National Institute for Health and Clinical Excellence

Hypertension
Quality Standard Consultation Comments Table
5th October 2012- 2nd November 2012

ID	Stakeholder	Statement No	Comments	Response
008	Arrhythmia Alliance	General	Hypertension is also a major risk factor which increases the chance of someone developing atrial fibrillation. Arrhythmia Alliance is in great support of a quality standard that will focus on the prevention and timely management of hypertension.	Thank you for your comment. The introduction to the quality standard has been updated.
008	Arrhythmia Alliance	General	We would encourage the practice of blood pressure monitoring, which could be conducted simultaneously to pulse checks e.g. during the NHS Health Checks performed for those over the age of 40, with an increased risk of CVD and arrhythmia. This is a cost-effective, high impact and effective method of screening for individuals.	Thank you for your comment. The topic expert group prioritised the areas of care they felt were most important for patients, based on the development sources listed. The topic expert group prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improved outcomes, and where there is potential to generate measurable indicators. The quality standard contains key markers of clinical and cost effective care across a care pathway. It remains important that other evidence-based guideline recommendations continue to be implemented.
008	Arrhythmia Alliance	General	A-A welcomes the holistic approach to creating a quality standard for hypertension which spans across services in the care pathway. We would also encourage a similar method to be used for various screening techniques such as blood pressure and pulse checks that can be combined into routine assessments of	Thank you for your comment. Pulse checks have been added within quality statement 5 on review of risk factors for CVD annually for people with

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			patients in primary and secondary care. This will address the need to identify and manage common risk factors for arrhythmias such as AF. We feel this is an important opportunity to improve detection and quality of life for those at risk, or living asymptomatically with hypertension or arrhythmia.	hypertension. The topic expert group prioritised the areas of care they felt were most important for patients, based on the development sources listed.
007	Blood Pressure UK	General	2) In our view, there needs to be a higher level of patient involvement. The decision about treatment should be a joint one between the individual and the person recommending the treatment. Given the controversy about the benefits of treatment of mild hypertension it would be helpful if the individual could take the decision where they are able to, in order to ensure greater compliance. 3) In our view, there needs to be a higher level of lifestyle advice - this can be very effective if the advice is given properly and the individual wishes to comply with it.	Thank you for your comment. Patient involvement is recognised as an important theme for all NHS care, and there are patient representatives on topic expert groups that develop the quality standards. The NICE quality standard on 'patient experience in adult NHS services', which is cross-cutting and referenced in this quality standard, covers this area in more detail. This includes shared decision-making and individualised health care. This should be used alongside the quality standard for hypertension. Quality standards are based on evidence-based recommendations from national accredited guidance. The hypertension quality standard is based on the NICE CG127 and CG67 clinical guidelines. It remains important that other evidence-based recommendations continue to be implemented. The quality standard should be used in the context of existing legislation and guidance. There is an indicator in the Quality

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				Outcomes Framework on providing lifestyle advice for people with hypertension (Indicator PP2: The percentage of people with hypertension diagnosed 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).
013	British Cardiovascular Society	General	Our comments are more radical and far-reaching than NICE may be expecting but the feedback proforma that is provided does not accommodate anything radical! It is divided into many small segments inviting comments on specified subsections of each of six quality statements. The essence is that NICE are going down the wrong road altogether, while the proforma takes it for granted that they are on the right road and seeks advice merely on the possible need for minor detours here and there. Instead of completing the proforma I am sending this email instead.	Thank you for your comment. The proforma is split into sections to make it easier for responses to be collated and analysed. The sections can however also be used for general comments on the quality standard if stakeholders feel that the quality standard is not addressing the correct areas.
013	British Cardiovascular Society	General	The concern is illustrated by what is said about statins - that anyone at high risk of cardiovascular disease for any reason should take a statin to reduce that risk. There is no mention of "hypercholesterolaemics" and “normocholesterolaemics”, there is not even mention of serum cholesterol being measured, the stance is that whatever a person’s cholesterol there is benefit from further reducing it. We agree with this stance and are puzzled that the same approach is not adopted with blood pressure. Instead NICE perseveres with the notion of hypertensives and normotensives. Hypertension is portrayed as a disease (it gets “diagnosed”), people have their blood pressure measured many times, and now even ambulatory blood pressure monitoring is advocated, as though there were some categorical distinction between people	Thank you for your comment. Quality standards are based on evidence-based recommendations from national accredited guidance. The hypertension quality standard is based on the NICE CG127 and CG67 clinical guidelines. The quality standards do not seek to reassess or redefine the evidence base. Please refer to the full clinical guideline for detailed summary of the underpinning evidence base for the clinical recommendations on which the quality standard is based.

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			with systolic blood pressure 141mmHg and 139mmHg. A decade or two ago people said similar things about cholesterol; for some years there was a threshold defining “hypercholesterolaemic” (it was 5.2mmol/L), but in recent years it has become accepted that this is incorrect. The evidence on lack of threshold is equally strong for blood pressure and cholesterol. The dose-response relationships of both with cardiovascular disease increase continuously (without threshold) across the population range. The Prospective Studies Collaboration has demonstrated this convincingly for both cholesterol and blood pressure. Randomised trials have confirmed the lack of threshold in a large meta-analysis of randomised controlled trials of blood pressure-lowering drugs (Law, Morris, Wald. BMJ 2009;338:b1665). Whatever the pre-treatment blood pressure (down to a value of at least 115mmHg systolic and 70mmHg diastolic), a specified blood pressure reduction reduces risk by the same proportion. If pre-treatment risk is high, then the proportional reduction in risk will be large irrespective of the pre-treatment blood pressure. So blood pressure-lowering drugs should be offered to anyone whose overall cardiovascular risk exceeds some threshold, irrespective of the blood pressure. Whilst this may be seen as radical, this is no different to what NICE already accepts for cholesterol.	
004	British Lung Foundation	General	**Obstructive Sleep Apnoea (OSA)** is a condition in which a person experiences repeated episodes of apnoea* because of a narrowing or closure of the airway in the upper throat (pharynx) during sleep. This is caused by a decrease in muscle tone while sleeping. It results in episodes of brief awakening (which the person may or may not be aware of) to restore normal breathing. ***Apnoea** = Greek word, meaning “Without breath”. The upper	Thank you for your comment. The topic expert group identified the development sources they felt were most relevant to developing the standard, within the framework of the quality standards development process. The hypertension quality standard is based on evidence-

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			airway in the throat closes during sleep for at least 10 seconds, and the person stops breathing or struggles to breathe OSA is a common condition. Up to 4 per cent of middle-aged men and 2 per cent of middle-aged women in the UK have OSA with symptoms [(1)], although estimates vary. It is also thought that 1 per cent of men in the UK – more than a quarter of a million people - have severe OSA.[(1)] Older people are even more at risk, with 15 to 20 per cent of those aged 70 and over estimated to have the condition.[(2)] This means that OSA is more common than severe asthma.[(3)] The number of people affected by OSA could also be rising due to more people being overweight.[(4)] However, up to 80 per cent of people with OSA have not yet been diagnosed [(5)] and some studies suggest this could be even higher. OSA also affects up to 3 per cent of children, most of whom have large tonsils. OSA is more common among children with certain disabilities, such as Down's syndrome, and in very obese children. [(6)] 1. National Institute for Health and Clinical Excellence (NICE) technology appraisal guidance 139: **Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome.** March 2008 2. Martinez-Garcia MA et al. **Sleep Apnoea in Patients of Elderly: Care Activity in Spain (2002-2008).** Archivos de Bronconeumologia. 2010; 3. Scottish Intercollegiate Guidelines Network (SIGN).	based recommendations from national accredited guidance, i.e. NICE CG127 and CG67. The quality standards do not seek to reassess or redefine the evidence base. Please refer to the full clinical guidelines for a detailed summary of the underpinning evidence base for the clinical recommendations on which the quality standard is based.

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			Management of Obstructive Sleep Apnoea/Hypopnoea Syndrome in Adults. A national clinical guideline. June 2003 4. Young T, Finn L, Peppard PE, Szklo-Coxe M, Austin D, Nieto FJ, Stubbs R, Hla KM: **Sleep Disordered Breathing and Mortality: Eighteen-Year Follow-up of the Wisconsin Sleep Cohort**. Sleep 2008. 5. Won Lee MD, Swamy Nagubadi MD, Meir H. Kryger MD, and Babak Mokhlesi MD, M.Sc. **Epidemiology of Obstructive Sleep Apnea: a Population-based Perspective.** Expert Rev Respir Med. 2008 Royal College of Paediatric and Child Health: **Standards for Services for Children with Disorders of Sleep Physiology**. 2009	
002	NHS Direct	General	NHS Direct welcome the standard. It is well written, very understandable and there are no comments following consultation	Thank you for your comment.
006	NHS Improvement	General	Hypertension is the area par excellence where patient involvement is really practical and relatively easy with HBPM. It is a pity that this has not been worked into the standards to emphasise that the more frequently BP is measured the better the control is likely to be (and on the whole GPs are not in a position to take BPs sufficiently often to be able to make well informed decisions). Patients need to be part of this process and take some responsibility for their own condition.	Thank you for your comment. Quality standards are based on evidence-based recommendations from national accredited guidance. NICE clinical guideline 127 recommends ABPM for diagnosis of hypertension but not for routine follow up of BP control. HBPM should be offered for diagnosis where ABPM cannot be tolerated. The equality and diversity considerations section of quality statement 1 highlights that HBPM should be offered as an alternative to ABPM where people are unable to tolerate it or

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				decline it.
009	Takeda UK Limited	General	Overall, Takeda UK are in agreement with all the proposed quality standards	Thank you for your comment.
009	Takeda UK Limited	General question 3	In our opinion the most important quality standard is the implementation of the evidence based blood pressure targets for both those under 80 years (<140/90 mmHg) and those 80 years and over (<150/90 mmHg). The current indicator (BP5) within the quality and outcomes framework (QOF) has a BP target of <150/90 mmHg. Implementation of the lower target for the under 80's will have a significant effect on lowering the cardiovascular mortality and morbidity at a population level.	Thank you for your comment.
001	Royal college of obstetricians and gynaecologists	Introduction/ general	The quality standards specifically exclude pregnant women. Whilst we care for non-pregnant women also, Gynaecologists will have but a limited role in the diagnosis and management of hypertension in non-pregnant women.	Thank you for your comment. As you have noted a quality standard is currently in development specifically for women with hypertension in pregnancy.
001	Royal college of obstetricians and gynaecologists	Introduction/ general	I do note that your hypertension guideline recommends the use of ACE inhibitors as first line treatment for the under 55s. This will include women of childbearing age of course so it is necessary to highlight the importance of awareness, contraception, pregnancy planning etc in sexually active women of reproductive age taking ACE inhibitors (because of their teratogenic potential).	Thank you for your comment. Use of ACE inhibitors is not covered in this quality standard; however this issue will be considered during development of the hypertension in pregnancy quality standard.
001	Royal college of obstetricians and gynaecologists	Introduction/ general	I note that quality standards relating to the NICE guidance on Hypertension in Pregnancy is anticipated in 2013 and the RCOG looks forward to commenting more fully on those standards in due course.	Thank you for your comment. We look forward to receiving your comments during consultation on the draft hypertension in pregnancy quality standard.

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007	Blood Pressure UK	Quality statement 1	1) In principle, we agree with offering 24 hour ambulatory blood pressure monitoring to confirm diagnosis, particularly in patients with mild hypertension. However, patients may have a range of differences between their home blood pressure, ambulatory blood pressure and clinic blood pressure and a decision has to be made by the health professional or the individual whose blood pressure is going to be treated as to which blood pressure measurement they are going to rely on (and subsequently carry on using) for the purposes of treatment.	Thank you for your comment. NICE clinical guideline 127 recommends using ambulatory blood pressure monitoring to confirm diagnosis of hypertension and clinic blood pressure measurements to monitor ongoing response to treatment. This has been followed in the quality standard. It remains important that other evidence-based guideline recommendations continue to be implemented. NICE clinical guideline 127 recommends that ABPM or HBPM should be considered as an adjunct to clinic blood pressure measurements for people identified as having a 'white-coat effect'.
010	Greater Manchester and Cheshire Cardiac and Stroke Network	Quality statement 1	The use of ABPM for diagnosis may increase pressure on cardiology departments	Thank you for your comment. NICE quality standards are intended to demonstrate what high quality care looks like for a particular topic based on the best available evidence. Cost effectiveness is considered by the topic expert group during development of quality standards and a supporting document has been published alongside the standard reviewing the potential cost impact and implications for commissioners and service providers, however, the configuration of services will be determined locally. Supporting documents are available from www.nice.org.uk. We hope this will help to address your concerns.
004	British Lung	Quality	**People with suspected hypertension are offered**	Thank you for your comment.

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	Foundation	statement 2	**investigations…** Obstructive Sleep Apnoea is associated with high blood pressure (1), and has been shown to be an independent risk factor for hypertension (2). OSA and hypertension commonly co-exist, with approximately half of patients with OSA being hypertensive, and approximately 30%-40% of patients with hypertension having OSA (3). In general there is a linear relationship between the number of apnoeas per hour (AHI) and the prevalence and severity of hypertension, that is, the more severe the OSA, the higher the risk of hypertension increasing in severity (3). Because of the very close relationship between OSA and hypertension, the British Lung Foundation (BLF) recommends that when people with suspected hypertension are offered investigations, this should include investigation for the possibility of OSA, particularly as OSA is known to cause hypertension. This investigation would begin with assessing if the patient has the core symptoms of OSA, which are excessive daytime sleepiness, loud snoring, and witnessed apnoeas / hypopnoeas during sleep. If the patient has these symptoms, then a referral to a sleep clinic for further investigation should take place. 1. NICE technology appraisal guidance 139: **Continuous Positive Airway Pressure for the treatment of OSAHS** 2008 2. IMPRESS: **Service Specification for Investigation and treatment of Obstructive Sleep Apnoea Syndrome** 2009 3. Calhoun and Harding: **Sleep and hypertension** CHEST	Quality standards are based on evidence-based recommendations from national accredited guidance. The topic expert selected the development sources that they felt were most relevant for the quality standard, i.e. the NICE CG127 and CG67 clinical guidelines. The quality standards do not seek to reassess or redefine the evidence base. Please refer to the full clinical guideline for a detailed summary of the underpinning evidence base for the clinical recommendations on which the quality standard is based.

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			2010	
012	Roche Diagnostics Limited	Quality statement 2	The current guidance recommends 12 lead ECG for assessment of any left ventricular hypertrophy (LVH) caused by hypertension; there is a building evidence base that NT-proBNP may provide a more accurate diagnosis than ECG, particularly given the issues around ECG interpretation in primary care. Andrade et al (Rev Esp Cardiol. 2011) compares diagnostic performances of ECG and NT-proBNP for left-ventricular hypertrophy; NT-proBNP demonstrates significantly better sensitivity and negative predictive value for LVH. There would be merit in considering the potential future replacement of ECG by NT-proBNP as the diagnostic of choice for identifying patients with hypertension that require referral to cardiology for echocardiography and specialist assessment. Reference*: Andrade et al - Diagnostic Accuracy of NT-proBNP Compared With Electrocardiography in Detecting Left Ventricular Hypertrophy of Hypertensive Origin. Rev Esp Cardiol. 2011;64(10):939–941*	Thank you for your comment. Quality standards are based on evidence-based recommendations from national accredited guidance, The topic expert selected the development sources that they felt were most relevant for the quality standard, i.e. the NICE CG127 and CG67 clinical guidelines. The quality standards do not seek to reassess or redefine the evidence base. Please refer to the full clinical guideline for detailed summary of the underpinning evidence base for the clinical recommendations on which the quality standard is based.
004	British Lung Foundation	Quality statement 3	**People with newly diagnosed hypertension…are offered statin therapy** As OSA is associated with high blood pressure (1), and has been shown to be an independent risk factor for hypertension, and it is thus relevant for cardio-vascular disease (2). The prevalence of OSA is higher in patients with cardio-vascular conditions, and studies have shown significant independent associations between OSA and hypertension, coronary heart disease, arrhythmias, heart failure and stroke (4). The presence of moderate-severe OSA is positively related to the prevalence and the severity of hypertension (3). Death from cardio-vascular disease is much higher in people with sleep-disordered breathing compared with	Thank you for your comment. Quality standards are based on evidence-based recommendations from national accredited guidance, i.e. the NICE CG127 and CG67 clinical guidelines. The quality standards do not seek to reassess or redefine the evidence base. Please refer to the full clinical guideline for detailed summary of the underpinning evidence base for the clinical recommendations on which the quality standard is based.

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			people who have no sleep-disordered breathing (5). The BLF recommends that in addition to offering statin therapy, a referral to a sleep clinic should be considered if the patient is displaying the core symptoms of OSA, which are excessive daytime sleepiness, loud snoring, and witnessed apnoeas / hypopnoeas during sleep. 1. NICE technology appraisal guidance 139: **Continuous Positive Airway Pressure for the treatment of OSAHS** 2008 2. IMPRESS: **Service Specification for Investigation and treatment of Obstructive Sleep Apnoea Syndrome** 2009 3. Calhoun and Harding: **Sleep and hypertension** CHEST 2010 4. Bradley TD and Floras JS: **Obstructive Sleep Apnoea and its cardiovascular consequences** Lancet 2009 5. Young T, Finn L, Peppard PE, Szklo-Coxe M, Austin D, Nieto FJ, Stubbs R, Hla KM: **Sleep Disordered Breathing and Mortality: Eighteen-Year Follow-up of the Wisconsin Sleep Cohort** Sleep 2008	

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	Greater Manchester and Cheshire Cardiac and Stroke Network	Quality statement 3	Evidence and opinion is that CV risk of 20% or more is too high for starting statin. Evidence points to 10% being a more acceptable risk. The guidance would have more of an impact on primary rather than secondary care.	Thank you for your comment. Quality standards are based on evidence-based recommendations from national accredited guidance. The topic expert selected the development sources that they felt were most relevant for the quality standard, i.e. the NICE CG127 and CG67 clinical guidelines. The quality standards do not seek to reassess or redefine the evidence base. Please refer to the full clinical guideline for detailed summary of the underpinning evidence base for the clinical recommendations on which the quality standard is based.
004	British Lung Foundation	Quality statement 4	**People with treated hypertension are targeted to a clinic blood pressure below…..** Treatment for OSA is simple and cost-effective. The recommended treatment for moderate to severe OSA is continuous positive airway pressure (CPAP) (1), although a variety of other treatment options are also available, particularly for obese patients and those with milder OSA. Effective treatment of OSA is accompanied by a reduction in blood pressure, although data vary across severity grades. CPAP treatment has been shown to have a significant effect on mean arterial blood pressure in those with severe OSA (1). Accordingly, CPAP treatment is associated with a reduction in cardiovascular risk. Effective treatment can serve as primary prevention and secondary prevention of adverse cardiovascular outcomes. It is estimated that treatment with CPAP reduces the	Thank you for your comment. Quality standards are based on evidence-based recommendations from national accredited guidance, i.e. the NICE CG127 and CG67 clinical guidelines. The quality standards do not seek to reassess or redefine the evidence base. Please refer to the full clinical guidelines for detailed summary of the underpinning evidence base for the clinical recommendations on which the quality standard is based.

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			10-year incidence of myocardial infarction by 49%, and the 10-year risk of stroke by 31% (2). Improved diagnosis and treatment of OSA can therefore contribute significantly to reducing cardiovascular morbidity and mortality. Successful treatment brings wider societal benefits, including an often transformative impact on quality of life for patients and families; significantly decreased risk of occupational and road traffic accidents; increased work productivity; and reduced long-term healthcare costs. Patients with untreated OSA are heavy users of healthcare services, and have been estimated to incur health costs of approximately double those of the general population (3). The British Lung Foundation recommends that a reference in the quality standard could be made to the impact which CPAP therapy might have on reducing the blood pressure levels of those people diagnosed with hypertension and OSA, and also highlight the potential benefits to the individual, healthcare costs, and society that could result from this treatment. 1. NICE technology appraisal guidance 139: **Continuous Positive Airway Pressure for the treatment of OSAHS** 2008 2. Pietzsch, Garner, Cipriano and Linehan: **An integrated health-economic analysis of diagnostic and therapeutic strategies in the treatment of moderate to severe OSA.** Sleep 2011	

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			3. **Management of Obstructive Sleep Apnoea/Hypopnoea Syndrome in Adults**: A national clinical guideline. Scottish Intercollegiate Guidelines Network, 2003	
010	Greater Manchester and Cheshire Cardiac and Stroke Network	Quality statement 4	It is interesting that the introduction to CG127 states: "Blood pressure is normally distributed in the population and there is no natural cut-off point above which 'hypertension' definitively exists and below which it does not. The risk associated with increasing blood pressure is continuous, with each 2 mmHg rise in systolic blood pressure associated with a 7% increased risk of mortality from ischaemic heart disease and a 10% increased risk of mortality from stroke." and yet this is not followed through in the quaity standards especially since a meta-analysis of RCTs demonstrates that they should (http://www.bmj.com/content/338/bmj.b1665). So there is the quality standard that: "People with newly diagnosed hypertension and a 10-year cardiovascular disease risk of 20% or higher are offered statin therapy." without any minimum threshold for total cholesterol:HDL ratio and yet the decision to treat blood pressure is based on the baseline blood pressure rather than the cardiovascular risk. If they did take this approach the qulity standard should not just be about a target blood pressure level but should also have a minimum blood pressure reduction as a proxy measure of adherence. In terms of risk factors, it is not clear why they have a standard for statin but not for managing hyperglycaemia.	Thank you for your comment. The topic expert group prioritised the areas of care they felt were most important for patients, based on the development sources listed. This includes areas of care where practice is variable, or where implementation could have a significant impact on patient care and improved outcomes, and where there is potential to generate measurable indicators. The quality standards are based on evidence-based recommendations from national accredited guidance. They do not seek to reassess or redefine the evidence base. Please refer to the full clinical guidelines (CG127 and CG67) for detailed summary of the underpinning evidence base for the clinical recommendations on which the quality standard is based. It remains important that other evidence based recommendations continue to be implemented, including other NICE guidance. All suggestions for additional statements were discussed by the topic expert group

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				who considered they were inappropriate for inclusion (for example, outside the scope of the quality standard), or already covered by existing statements. Quality statement 5 deals with a review of risk factors for CVD annually, including blood glucose level.
006	NHS Improvement	Quality statement 4	Unless you describe how BP is to be taken, the target is meaningless. The statement needs to refer to CG 127 on how to take BP. There seems to be a missed opportunity to set some standard around appropriate frequency of BP measurement when monitoring the success or otherwise of treatment. By stating that there should be an annual assessment of risk factors the standard almost seems to suggest that measuring BP once a year is adequate. Patients need to be aware that measuring BP is the only way of documenting how well the treatment is working (see general comments)	Thank you for your comment. Quality statement 4 refers to clinic blood pressure measurements. The quality standard contains key markers of clinical and cost effective care across a care pathway. It remains important that other evidence-based guideline recommendations continue to be implemented. Quality statement 5 now states in the definitions section that blood pressure should be measured more frequently than annually for patients who need more frequent monitoring. The quality standard should be read in the context of national and local guidelines on training and competencies.
004	British Lung Foundation	Quality statement 5	**People with hypertension are offered a review of care at least annually** The above statements indicate the potential impact that identification of and treatment for OSA could have on hypertension and cardiovascular outcomes.	Thank you for your comment. The topic expert group prioritised the areas of care they felt were most important for patients, based on the development sources listed. The quality standards do not seek to reassess or redefine the evidence base.

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			Accordingly, the BLF recommends that at the annual review of patients with hypertension, a question could be included to asses if the patient is displaying the core symptoms of OSA, which are excessive daytime sleepiness, loud snoring, and witnessed apnoeas / hypopnoeas during sleep.	Please refer to the full clinical guidelines (CG127 and CG67) for detailed summary of the underpinning evidence base for the clinical recommendations on which the quality standard is based.
005	Daiichi-Sankyo UK Ltd.	Quality statement 6	Within the draft quality standard (statement six) when a patient's hypertension is uncontrolled by four antihypertensive medications (step 4 in the NICE BHS guideline GC127) a referral to a specialist is recommended. We assume that as inferred in NICE guidance CG127 before specialist referral a range of interventions around adherence (NICE guidance CG76) would be implemented in order to assess whether the patient has true resistant hypertension or if there is an issue with adherence. One of the recommended interventions is a simplification of the dosing regimen. It would seem logical that the simplification would best be served by initiating a Single Tablet Regimen (STR); also known as a Fixed Dose Combination (FDC). The British Hypertension Society (BHS) have recently issued (Sept 2012) a statement regarding STRs entitled "The Use of Single Pill Combination Treatments in Patients with Hypertension". In this document they compare the use of monotherapy, combination therapy using two agents as separate "free" tablets and the equivalent FDC. A table of their findings is shown below. It is interesting to note how well the FDC performs across all of the criteria the BHS have set.  table.doc **The effect of enhanced adherence on perceived resistant hypertension** Bunker et al (2011) conducted a clinic based study where patients	Thank you for your comment. The quality standard contains key markers of clinical and cost effective care across a care pathway. It remains important that other evidence-based guideline recommendations continue to be implemented. A quality standard on medicines optimisation has been referred to the quality standards library of topics to cover medicines adherence.

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			with resistant hypertension had their antihypertensive drugs administered under observation and their blood pressure closely monitored in a clinic setting. It was found that the resistant hypertension of about two thirds of the patients was caused by poor adherence to their drug treatment. **Adherence and outcomes** Belsey (2012) conducted a retrospective cohort analysis using a primary care database comparing 9929 hypertensive patients on STRs with 18665 on individual component therapy. It was concluded that patients treated with the individual component therapies experienced significantly more cardiovascular events than those treated with an STR. **Conclusion** We feel that since adherence has such a critical influence on blood pressure control the Quality Standard for hypertension should include a section covering patient education, adherence and the diagnosis of resistant hypertension prior to statement six. Where this section makes reference to simplifying the dosing regimen it would be good to see an example cited such as "consider an STR".	
009	Takeda UK Limited	Quality statement 6	The language included in quality statement 6 is ambiguous and could be misinterpreted. The draft quality statement reads 'People with resistant hypertension who have received 4 antihypertensive drugs and whose blood pressure remains uncontrolled are referred for specialist assessment' This could be read as the patient having to have received 4 antihypertensive drugs at some point in their past rather than them actually being on 4 concurrent antihypertensive drugs now. E.g. they may have been treated with 4 different antihypertensive drugs in the past but are actually only receiving dual therapy currently.	Thank you for your comment. The wording of quality statement 6 has been amended.

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			The language used in NICE clinical guideline 127 (recommendations 1.6.18 and 1.6.22) makes it clear that we are talking about 4 concurrent antihypertensive drugs: **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]** Suggested revised wording for the quality statement: 'People with resistant hypertension who are receiving treatment with 4 antihypertensive drugs and whose blood pressure remains uncontrolled are referred for specialist assessment'	
006	NHS Improvement	Specific question 5	I cannot see the reason for investigating target organ damage prior to the confirmation of hypertension diagnosis unless it were to influence the ultimate actions re the blood pressure (eg some doctors are more likely to treat BP in patients with LVH even if the BP is borderline). If you have to investigate all patients with suspected hypertension for target organ damage there could be a lot of unnecessary investigation.	Thank you for your comment. The quality standard has been further refined by the topic expert group in consideration of consultation feedback. Quality statement 2 focuses on investigations for target organ damage in people with newly diagnosed hypertension.
006	NHS Improvement	Specific question 6	Patients should be offered statins at any point in the care pathway when they are deemed to have a >20% risk. Otherwise there might be a feeling that if they had not been offered statins at the point that hypertension was diagnosed they would not have a	Thank you for your comment. The quality standard has been further refined by the topic expert group in

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			second ‘chance’	consideration of all feedback from consultation.
008	Arrhythmia Alliance	Specific question 7	An annual review of CVD risk factors is something that we would encourage. As part of this, A-A would like to see pulse checks as an additional health check.	Thank you for your comment. Pulse checks have been added to quality statement 5 on review of risk factors for CVD annually.