice. **Process:** Numerator – the number of people in the denominator who are offered a fourth hypertensive drug and/or referral for specialist advice. Denominator – the number of people with clinic blood pressure that remains higher than 140/90 mmHg after treatment with optimal or best tolerated doses of third line treatment (optimal or best tolerated doses of an ACE inhibitor or an ARB plus a CCB plus a diuretic).

8.1.2 Clinical and cost-effectiveness evidence

The GDG agreed to define the term ‘resistant hypertension’ in the guideline as someone whose blood pressure is not controlled to <140/90mmHg, despite optimal or best tolerated doses of third line treatment. Based on health survey for England data, the GDG estimated that resistant hypertension is likely to affect approximately 500,000 people with treated hypertension in the U.K. and thus represents an important clinical problem. These people will be older and often have established cardiovascular disease, diabetes or CKD and thus, be at high cardiovascular risk. From a cardiovascular risk perspective, such

people potentially have much to gain in terms of absolute benefit from further blood pressure lowering.

The GDG noted that the treatment of resistant hypertension has not been studied in detail, in part because few drugs are developed that are specifically targeted at resistant hypertension. For the 2006 pharmacological update of the NICE Hypertension guideline, there was no formal evidence review for step 4 treatment and the GDG cautiously recommended a range of options that included; “further diuretic therapy”, alpha blockers or beta blockers. Six studies were identified for the 2011 review, although these were all retrospective cohort studies.

The best evidence suggests that low dose spironolactone (e.g. 25mg o.d.), when safe to use and when tolerated, can be an effective means of further lowering blood pressure. It is unclear if this is the optimal treatment for most people with resistant hypertension or whether other treatment options would be more effective in most or some cases. When use of spironolactone is not possible or not tolerated, then higher dose thiazide-like diuretic, alpha blockers or beta blockers are suitable alternatives for step 4 treatment, with the caveat that the evidence base is very limited and careful monitoring of electrolytes and renal function is essential.

The GDG concluded from review of the evidence that resistant hypertension is an important clinical problem that has been poorly studied with regard to the underlying causes and the most effective treatment options. Clinicians should consider referral of people with resistant hypertension for specialist advice/evaluation – especially those who are younger and those with complex co morbidities.

The GDG noted that poor compliance with therapy and white coat hypertension could each manifest as apparent resistance to drug treatment and should be considered. Secondary causes for hypertension should also be reconsidered in people with resistant hypertension and discussion with a specialist may be required to address some of these issues.

No relevant cost-effectiveness evidence was identified.

8.1.3 Patient experience

No patient experience evidence was identified.

8.1.4 Patient safety

No patient safety evidence was identified (see full report from the patient safety function at the NHS Commissioning Board Special Health Authority for broader themes).

8.1.5 Current practice

No current practice evidence was identified.

8.1.6 Current indicators

No current indicators were identified.

Appendix A: Definition of patient safety

The patient safety function at the NHS Commissioning Board Special Health Authority defines patient safety in the following terms:

Every day more than a million people are treated safely and successfully in the NHS, but the evidence tells us that in complex healthcare systems things will and do go wrong, no matter how dedicated and professional the staff. When things go wrong, patients are at risk of harm, and the effects are widespread and often devastating for patients, their families and the staff involved. Safety incidents also incur costs through litigation and extra treatment, and in 2009/10 the NHSLA paid out approximately £827, 000,000 in litigation costs and damages. These incidents are often caused by poor system design rather than the error of individuals i.e. 'they are an accident waiting to happen'.

In short patient safety could be summarised as 'The identification and reduction of risk and harm associated with the care provided to patients 'or 'Preventing patients from being harmed by their treatment'. Examples of this might be 'operating on or removing the wrong organ, ten times the dose of an opioid, giving a colonoscopy to the wrong patient with the same name as someone else in the waiting room etc.' These risks are unlikely to be identified through clinical trials or traditional evidence bases and so other evidence sources, such as the National Reporting and Learning System, need to be analysed to highlight the risks and improve system development. This does not however give an accurate picture of prevalence in that way that methods such as casenote review may do.

Appendix B: Status of indicators for the Quality and Outcomes Framework (QOF)

Background

NICE is responsible for the development of new clinical and public health indicators for potential inclusion in the QOF. The Independent Primary Care Quality and Outcomes Framework Indicator Advisory Committee prioritises indicators for development and then reviews the results of consultation and piloting, in order to recommend which indicators should be published on the 'menu of indicators' on the NICE website. A process of negotiation between NHSE, on behalf of the four UK Health Departments, and the GPC, on behalf of the British Medical Association (BMA) decides which indicators are adopted into the QOF. The results of negotiations for the 2013/14 QOF are expected to be announced in Feb/Mar 2013.

Indicators in development for the QOF

This is the first stage of indicator development. Topics recommended for indicator development by the QOF Advisory Committee are subject to piloting and consultation before they can be considered for inclusion on the NICE menu of indicators by the QOF Advisory Committee.

Indicators on the NICE menu of indicators

Indicators that have been through development (piloting and consultation) and are recommended for potential inclusion in the QOF by the Advisory Committee are included on the NICE menu of indicators. These indicators may form part of the National QOF guidance. Indicators not negotiated into the QOF will remain on the NICE menu.

Indicators in the QOF

These are indicators from the NICE menu which are adopted into the National QOF following negotiation between NHSE and the GPC.