

National Institute for Health and Clinical Excellence

Chronic Kidney Disease (update)
Scope Consultation Table
 16th May – 15th June 2012

| Stakeholder | Order No | Section No | Comments Please insert each new comment in a new row. | Developer's Response Please respond to each comment |
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| Kidney Research UK | 1.1 | 3.1 & 3.2; 4.3.1 b; 4.1.2 b | Regarding investigation of CKD, classification and early identification, it is presumed that the scope will include: <input type="checkbox"/> Updating on proteinuria, including re-classification of albuminuria (micro to high albuminuria; macro to very high albuminuria) <input type="checkbox"/> Consideration for providing a recommendation on follow-up monitoring of patients with AKI that has not recovered to baseline (normal kidney function) by the end of the acute episode. | Thank you for your comment, proteinuria and albuminuria measurement and frequency of monitoring will be considered when investigation and classification of CKD are reviewed. We acknowledge that people with AKI are an important population and have added a bullet point to the scope 'Risk of developing CKD after an episode of AKI' in 4.3.1 j The risk of progression of CKD in people already with CKD (after an episode of AKI) will also be covered within the review questions. |
| Kidney Research UK | 1.2 | Not currently in Scope | Assessment of progression thresholds (defining progression of CKD) for referral (5 ml/min/yr should be considered for re-review) | Thank you for your comment. Frequency of monitoring will be considered when investigation of CKD is reviewed. We agree that the definition of progression is an imperfect area. |
| Kidney Research UK | 1.3 | Not currently in Scope | Practicalities of use of ACEi and ARBs – particularly around the use of these agents in the setting of intercurrent illness and in people with an accelerated decline in eGFR | Thank you for your comment. No new evidence was identified in the review for update that would change the current recommendations from CG73 in this area. The adverse effects of treatment and high risk groups will be considered when the evidence for ACEi and ARBs is reviewed. The practicalities of use of ACEi and ARB therapy in patients with diarrhoea and vomiting or sepsis are being addressed in |

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| | | | | the NICE clinical guideline on acute kidney injury which is currently in development. |
| Kidney Research UK | 1.4 | Not currently in Scope | Frequency of monitoring and necessity of monitoring in lower risk CKD (3a without proteinuria in older people) | Thank you for your comment, frequency of monitoring will be considered when investigation of CKD is reviewed. All of the groups stated in 4.1.1 of the review will be considered. |
| Kidney Research UK | 1.5 | Not currently in Scope; 4.1.1 b | Risk stratification tools | Thank you for your comment. Risk stratification tools were not identified in the review for update and therefore we are unable to prioritise them within this guideline update. The implementation team are aware of new risk stratification tools and these will be considered when the updated guideline is published with other updated implementation tools. |
| Kidney Research UK | 1.6 | 4.1.1 b; 4.3.1 d | Enhanced information and care planning in high-risk patients. Encourage the use of patient held care plans which would hopefully also encourage more engagement with the patient which would increase the patient's own responsibility for their health and empower them to be successful in this. | Thank you for your comment. It is our intention that this aspect will be included within the guideline under 4.3.1d) 'Effectiveness of self management support systems for people with CKD', if any evidence is identified. |
| Kidney Research UK | 1.7 | 4.3.1c & d | Self-management is vital to the long-term health of CKD patients. This review gives the opportunity for more emphasis on self care/management and generally promoting health alongside treating disease. As stated, dietary interventions such as low protein diets slow down progression. However, is self-management in terms of low phosphate and low potassium diets within scope? The side effects of having high amounts of phosphate and potassium within the blood can potentially be catastrophic. For example, Hyperkalemia, can, in the worst cases cause the heart to stop beating. Hyperphosphatemia can also cause long term health problems. Is all that is known on these complications that have | Thank you for your comment. We are unable to prioritise low phosphate or potassium diets within this guideline update. No new evidence was identified that would change the recommendations in CG73 relating to low potassium diets. Hyperphosphatemia is covered in a separate guideline currently under development: Management of hyperphosphataemia, This is referred to under '5.2 Guidance under development' in |

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| | | | an intrinsic link with CKD and especially end-stage renal failure conveyed to the patient in terms of their self-management? | the scope, and will also be listed in the full guideline. |
| Kidney Research UK | 1.8 | Not currently in Scope; 4.1.1; 4.1.2 c | Believe that the 'Children and under 18' population, although relatively small, should be in scope as the earlier low eGFR is identified, the earlier CKD can be treated. Patient quote: "I feel that being identified as having CKD at the age of 5, the experience of the healthcare professionals that treated me, helped prolong the life of my native kidneys from the estimated 3-5 years to the actual 15+ years that my kidneys functioned on their own – without dialysis at any point before transplantation." | Thank you for your comment. The remit from the Department of Health for the guideline is for adults only. However we recognise that CKD is important in children and NICE have raised this with the Department of Health. There are several key issues for children requiring specific guidance not encompassed by existing adult guidance. Addressing these is not possible within the scope for this guideline update but the views of stakeholders concerning the exclusion of children have been clearly heard and will be discussed further with the Department of Health. Children will be included in the scope of forthcoming guidelines on renal replacement therapy and renal stones. |
| Kidney Research UK | 1.9 | 4.5; 4.3.2e & c; 3.2 | Aspects for consideration in reference to Primary Care: With GP consortia becoming the commissioning bodies in Primary Care this is an ideal opportunity to provide Advanced Primary Care services for CKD which would be more cost effective than many visits to Out Patients Department. The transition to secondary care from primary care needs to have a structure which is effective and with the patient at the heart of the process. Including more active links between primary and secondary care so that patient care problems are addressed with the full knowledge of both services Pre-dialysis anaemia could be very useful here especially with advanced practitioner support. Primary care has the opportunity expand what is presently required by QOF which would support all aspects of the patient with CKD as a long term condition, bearing in mind a lot of these patients have other long term conditions eg diabetes. | Thank you for your comment. We are unable to cover this in more detail in this update of the Chronic Kidney Disease Guideline. The NICE guide for commissioners on 'Early identification and management of chronic kidney disease in adults' (CMG73) was designed to facilitate the implementation of, and is underpinned by, NICE guidance and quality standards through commissioning. CMG37 includes the following text: 'Integrated services for the early identification and management of CKD in adults can be commissioned in a number of different ways, and mixed models of provision may be appropriate across a local |

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| | | | | <p>health economy including shared care models across primary and secondary care (for people with stage 3 CKD) or integrated chronic disease management arrangements (for people with stage 4 and some stage 5). (Section 2.4 Service Models)</p> <p>This commissioning guide covers early identification and management of chronic kidney disease in adults within the pathway for chronic kidney disease. To maximise the use of resources and improve health outcomes for people with CKD, commissioners should commission the whole condition-specific pathway for CKD. They should integrate this with a generic model of care for people with long-term conditions. The long-term conditions workstream of the Quality, Innovation, Productivity and Prevention (QIPP) programme supports local areas in implementing a generic model of care for people with long-term conditions. The key outcome for patients with long-term conditions is to provide continuous care-coordination within the community and across organisations. This allows care-coordination to remain with one health or social care professional throughout the pathway, and not get transferred as a patient moves from one service to another'.</p> <p>The management of anaemia in people with CKD is covered by separate NICE guidance, CG114. This is referred to under</p> |

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| | | | | ‘5.1.3 Other related NICE guidance’ in the scope, and will also be listed in the full guideline. |
| Kidney Research UK | 1.10 | n/a | Aspects for consideration in reference to Secondary Care: Have improved links and communication with primary care to provide best care for patients, as mentioned above 9. Ensuring that primary care has the knowledge and training to support CKD patients in the community. Pro active in discussion as appropriate concerning conservative care. | Thank you for your comment. We are unable to cover this in more detail in this update of the Chronic Kidney Disease Guideline. The NICE guide for commissioners on ‘Early identification and management of chronic kidney disease in adults’ (CMG73) was designed to facilitate the implementation of, and is underpinned by, NICE guidance and quality standards through commissioning. CMG37 includes the following text: ‘Integrated services for the early identification and management of CKD in adults can be commissioned in a number of different ways, and mixed models of provision may be appropriate across a local health economy including shared care models across primary and secondary care (for people with stage 3 CKD) or integrated chronic disease management arrangements (for people with stage 4 and some stage 5). (Section 2.4 Service Models) This commissioning guide covers early identification and management of chronic kidney disease in adults within the pathway for chronic kidney disease. To maximise the use of resources and improve health outcomes for people with CKD, commissioners should commission the whole condition-specific pathway for CKD. |

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| | | | | They should integrate this with a generic model of care for people with long-term conditions. The long-term conditions workstream of the Quality, Innovation, Productivity and Prevention (QIPP) programme supports local areas in implementing a generic model of care for people with long-term conditions. The key outcome for patients with long-term conditions is to provide continuous care-coordination within the community and across organisations. This allows care-coordination to remain with one health or social care professional throughout the pathway, and not get transferred as a patient moves from one service to another'. |
| Renal Association | 2.1 | General Comment | I recommend that the scope includes characterisation of the risk of CKD following an episode of AKI. What factors increase the risk and how can the risk be reduced. | Thank you for your comment. We acknowledge this is an important area and have added a bullet point to the scope 'Risk of developing CKD after an episode of AKI' in 4.3.1 j The risk of progression of CKD in people already with CKD (after an episode of AKI) will also be covered within the review questions. |

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| The Association for Clinical Biochemistry | 3.1 | 4.3.1 a) | <p>Uniformity of classification based on biochemical methods is dependent upon on use of fit for purpose analytical methods with consistent performance characteristics. Inaccuracy and impression of measurement will lead to misclassification of subjects and variability in distribution of CKD populations across geography. Some thought must be given to identifying the required analytical performance characteristics of any methodologies used and communication of the potential impact of analytical systems that do not meet those characteristics.</p> <p>The impact of shifts to alternative equations should be assessed in terms of potential reclassification of existing groups.</p> <p>There needs to be consideration of the impacts of biological variability in measured parameters on assessment of significance of change and how the use of parameters such as reference change value can be utilised to aide practitioners in the continuing assessment of CKD patients.</p> | Thank you for your comment. Methods of classification and alternative equations and the associated issues raised will be considered when the investigation and classification of CKD is reviewed. |
| Royal College of Paediatrics and Child Health | 4.1 | General - inequality for age | <p>The exclusion of children is unfortunate. The 13th Annual Report of the UK Renal Registry documents there were 751 children under the age of 16 requiring RRT. This report also highlighted an increase in the annual incidence of children requiring RRT over the last 14 years, increasing from 8.1 per million age related population (1995-99) to 9.6 per million age related population (2005-9). Virtually all of these children will have undergone a period of CKD before requiring RRT. Although there is little epidemiological data upon which to base the incidence or prevalence of CKD in UK children, there are likely to be at least 5 children with CKD 1-4 for every child presently requiring RRT. The prevalence of CKD is reported to be 50-75 per million age related population in various European studies not including the UK (Epidemiology of chronic kidney disease in children. Harambat J, Karlijn J. van Stralen,</p> | Thank you for your comment. The remit from the Department of Health for the guideline is for adults only. However we recognise that CKD is important in children and NICE have raised this with the Department of Health. There are several key issues for children requiring specific guidance not encompassed by existing adult guidance. Addressing these is not possible within the scope for this guideline update but the views of stakeholders concerning the exclusion of children have been clearly heard and will be discussed further with the Department of Health. Children will be included in the scope of forthcoming guidelines on renal |

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| | | | <p>Kim JJ, Tizard JE. <i>Pediatr Nephrol</i> 2012; 27: 363-73). While paediatric CKD patient numbers are smaller than those of the adult population, nationally the number of affected individuals is large and the population is probably increasing. The need for high quality care is just as pertinent for this group as for adults – indeed, it could be argued the need is greater as children with CKD become adults with CKD and will have accrued significant CKD-associated morbidity.</p> <p>The vast majority of the clinical questions in the CG73 guideline apply to children. Key among these issues are those relating to blood pressure control, treatment of proteinuria, cardiovascular disease and treatment for bone disease. There are paediatric studies in all these areas. Of particular significance linking paediatric and adult CKD is the evidence that demonstrates the increased risk of cardiovascular disease appears in paediatric CKD and that these risks may be ameliorated by therapy. The ESCAPE trial (<i>N Engl J Med</i> 2009;361:1639-50.) demonstrates progression of CKD can be modified in children. Publications relating to control of phosphate and calcium emphasise the importance of good dietary control in children with CKD. As with adults, early interventions can significantly modify disease progression and mitigate the detrimental effects of CKD, especially in reducing the cardiovascular morbidity an adolescent takes into adulthood. Some key references are:</p> <p>Uraemic vasculopathy in children with chronic kidney disease: prevention or damage limitation?. <u>Shroff R. Quinlan C. Mitsnefes M</u> <i>Pediatr Nephrol.</i> 26(6):853-65, 2011 Jun.</p> <p>Other references among others are: <u>-Cigarette smoking and second-hand smoking exposure in adolescents with chronic kidney disease: a study from the Midwest Pediatric Nephrology Consortium.</u></p> | <p>replacement therapy and renal stones.</p> |

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| | | | <p>Omoloja A. Chand D. Greenbaum L. Wilson A. Bastian V. Ferris M. Bernert J. Stolfi A. Patel H. Nephrology Dialysis Transplantation. 26(3):908-13, 2011</p> <p>-<u>When does the cardiovascular disease appear in patients with chronic kidney disease?</u>. Sozeri B. Mir S. Kara OD. Levent E. Pediatric Cardiology. 31(6):821-8, 2010</p> <p>-<u>A comprehensive study of cardiovascular risk factors, cardiac function and vascular disease in children with chronic renal failure.</u> Rinat C. Becker-Cohen R. Nir A. Feinstein S. Shemesh D. Algur N. Ben Shalom E. Farber B. Frishberg Y. Nephrology Dialysis Transplantation. 25(3):785-93, 2010 Mar.</p> <p>-Mitsnefes MM, Kimball TR et al 2005: Cardiac and vascular adaptations in pediatric patients with chronic kidney disease: role of calcium-phosphorus metabolism. J Am Soc Nephrol 16;2796-2803</p> <p>The 4C study (http://www.4c-study.org/index.php?id=2) is ongoing and seeks to better define cardiovascular risk factors in children with CKD – although this study has not yet been completed results will become available in due course and demonstrates paediatric nephrologists are actively working to obtain more data in this field.</p> | |

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| Amgen Ltd | 5.1 | 4.3.2 | The draft scope specifies within this section that no new evidence has been identified to directly change the 2008 recommendations in relation to specific complications of CKD – anaemia. This section of the guideline makes reference to NICE clinical guideline 39: 'Anaemia management in people with chronic kidney disease', given clinical guideline 39 has been superseded by clinical guideline 114, it is our view that this section of the clinical guideline should be updated to reference the current version of NICE's clinical guideline on anaemia management in CKD. | Thank you for pointing this out. Editorial changes to the original guideline will be made as necessary when updating the guideline. |
| British Renal Society | 6.1 | 4.3.2 f | 'Information and support for people and their carers' should be updated. There is new information particularly around self-management, so it seems odd that self-management as a topic is now being included but the 'Information and support for people and their carers' is not . | Thank you for your comment. If evidence on information and support specific to self management is identified when this topic is reviewed, it will be included in the guideline update. 4.3.1e has been reworded in the scope to clarify this. We are unable to prioritise the whole of the 'Information and support for people and their carers' section from CG73 for update in this guideline as no new evidence was been identified in the review for update. |
| British Renal Society | 6.2 | 4.1.2.c | The scope does not include people under 18 years but there is a need to provide guidance for this group. Suggest either this proposed work includes people under 18 or another GDG is implemented to review the evidence for younger people. | Thank you for your comment. The remit from the Department of Health for the guideline is for adults only. However we recognise that CKD is important in children and NICE have raised this with the Department of Health. There are several key issues for children requiring specific guidance not encompassed by existing adult guidance. Addressing these is not possible within the scope for this guideline update but the views of stakeholders concerning the exclusion of children have been clearly heard and will be discussed further with the Department of Health. |

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| | | | | Children will be included in the scope of forthcoming guidelines on renal replacement therapy and renal stones. |
| British Renal Society | 7.3 | 4.3.2. | Although an update on progression is not included, primary care feel the existing advice is not necessarily helpful and clarity is about progression is needed. Further advice around progression in the context of referral from primary care would be helpful. Progression is mentioned in 4.4.d as outcome, it is not clear if 4.4.d is being included? | Thank you for your comment. Progression of CKD will be included as one of the outcomes reported for reviews. We are unable to cover progression in the context of referral from primary care within the scope of this guideline update. |
| Kidney Alliance | 8.1 | 4.3.1 d) | 'Effectiveness of self management support systems for people with CKD.' The Alliance welcomes the inclusion of this point into the scope as recognition that offering people the opportunity to be involved in their care can affect their outcomes. | Thank you for your comment. |
| Kidney Alliance | 8.2 | 4.3.2 f) | 'Information and support for people with CKD and their carers.' The inclusion of 4.3.1 d) suggests that at least some of this will be reviewed and so this may well be in rather than out of scope. | Thank you for your comment. If evidence on information and support specific self management is identified when this topic is reviewed, it will be included in the guideline update. 4.3.1e has been reworded in the scope to clarify this. We are unable to prioritise the whole of the 'Information and support for people and their carers' section from CG73 for update in this guideline as no new evidence was been identified in the review for update. |
| Kidney Alliance | 8.3 | 4.1.2 c) | We should like to understand why children and young people have not been included in this scope as there are current guidelines in development for related conditions (e.g. Acute Kidney Injury and Hyperphosphataemia which do cover this group) and what NICE plans to do to address this group. | Thank you for your comment. The remit from the Department of Health for the guideline is for adults only. However we recognise that CKD is important in children and NICE have raised this with the Department of Health. There are several key issues for children requiring specific guidance not encompassed by existing adult guidance. Addressing these is not |

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| | | | | possible within the scope for this guideline update but the views of stakeholders concerning the exclusion of children have been clearly heard and will be discussed further with the Department of Health. Children will be included in the scope of forthcoming guidelines on renal replacement therapy and renal stones. |
| Kidney Alliance | 8.4 | General | We suggest consideration of the inclusion of vaccination and its role for people with CKD. Whilst the effectiveness of certain vaccines in patients with CKD may vary, there is some evidence of benefit to vaccination in these populations. However, vaccination rates are relatively low and inconsistently applied so adding this into the scope could benefit those with CKD. | Thank you for your comment. We acknowledge that this is an important area for guidance, but unfortunately we are unable to prioritise vaccination within this update. |
| Department of Health (DH) | 9.1 | General (Donal O'Donoghue) | I think we need to flag the importance of prevention of AKI in CKD and emphasize that AKI is a complication of CKD. As it stands, the scope is a little ambiguous on that. I was also disappointed to see that the section on information and support for people and their carers was not going to be updated: much has happened with patient engagement, for example renal patient view and shared decision making in the past five years, and I think we should recommend its inclusion. Effectiveness of self-management support systems in CKD is in, so it could be covered within that, but we should seek assurance at the very least. | <p>Thank you for your comment. We acknowledge this is an important area and have added a bullet point to the scope 'Risk of developing CKD after an episode of AKI' in 4.3.1 j</p> <p>The risk of progression of CKD in people already with CKD (after an episode of AKI) will also be covered within the review questions.</p> <p>AKI will be an outcome recorded in review questions (within adverse outcomes in the scope) which will address the increased risk of AKI in those with CKD.</p> <p>If evidence on information and support specific self management is identified when this topic is reviewed, it will be included in the guideline update. 4.3.1e has been reworded in the scope to clarify this.</p> |

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| | | | | We will also cross-refer to the patient experience guideline in the update (CG138). |
| Department of Health (DH) | 9.2 | General (Jane Heaton) | We would like the guideline review to cover the importance of a single primary currency for proteinuria testing. We know that there is wide variation between GPs. In one PCT, GPs reviewing diabetes patients were using six different measures of albumin or protein excretion, only one of which was approved by NICE. We think it would be timely to move towards ACR measured in laboratory being the standard for all forms of kidney disease - with or without diabetes - and would be grateful if NICE would include this in the scope of its review. | Thank you for your comment. This was included in the original guideline CG73 and we will not be able to prioritise it in this guideline. We acknowledge your concern and have highlighted this to the implementation team, and will raise this when deciding on key priorities for implementation, which will include consideration of all recommendations from the original and updated sections of the guideline. Proteinuria and albuminuria measurement and frequency of monitoring will be considered when investigation and classification of CKD are reviewed. |

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| Royal College of Nursing | 10.1 | General | The Royal College of Nursing welcomes proposals to develop this guideline. It is timely. | Thank you for your comment. |
| Royal College of Nursing | 10.2 | 4.1.1 b | In considering the needs of older people (75 years and older) it may be useful to differentiate between CKD as a normal part of the ageing process requiring minimal monitoring, and CKD as a progressive disease process i.e. what are the consequences of labelling individuals with a disease process both to the individual and financially. | Thank you for your comment. It is our intention that this will be included when this subgroup is considered, if the information is available. |
| Royal College of Nursing | 10.3 | 4.1.2.c | The scope does not include people under 18 years – we had a lot of discussion at the Scoping workshop about the need to provide guidance for under 18s so wonder why this has not been incorporated. | Thank you for your comment. The remit from the Department of Health for the guideline is for adults only. However we recognise that CKD is important in children and NICE have raised this with the Department of Health. There are several key issues for children requiring specific guidance not encompassed by existing adult guidance. Addressing these is not possible within the scope for this guideline update but the views of stakeholders concerning the exclusion of children have been clearly heard and will be discussed further with the Department of Health. Children will be included in the scope of forthcoming guidelines on renal replacement therapy and renal stones. |
| Royal College of Nursing | 10.4 | 4.3.2 f | 'Information and support for people and their carers' should be updated, especially if evidence around self-management strategies for people with CKD is now being included in the scope. If the evidence suggests that self-management can be beneficial, specific information related to what self-management actually means for patients and their carers should be included. | Thank you for your comment. If evidence on information and support specific self management is identified when this topic is reviewed, it will be included in the guideline update. 4.3.1e has been reworded in the scope to clarify this. We are unable to prioritise the whole of the 'Information and support for people and their carers' section from CG73 for update in this guideline as no new evidence was |

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| | | | | been identified in the review for update. |
| Leeds Teaching Hospitals NHS Trust | 11.1 | 1.1.9 | My comments are as follows - the frequency of review/testing for patients with CKD 4 and 5 is too often. It has no evidence base and fails to reflect the realities of providing a CKD service in the real world. In earlier sections, the guidance states that CKD 4 and 5 should normally be referred to secondary care for assessment. In my unit (Leeds) there are >1800 patients with CKD 4 and 5 under review. If we were to review them as frequently as stated in the guidance, we would need to employ an additional consultant to undertake the 170 patient visits per week this would generate, let alone the additional laboratory tests, or the significant patient anxiety and dislocation it would produce, travel, review time, etc etc. Firstly, this is unworkable due to the volume of patients. Secondly, as patients approach end-stage renal failure and need to start renal replacement therapy the need to start is based on symptoms rather than eGFR; studies have not shown any benefit of starting dialysis earlier than when patients are symptomatic. I do not believe it adds any value to patient care to repeatedly measure eGFR in asymptomatic patients no matter what stage the CKD. I think NICE guidance should instead suggest frequency of review should be dictated by stage of CKD AND PATIENT CIRCUMSTANCES AND PREFERENCES. Such an approach would allow more flexible and appropriate review and also be much more in keeping with other DH initiatives such as shared decision making, shared care, patient involvement and patient empowerment. | Thank you for your comment. Frequency of monitoring will be considered when investigation of CKD is reviewed. |
| Vascular Society | 12.1 | General | We would require that the final document will make reference to reno-vascular disease. | Thank you for your comment. We agree that this is an important population requiring guidance, however we are unable to prioritise populations with such specific and complex needs within this update of the chronic kidney disease guideline. |
| Vascular Society | 12.2 | General | We would request the NICE provide clear guidelines on the management of renal artery stenosis in the context of severe | Thank you for your comment. We agree that this is an important population requiring |

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| | | | CKD (3-5). | guidance, however we are unable to prioritise populations with such specific and complex needs within this update of the chronic kidney disease guideline. |
| Merck Sharp & Dohme UK Ltd | 13.1 | 4.3.1 (f) | <p>The 2008 CG73 on chronic kidney disease (CKD) included a section on 'Statins and antiplatelet drugs' within the chapter on Pharmacotherapy. Section 4.3.1 of the draft scope, regarding areas of the original guideline which will be updated includes section (f) on 'Reducing cardiovascular disease'. This description is, however, limited to updates for antiplatelet and antithrombotic therapy; cholesterol lowering treatments are not described. We find this surprising, given the publication of the SHARP¹ trial in 2011.</p> <p>SHARP¹ studied the effects of lowering LDL cholesterol with simvastatin plus ezetimibe in patients with CKD, and provides the first cardiovascular outcomes data for simvastatin plus ezetimibe.</p> <p>Section 10.2 of the full CKD guideline (lipid-lowering in people with CKD) stated "<i>Although people with CKD are at increased risk of CVD and might reasonably be expected also to benefit from the effects of lipid lowering therapy, the published randomised controlled trials have largely excluded people with most types of kidney disease.</i>" Section 4.2 of the NICE-version also states "<i>Research is urgently needed to determine the mechanisms that increase CVD risk in people with CKD and to determine the relative contribution of the key factors</i>".</p> <p>We therefore suggest that the results from SHARP¹ should be considered in this guideline update, regardless of inclusion (or otherwise) in the update to CG67 (Lipid Modification). Since publication of CG73, there has also been the publication of two Cochrane reviews^{2,3} and the AURORA⁴ clinical trial.</p> | Thank you for your comment. Statins will be covered within the Lipid Modification guideline update of GC67 and 'Statins for the prevention of cardiovascular events' (NICE technology appraisal guidance 94) where people with CKD will be considered as a subgroup within the population. This is referred to under '5.2 Guidance under development' in the scope, and will also be listed in the full guideline. |

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| | | | <p>Ref 1: Baigent, C., Landray, M.J., Reith, C., et al., for the SHARP investigators (2011) The effects of lowering LDL cholesterol with simvastatin plus ezetimibe in patients with chronic kidney disease (Study of Heart and Renal Protection): a randomised placebo-controlled trial. <i>Lancet</i> 377(9784): 2181-2192</p> <p>Ref 2: Navaneethan, S.D., Pansini, F., Perkovic, V., et al. (2009) HMGCoA reductase inhibitors (statins) for people with chronic kidney disease not requiring dialysis. <i>Cochrane Database of Systematic Reviews</i> Issue 2. Art. No.: CD007784.</p> <p>Ref 3: Navaneethan, S.D., Perkovic, V., Johnson, D.W., et al. (2009) HMG CoA reductase inhibitors (statins) for kidney transplant recipients. <i>Cochrane Database of Systematic Reviews</i> Issue 2. Art. No.: CD005019.</p> <p>Ref 4: Fellström B, Zannad F, Schmieder R, Holdaas H, Jardine A, Armstrong J, Siewert-Delle A 2003 A study to evaluate the use of rosuvastatin in subjects on regular haemodialysis: an assessment of survival and cardiovascular events — the AURORA study. <i>Nephrol Dial Transplant</i> 18(Suppl):713 (Abstract W520)</p> | |
| Merck Sharp & Dohme UK Ltd | 13.2 | 4.4 (c) | <p>As cardiovascular disease is to be one of the main outcomes, it would be appropriate to consider a review of the evidence form SHARP¹ when updating the guideline.</p> <p>Ref 1: Baigent, C., Landray, M.J., Reith, C., et al., for the SHARP investigators. (2011) The effects of lowering LDL cholesterol with simvastatin plus ezetimibe in patients with chronic kidney disease (Study of Heart and Renal Protection): a randomised placebo-controlled trial. <i>Lancet</i> 377(9784): 2181-2192</p> | Thank you for your comment. Statins will be covered within the Lipid Modification guideline update of GC67 and 'Statins for the prevention of cardiovascular events' (NICE technology appraisal guidance 94) where people with CKD will be considered as a subgroup within the population. This is referred to under '5.2 Guidance under development' in the scope, and will also be listed in the full guideline. |

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| The Society and College of Radiographers | 14.1 | General | Increased prevalence of CKD would naturally have implications for imaging services and needs to be assessed – apart from the decision not to review the indicators for renal ultrasound. | Thank you for your comment. We are unable to prioritise the impact on imaging services within this update. No new evidence for indicators for renal ultrasound was identified from that used in the development of CG73. |
| NHS Direct | 15.1 | General | NHS Direct welcome the update to the guideline and have no comments on the content of the draft scope. | Thank you for your comment. |
| PPIP at NICE | 16.1 | 4.3.1 b | <p>PPIP does not normally comment on the draft scope, but a comment has come to us from a lay person who was unable to make this point through a stakeholder organisation. We sometimes undertake to report back such comments when they seem important or relevant from a patient perspective. It is in regard to 'labelling' of people with Stage 3 CKD, and I copy the comments verbatim, as they seem to raise important issues for people at this stage of the disease, which perhaps could be factored into discussions by the GDG on the impact of 'labelling' people according to the international classifications:</p> <p>'...having been diagnosed last August following a routine blood test, with the condition on the basis of 2 raised creatinine levels and lower than normal estimated glomerular filtration rate.</p> <p>As a stage 3a CKD patient there are no requirements to investigate further into cause or kidney function, but simply to monitor blood, BP and urine.</p> <p>I feel there are a number of ethical issues raised with the guidance as it stands and would like confirmation these issues would be part of the review. For example, as an individual I have been labelled as having a long term condition though I have no symptoms other than a raised creatinine level, and my GP practice has to monitor me for QOF purposes. There is no treatment and no investigation linked with stage 3a, but I am obliged to disclose the condition for insurance and</p> | <p>Thank you for your comment. We acknowledge your concerns and agree that the needs of people with all stages of CKD should be considered and addressed in the guideline.</p> <p>The GDG will be aware of the issue of labelling. Although this wont be specifically addressed, they will raise in the 'linking evidence to recommendations' sections, where appropriate, in the guideline</p> |

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| | | | occupational health purposes, thus potential increasing financial costs and possibly reducing employability. I requested my GP labelled me as having raised creatinine but not as having CKD –in view of having no symptoms- but was advised this was not possible because of NICE guidance. There does not seem to be anything that a healthy person, who exercises regularly, is not overweight, does not smoke and drinks moderately could do to alter the course of the illness until symptoms show, so I find it hard to see the point of early identification, which simply raises anxiety. | |
| Royal College of Pathologists | 17.1 | General | The scope is fine as an update of the previous guidance but there is probably a need for separate guidance on paediatric CKD | Thank you for your comment. The remit from the Department of Health for the guideline is for adults only. However we recognise that CKD is important in children and NICE have raised this with the Department of Health. There are several key issues for children requiring specific guidance not encompassed by existing adult guidance. Addressing these is not possible within the scope for this guideline update but the views of stakeholders concerning the exclusion of children have been clearly heard and will be discussed further with the Department of Health. Children will be included in the scope of forthcoming guidelines on renal replacement therapy and renal stones. |
| Royal College of Pathologists | 17.2 | General | It is unclear to me whether the position of 'co-opted expert' for the biochemist on the group gives them equal status with other members of the GDG. Whilst there will be some clinical questions for which their expertise is less relevant, this is equally true of the professions identified as 'full' GDG members. Any attempt to reduce the contribution of clinical biochemistry to this guideline would be retrograde, and would | Thank you for your comment. We have reviewed the revised scope after all stakeholder comments received and areas to be covered have been finalised. We agree a biochemist would provide useful expertise as a full member of the guideline. This post will be advertised for during July – |

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| | | | impair implementation of guideline recommendations – some of which I suspect will crucially involve laboratory recommendations. | August 2012. |
| Royal College of Psychiatrists | 18.1 | 4.1.1 | Suggest further subgroups to be considered; 1) People with a learning disability 2) People with a long term mental health problem | Thank you for your comment. These groups will not be excluded from the analysis. Although they are not specific subgroups, the guideline development will ensure their needs are considered and they will be included within the equality impact assessment. |
| Royal College of Psychiatrists | 18.2 | 4.3 | Suggest in clinical management, the needs of people with psychological or psychiatric problems secondary to kidney disease be considered. | Thank you for your comment. We agree that these are important populations requiring guidance, however we are unable to prioritise this within the update of the chronic kidney disease guideline. The original guideline included a recommendation (R74) Healthcare professionals working with people with CKD should take account of the psychological aspects of coping with the condition and offer access to appropriate support (for example, support groups, counselling or a specialist nurse). This will remain in the updated guideline. As well as this, NICE guideline CG91 provides guidance on Depression in adults with a chronic physical health problem. |
| Bonpharma Ltd | 19.1 | General | The update is to be welcomed as much has changed in the identification and management of CKD in England and Wales since the original guideline (CG73) was written. | Thank you for your comment. |
| Bonpharma Ltd | 19.2 | 4.1.2 c | The exclusion of paediatric patients is disappointing. Would NICE consider a specific guidelines for this patient group? | Thank you for your comment. The remit from the Department of Health for the guideline is for adults only. However we recognise that CKD is important in children |

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| | | | | and NICE have raised this with the Department of Health. There are several key issues for children requiring specific guidance not encompassed by existing adult guidance. Addressing these is not possible within the scope for this guideline update but the views of stakeholders concerning the exclusion of children have been clearly heard and will be discussed further with the Department of Health. Children will be included in the scope of forthcoming guidelines on renal replacement therapy and renal stones. |
| Bonpharma Ltd | 19.3 | 4.1.1 b | Is it worth specifically including those patients who have been identified with CKD as a result of family history? | Thank you for your comment. This group will not be excluded from our analysis. |
| Bonpharma Ltd | 19.4 | 4.3.1 h | A timely inclusion in the scope though one issue here is the lack of availability of a suitable licensed high dose vitamin D in the UK | Thank you for your comment. |
| British Association for Paediatric Nephrology | 20.1 | General – inequality for age | The exclusion of children is unfortunate. The 13 th Annual Report of the UK Renal Registry documents there were 751 children under the age of 16 requiring RRT. This report also highlighted an increase in the annual incidence of children requiring RRT over the last 14 years, increasing from 8.1 per million age related population (1995-99) to 9.6 per million age related population (2005-9). Virtually all of these children will have undergone a period of CKD before requiring RRT. Although there is little epidemiological data upon which to base the incidence or prevalence of CKD in UK children, there are likely to be at least 5 children with CKD 1-4 for every child presently requiring RRT. The prevalence of CKD is reported to be 50-75 per million age related population in various European studies not including the UK (Epidemiology of chronic kidney disease in children. Harambat J, Karlijn J. van Stralen, Kim JJ, Tizard JE. <i>Pediatr Nephrol</i> 2012; 27: 363-73). While | Thank you for your comment. The remit from the Department of Health for the guideline is for adults only. However we recognise that CKD is important in children and NICE have raised this with the Department of Health. There are several key issues for children requiring specific guidance not encompassed by existing adult guidance. Addressing these is not possible within the scope for this guideline update but the views of stakeholders concerning the exclusion of children have been clearly heard and will be discussed further with the Department of Health. Children will be included in the scope of forthcoming guidelines on renal replacement therapy and renal stones. |

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| | | | <p>paediatric CKD patient numbers are smaller than those of the adult population, nationally the number of affected individuals is large and the population is probably increasing. The need for high quality care is just as pertinent for this group as for adults – indeed, it could be argued the need is greater as children with CKD become adults with CKD and will have accrued significant CKD-associated morbidity.</p> <p>The vast majority of the clinical questions in the CG73 guideline apply to children. Key among these issues are those relating to blood pressure control, treatment of proteinuria, cardiovascular disease and treatment for bone disease. There are paediatric studies in all these areas. Of particular significance linking paediatric and adult CKD is the evidence that demonstrates the increased risk of cardiovascular disease appears in paediatric CKD and that these risks may be ameliorated by therapy. The ESCAPE trial (N Engl J Med 2009;361:1639-50.) demonstrates progression of CKD can be modified in children. Publications relating to control of phosphate and calcium emphasise the importance of good dietary control in children with CKD. As with adults, early interventions can significantly modify disease progression and mitigate the detrimental effects of CKD, especially in reducing the cardiovascular morbidity an adolescent takes into adulthood. Some key references are:</p> <p>Uraemic vasculopathy in children with chronic kidney disease: prevention or damage limitation?. <u>Shroff R. Quinlan C. Mitsnefes M</u> <i>Pediatr Nephrol.</i> 26(6):853-65, 2011 Jun.</p> <p>Other references among others are: <u>-Cigarette smoking and second-hand smoking exposure in adolescents with chronic kidney disease: a study from the Midwest Pediatric Nephrology Consortium.</u> Omoloja A. Chand D. Greenbaum L. Wilson A. Bastian V.</p> | |

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| | | | <p>Ferris M. Bernert J. Stolfi A. Patel H. Nephrology Dialysis Transplantation. 26(3):908-13, 2011</p> <p>-When does the cardiovascular disease appear in patients with chronic kidney disease?. Sozeri B. Mir S. Kara OD. Levent E. Pediatric Cardiology. 31(6):821-8, 2010</p> <p>-A comprehensive study of cardiovascular risk factors, cardiac function and vascular disease in children with chronic renal failure. Rinat C. Becker-Cohen R. Nir A. Feinstein S. Shemesh D. Algur N. Ben Shalom E. Farber B. Frishberg Y. Nephrology Dialysis Transplantation. 25(3):785-93, 2010 Mar.</p> <p>-Mitsnefes MM, Kimball TR et al 2005: Cardiac and vascular adaptations in pediatric patients with chronic kidney disease: role of calcium-phosphorus metabolism. J Am Soc Nephrol 16;2796-2803</p> <p>The 4C study (http://www.4c-study.org/index.php?id=2) is ongoing and seeks to better define cardiovascular risk factors in children with CKD – although this study has not yet been completed results will become available in due course and demonstrates paediatric nephrologists are actively working to obtain more data in this field.</p> | |
| National Kidney Federation | 21.1 | Guideline Title | <p>The NKF are concerned that the scope does not include Paediatrics. This was mentioned at the scoping event by a number of people and reasons, one being time, were put forward for its omission. It was stressed that if paediatrics was to be omitted then a separate guidance for this patient group should be a priority and approval for such guidance should be given straight away. If a separate guidance cannot be given approval then serious consideration should be given to include paediatrics at this stage as an opportunity to do this may not arise in the near future.</p> | <p>Thank you for your comment. The remit from the Department of Health for the guideline is for adults only. However we recognise that CKD is important in children and NICE have raised this with the Department of Health. There are several key issues for children requiring specific guidance not encompassed by existing adult guidance. Addressing these is not possible within the scope for this guideline update but the views of stakeholders</p> |

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| | | | | concerning the exclusion of children have been clearly heard and will be discussed further with the Department of Health. Children will be included in the scope of forthcoming guidelines on renal replacement therapy and renal stones. |
| National Kidney Federation | 21.2 | 4.1.1 Groups to be covered | <p>The NKF would like serious consideration to be given to the following two groups as we feel they are considerable omissions from the list and should be included:</p> <ol style="list-style-type: none"> 1. Kidney Cancer 2. HIV <p>Kidney Cancer patients are at an increased risk of developing CKD leading to End Stage Renal Failure as a consequence of taking drugs to treat the cancer.</p> <p>Many HIV patients are kept healthy due to the modern antiretroviral drugs as a consequence they are not progressing to AIDS. Instead many of these patients are beginning to suffer the nephrotoxic effects of their antiretroviral regime and see a decline in their eGFR. Other HIV patients develop HIV associated nephropathy or HIVAN.</p> | <p>Thank you for your comment. We agree that these are important populations requiring guidance, however we are unable to prioritise populations with such specific and complex needs within this update of the chronic kidney disease guideline.</p> <p>The introduction of the guideline will highlight other causes of CKD to acknowledge these, although their management will not be covered.</p> |
| AMORE Studies Group | 22.1 | General | This scope for CKD looks good and key points are being updated. | Thank you for your comment. |
| AMORE Studies Group | 22.2 | 4.1 | <p>Would it be possible to make a comment on the update about the linkage with screening programs such as the NHS Vascular Health Checks in which CKD testing is advised for individuals found to have raised blood pressure?</p> <p>This would show good collaborative efforts to join up programmes.</p> | <p>Thank you for your comment. We are unable to cover screening programmes within this update as it is beyond the remit of the guideline.</p> <p>The implementation team at NICE have been made aware of this comment and will cover linking to screening programmes as part of their package.</p> |
| AMORE Studies Group | 22.3 | 4.3.1 | Also is there a place to consider the role of point of care tests in the diagnosis of CKD or will this be covered elsewhere. | Thank you for your comment. Point of care tests were not identified in the review for |

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| | | | These devices would also be implicated in self management as these technologies become available through pharmacies. | update and therefore we are unable to prioritise them within this update of the chronic kidney disease guideline. |
| AMORE Studies Group | 22.4 | 4.3.1 | Also – it is difficult for practitioners to understand the interaction of heart failure and CKD and when to continue or withdraw therapies and any special provision for such patients – rules of monitoring etc. would help greatly. | We believe what you're referring to is the increased risk of AKI in people with CKD on certain heart failure treatments, and this will be addressed in the NICE guideline on acute kidney injury which is currently in development. |

These organisations were approached but did not respond:

A Little Wish
 Abbott Laboratories
 Alder Hey Children's NHS Foundation Trust
 AMORE health Ltd
 Association for Continence Advice
 Association for Spina Bifida and Hydrocephalus
 Association of Anaesthetists of Great Britain and Ireland
 Association of British Clinical Diabetologists
 Association of British Healthcare Industries
 Association of Clinical Pathologists
 Association of Renal Industries
 Astrazeneca UK Ltd
 Barnsley Hospital NHS Foundation Trust
 Barnsley Primary Care Trust
 Barts and the London NHS Trust
 Baxter Healthcare

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Bedfordshire Primary Care Trust
Birmingham, Sandwell and Solihull Cardiac and Stroke Network
Blood Pressure Association
Boehringer Ingelheim
Bolton Primary Care Trust
Bonpharma Ltd
Bradford District Care Trust
Bristol-Myers Squibb Pharmaceuticals Ltd
British Association for Counselling and Psychotherapy
British Association of Critical Care Nurses
British Association of Social Workers
British Association of Urological Surgeons
British Dietetic Association
British Geriatrics Society
British Hypertension Society
British Lymphology Society
British Medical Association
British Medical Journal
British Medical Ultrasound Society
British National Formulary
British Nuclear Medicine Society
British Psychological Society
British Society for Immunology
British Society of Interventional Radiology

British Society of Urogynaecology
British Transplantation Society
Calderdale Primary Care Trust

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Cambridge University Hospitals NHS Foundation Trust
Camden Link
Capsulation PPS
Capsulation PPS
Cardiff and Vale University Health Board
Care Quality Commission (CQC)
Central & North West London NHS Foundation Trust
Church Grange Surgery
CIS' ters
CM&D Pharma Limited
Commission for Social Care Inspection
Community District Nurses Association
Coventry and Warwickshire Cardiac Network
Cybex Ventures
Daiichi Sankyo UK
David Lewis Centre, The
Department for Communities and Local Government
Department of Health, Social Services and Public Safety - Northern Ireland
Dept of Primary Health Care Sciences, University of Oxford
Derbyshire Mental Health Services NHS Trust
Diabetes UK
Division of Public Health & Primary Health Care
Dorset Primary Care Trust
Drinksense
Dudley Primary Care Trust
East Kent Hospitals University NHS Foundation Trust
Education for Health

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Elcena Jeffers Foundation
Faculty of Public Health
Fellowship of Postgraduate Medicine
Fresenius Medical Care
GE Healthcare
Genzyme Therapeutics
George Eliot Hospital NHS Trust
GlaxoSmithKline
Great Western Hospitals NHS Foundation Trust
Greater Manchester and Cheshire Cardiac and Stroke Network
Hammersmith and Fulham Primary Care Trust
Harrogate and District NHS Foundation Trust
Havering Primary Care Trust
Health and Safety Executive
Health Protection Agency

Health Quality Improvement Partnership
Healthcare Improvement Scotland
Healthcare Inspectorate Wales
Heart of England NHS Foundation Trust
Help the Hospices
Hindu Council UK
Independent Healthcare Advisory Services
Institute of Biomedical Science
Integrity Care Services Ltd.
iQudos
James Whale Fund for Kidney Cancer
KCARE

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Kimal PLC
Lancashire Care NHS Foundation Trust
Leeds Community Healthcare NHS Trust
Leeds Primary Care Trust (aka NHS Leeds)
Lilly UK
Liverpool Primary Care Trust
McDonald Obstetric Medicine Society
Medicines and Healthcare products Regulatory Agency
Mental Health Act Commission
Ministry of Defence
Mother and Infant Research Unit
Myeloma UK
National Council for Palliative Care
National Institute for Health Research Health Technology Assessment Programme
National Osteoporosis Society
National Patient Safety Agency
National Public Health Service for Wales
National Treatment Agency for Substance Misuse
NDR UK
Neonatal & Paediatric Pharmacists Group
NHS Blood and Transplant
NHS Bournemouth and Poole
NHS Clinical Knowledge Summaries
NHS Connecting for Health
NHS Derbyshire county
NHS Kirklees
NHS National Specialised Commissioning Team

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NHS Plus
NHS Plymouth
NHS Sefton
NHS Sheffield
NHS South Birmingham
NHS South Central vascular Network
NHS Warwickshire Primary Care Trust
Norfolk Suffolk & Cambridgeshire Strategic Health Authority
North Cheshire Hospitals NHS Trust
North Yorkshire & York Primary Care Trust
Northern Ireland Nephrology Forum
Nottingham City Hospital
Nova Biomedical UK
Novartis Pharmaceuticals
Nutricia Clinical Care
Nutrition and Diet Resources UK
Nutrition Society
Oxford Nutrition Ltd
Parkwood Healthcare
PERIGON Healthcare Ltd
Pfizer
Pharmacosmos
Pharmametrics GmbH
Pilgrims Hospices in East Kent
Polycystic Kidney Disease Charity
Primary Care Cardiovascular Society
Primary Care Pharmacists Association

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Public Health Wales NHS Trust
Queen Elizabeth Hospital
Renal Nutrition Group, British Dietetic Association
Roche Diagnostics
Roche Products
Royal Berkshire NHS Foundation Trust
Royal Brompton Hospital & Harefield NHS Trust
Royal College of Anaesthetists
Royal College of General Practitioners
Royal College of General Practitioners in Wales
Royal College of Midwives
Royal College of Obstetricians and Gynaecologists
Royal College of Paediatrics and Child Health , Gastroenterology, Hepatology and Nutrition
Royal College of Physicians
Royal College of Physicians of Edinburgh
Royal College of Radiologists
Royal College of Surgeons of England
Royal Free Hospital
Royal Free Hospital NHS Foundation Trust
Royal Pharmaceutical Society
Royal Society of Medicine
Royal Surrey County Hospital NHS Trust
Sandwell Primary Care Trust
Sanofi
Schering-Plough Ltd
Scottish Intercollegiate Guidelines Network
Sheffield Childrens Hospital

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Sheffield Primary Care Trust
Sheffield Teaching Hospitals NHS Foundation Trust
Shire Pharmaceuticals Ltd
Siemens Medical Solutions Diagnostics
Sigma-tau Spa
SNDRi
Social Care Institute for Excellence
Solvay
South Asian Health Foundation
South Staffordshire Primary Care Trust
South West Yorkshire Partnership NHS Foundation Trust
Stockport Primary Care Trust
Takeda UK Ltd
Thames Ambulance Service Ltd
The British In Vitro Diagnostics Association
The Hindu Forum of Britain
The Phoenix Partnership
The Rotherham NHS Foundation Trust
The University of Glamorgan
UK Anaemia
UK Lung Cancer Coalition
United Lincolnshire Hospitals NHS
University Hospital Birmingham NHS Foundation Trust
University of Nottingham
Vitaline Pharmaceuticals
Welsh Government

Welsh Scientific Advisory Committee

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West Midlands Ambulance Service NHS Trust
West Sussex Public Health
West Yorkshire Cardiac Network
Western Cheshire Primary Care Trust
Western Health and Social Care Trust
Westminster Local Involvement Network
Whipps Cross University Hospital NHS Trust
Wiltshire Primary Care Trust
Wirral University Teaching Hospital NHS Foundation Trust
Worcestershire Acute Hospitals Trust
Wye Valley NHS Trust
York Hospitals NHS Foundation Trust
Yorkshire & The Humber Specialised Commissioning Group

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