TENDER DOCUMENTATION FOR THE NATIONAL CLINICAL AUDIT AND QUALITY IMPROVEMENT PROGRAMME FOR CHRONIC KIDNEY DISEASE IN PRIMARY CARE

Section 5 - SPECIFICATION

Internal Ref: HQIP NCA 099
9/4/2012
2012-122318
**Contents**

SECTION A: Project-specific requirements

1. Background ............................................................................................................. 3
2. Outline ...................................................................................................................... 4
3. Aims of the Audit ..................................................................................................... 4
4. Scope of the Audit ................................................................................................... 5
5. Alignment with Health Policy Direction ................................................................. 7
6. Standards and Guidelines ....................................................................................... 8

SECTION B: Overarching requirements for the National Clinical Audit and Patient Outcomes Programme ........................................................................................................ 9

1. Organisational Structure, Governance and Management .......................................... 9
   1.1 Clinical Leadership ............................................................................................. 9
   1.2 Methodologist Involvement ................................................................................. 9
   1.3 Public / Patient Involvement ............................................................................. 9
   1.4 Audit Governance Structure and Strategy .......................................................... 9
   1.5 Risks and Risk Management ............................................................................. 10

2. Data Collection, IT Systems and Data Analysis .......................................................... 10
   2.1 Assessment of Equity of Care .......................................................................... 10
   2.2 Local Contributor Requirements ...................................................................... 10
   2.3 Exploitation of Existing Data ........................................................................... 10
   2.4 Data Quality ...................................................................................................... 10
   2.5 Linkage to Other Databases ............................................................................ 10
   2.6 Data Security ..................................................................................................... 11
   2.7 Confidentiality and Consent ............................................................................. 11

3. Communications, Reports and Change Initiatives ....................................................... 11
   3.1 Professional Audiences .................................................................................... 11
   3.2 Public Audiences .............................................................................................. 12
   3.3 Management of Outliers ................................................................................ 12

4. Uses of the Data ...................................................................................................... 12
   4.1 Incorporation in NHS Outcomes Framework, Quality Accounts and on Data.gov.uk .......................................................... 12
   4.2 Revalidation of Professionals .......................................................................... 12
   4.3 Regulation of Organisations ............................................................................ 12
   4.4 International comparisons .............................................................................. 12
   4.5 Research ........................................................................................................... 12
SECTION A: Project-specific requirements

1. Background

The commissioning of the National Clinical Audit and Quality Improvement Programme for Chronic Kidney Disease (CKD) in Primary Care arose following a formal request by HQIP in the spring of 2011 for proposals for new topics to join their National Clinical Audit and Patient Outcomes Programme (NCAPOP). A number of professional and patient groups came together to develop and write the new topic proposal for this topic area. These comprised:

- National Clinical Director for Kidney Services
- NHS Kidney Care

with support from:

- Royal College of General Practitioners
- National Kidney Federation
- University of Southampton
- East Midlands Public Health Observatory
- NHS National Clinical Commissioning Network
- NHS Information Centre
- The Renal Association
- The Royal College of Physicians

The proposal was taken through a specification development process in which the funding bodies and individuals with relevant expertise informed the scope of the audit to be procured. This process ensured that the final specifications are firmly rooted in the requirements of the relevant clinical and patient groups: a key principle underpinning the National Clinical Audit and Patient Outcome Programme (NCAPOP). It provided a forum for the funders and commissioners of the audit to consider the potential strengths and weaknesses of the audit proposed and how it would align with other national quality improvement initiatives. Finally, it allowed for open discussion of the potential risks and benefits of incorporating enhanced local quality improvement functionality in the national audit web tool to be commissioned. This duality of function is a first for the NCAPOP.

One aspect of discussions during specification development centred on the inclusion of patient reported experience measures (PREMs). Whilst there is some development work currently being undertaken around primary care PREM methodology, at present no appropriate, validated CKD-specific PREM tool exists, and the patient-reported outcomes measure (PROMs) tool which is in use is for end-stage renal disease only. PREM and PROM development and validation are not currently included in NACPOP funding. Inclusion of PROMs / PREMs in this Programme will be considered if and when appropriate tools have been developed.
HQIP is grateful to the many individuals whose thought and work contributed to the new topic proposal and the specification development. This document has incorporated many of those contributions.

2. Outline

The successful supplier will provide a national comparative clinical audit and quality improvement programme for the identification and management of adults with CKD in all NHS primary care settings in England and Wales. Other devolved nations could be included should their funding bodies choose.

The programme will comprise:

- annual extraction, central analysis and comparative reporting of process and outcomes data from primary care,
- the provision of local quality improvement functionality within the programme’s IT capacity,

The initial contract will be for three years, with the potential to extend for up to a further two years. Responses in Schedule B should therefore reflect a vision for the project which encompasses the possibility of a five-year time frame. In addition, proposals for an effective longer-term strategy for the audit are also expected, and should be included in the tender response.

3. Aims of the Audit

The overarching aims of this Programme are as follows:

1. To enable the improvement of the accuracy and timeliness with which patients with CKD in primary care are identified.

2. To enable the improvement of the quality of care and outcomes achieved for patients with CKD in primary care through the provision of high quality data that compares providers.

3. To achieve and maintain close alignment with NICE national guidance and quality standards throughout the audit.

4. To link data at the individual patient level to other relevant datasets as required in order to achieve the first four aims.

5. To consider the potential value of other linkage activity which, whilst not required to meet the current scope, might in the future facilitate extension of the audit further along the patient care pathway.
6. To directly enhance the capacity of primary care providers to improve the quality of CKD care they deliver by providing all participants with a local quality improvement tool delivered alongside the national audit IT mechanism (see section 4, Element 2 for details). Whilst the Programme funding will not cover the costs of implementing change locally (as these should be instigated and managed by those providing services), the Programme supplier is expected to align the functionality of this mechanism closely with the audit design and dataset, ensuring that maximal local impact can be anticipated.

4. Scope of the Audit

The aims of the audit will be realised by the execution of a Programme with the following features:

**Element 1: a national audit of the identification and management of adults with CKD in primary care.**

Key features:

a) All adults aged 18 years with all stages (1 to 5 inclusive) of chronic kidney disease receiving NHS primary care in England and Wales will be included.

b) Central data collection will be achieved via an annual extraction from GP practices of routinely-collected machine-readable data (read coded and non-read coded items) including relevant blood and urine test results and key demographic, process and outcome measures. Co-morbidities and other relevant risk factors for patients with CKD will also be extracted and analysed as well as medications prescribed.

c) Informing patients of their diagnosis is recognised to be an important component of patient care but is not currently read-coded; however a code has been requested. It is expected that this data would be captured in the Programme if and when the code is available and in use.

d) Consideration to be given during the IT development / selection phase to the variety of IT systems already in use in primary care in England and Wales both in terms of electronic patient records and IT systems designed to support audit activities, including those specifically tailored to CKD.

e) A robust risk adjustment model will be developed and applied as appropriate.

f) Linkage activity for this element will have to be planned carefully, given the overall complexity of the project. Referral activities and other professional liaisons with secondary care specialists will be important to capture. Extraction of relevant data from primary care data sources should be considered in the first instance, and any linkage with non-primary care datasets required in addition should be proposed and justified. Linkage with the
National Diabetes Audit is expected to be beneficial. The tenderer should describe the linkage activities that they propose, identify the purposes and benefits of each, and clarify that time and resources will not be unnecessarily diverted from the delivery of the key requirements of the Programme.

g) All data items for audit will be, or will derive from, evidence-based measures proven to indicate high quality care. They must align with the NICE QS for chronic kidney disease and to the relevant NICE guidelines in section 6, as well as to other national standards and guidance as appropriate. Every item in the dataset must be justifiable and utilised effectively. The relationships between the data items selected and the standards and guidance must be made explicit via appropriate project information documents. Tenderers will be expected to engage in an appropriate stakeholder consultation, to include patient representatives, during the development of the dataset.

h) Tenderers will be required to propose provider participation rate and data completion targets for the first three years of the contract, taking into account the values already achieved in the National Diabetes Audit.

i) Analysis and reporting will be performed to the level of granularity appropriate to the organisation of care and the response rates achieved. This is likely to be a mixture of practice-level, CCG level, regional and national and will take place annually. All reports produced are expected to be available in the public domain, excluding any information that might make individual patients identifiable.

GP practices are expected to have received their reports within three months of national data extraction. The comparative national report would be expected to be available in the public domain no more than two months later. Practice CKD prevalence rates will be published alongside expected prevalences from observatory data.

j) The addition of patient-reported data collection within this element will be considered by the funding bodies if and when relevant development and validation work which is being undertaken outside of this contract is completed. The tenderer is required to propose an appropriate timeframe for periodic review of progress in this area and reporting on this to HQIP.

**Element 2: local quality improvement functionality for primary care.**

In addition to the ability to extract, link, analyse and report data centrally, the Programme will also directly support the improvement of care quality for CKD within each participating practice via a
system which can be run locally. The following key features would be expected to be included. The tenderer is invited to use these as the basis for the vision and detail they propose for this element:

a) Analyses and reports practice CKD registers for accuracy, e.g. by reviewing blood results to identify patients who have been wrongly included or wrongly categorised in terms of stage of CKD.

b) Searches other relevant practice registers (such as diabetes, hypertension, CVD, Atrial Fibrillation) for CKD patients who have not been appropriately registered.

c) Provides local audit functionality against NICE standards and other key indicators to allow ad hoc local audit activity between the annual rounds of national data collection.

d) Provides other local utility from the data such as risk stratification and / or referral advice at an individual patient level.

e) Provides appropriate output formats for the practice to disseminate and present their data.

The proposed activities and timelines for each element should be included in the relevant sections of the tender return.

5. Alignment with Health Policy Direction

HQIP requires that all National Clinical Audits ensure that their audit design, tools and data items remain aligned with and responsive to contemporary health policy directives, and in particular must evolve in response to updated NICE guidelines and quality standards. The programme is also expected to align where appropriate with the NHS Outcomes Framework, including the collection of data for relevant Framework Indicators and / or contributing to the development of new Indicators if required.

The management of chronic kidney disease is a priority area for the funding bodies at present, overlapping with the cardiovascular disease strategy and with the drive to improve care quality for patients with chronic conditions and multiple morbidities. An assessment of risk for kidney disease and the targeted identification of kidney disease in those at risk is an important component of the NHS Health Check.

The key publications from NICE are referenced in the next section. In addition, four principles key to improving care for people with long-term conditions are outlined in the QIPP long-term conditions workstream: commissioners understanding the needs of their population and managing those at risk to prevent disease progression; integration of care; empowering patients to self-manage; and strong clinical leadership. This audit is expected to align with these principles.
A CKD domain within QOF has been present since 2006. Practice payments are supported through registration of people with Stage 3-5 CKD; and in those registered:

- annual measurement and treatment of blood pressure to an audit standard of 140/85mmHg,
- annual measurement of proteinuria, and
- appropriate use of renin-angiotensin blocking drugs in people with proteinuria.

The QOF covers only a small proportion of the expected activities for patients with CKD as captured in the NICE Quality Standard. This audit, with its dataset aligned with the NICE recommendations, is expected to work in a complimentary fashion alongside QOF to enable and empower quality improvement in the primary care of CKD.

6. Standards and Guidelines

The following list captures some of the key relevant documents which are likely to underpin the audit. The Tenderer is expected to review these standards and guidelines and their relevance to the audit, as well as identifying any other key documents which they feel should be considered. During the contract it is expected that a regular review of such standards is performed so that the Programme’s dataset can be adapted and updated if and when appropriate.

The key document which will underpin this Programme is the Quality Standard for CKD was published by NICE in March 2011. The quality measures span the entire pathway of kidney disease (stage 1-5) and are relevant to both primary and secondary care.

SECTION B: Overarching requirements for the National Clinical Audit and Patient Outcomes Programme

1. Organisational Structure, Governance and Management

2.1 Clinical Leadership
Effective clinical leadership must be integral to the audit delivery. In this context, clinical leadership means that individual(s) with relevant clinical expertise, appropriate experience with national project delivery and demonstrably high professional peer respect and authority are integral to the audit’s governance structure and lead the project. It is essential that clinical leaders represent the specialties responsible for delivery of the care that is being audited as these are the clinicians who will need to accept the findings and lead service improvements.

1.2 Methodologist Involvement
Appropriate methodological input must be integral to the audit planning and delivery from the outset as well as providing input during analysis and interpretation of the data and for linkage to and extraction from other databases. These individuals would have a key role in the design of the audit, ensuring that it meets the requirements of the audit aims and objectives.

1.3 Public / Patient Involvement
Effective and meaningful public/patient involvement in the audit governance structure is required, and must be integrated appropriately throughout every stage of the design and delivery of the audit.

1.4 Audit Governance Structure and Strategy
The audit must be governed by a robust management structure with clearly-defined governance groups, designed to maximise effectiveness. The decision-making hierarchy must be explicit. Details
of the structure should be included in Schedule B along with any other proposed mechanisms for achieving audit governance.

1.5 Risks and Risk Management
A preliminary assessment of risks associated with the audit must be undertaken during the tendering process and included in Schedule B. Suppliers will also be expected to demonstrate how risks will be monitored, highlighted appropriately and addressed during delivery of the audit.

2 Data Collection, IT Systems and Data Analysis

2.1 Assessment of Equity of Care
HQIP aligns with the Department of Health’s identified duty to promote equality through the health and care system and pay particular attention to groups or sections of society where improvements in health and care outcomes are not keeping pace with the rest of the population. The predicted impact of all audit tools and patient recruitment strategies developed must be systematically reviewed and reported publically by the supplier, with associated commentary as required.

2.2 Local Contributor Requirements
The audit design must take into account the workload anticipated locally during participation in the audit and minimise this wherever possible. The dataset size should be the minimum required to effectively meet the requirements of the audit.

The platform supplied for data entry must provide a fast, secure and user-friendly interface. Data inputted by each service should be extractible locally and supported by appropriate tools to facilitate its use in relevant local activities such as for presentations or for comparisons with other local data sources.

2.3 Exploitation of Existing Data
Tenderers are expected to identify any existing data collections of relevance. Unnecessary duplication of data entry must be avoided and the provision of upload facilities from local databases or hospital patient administration systems should be considered. All efforts must also be made to locate any pre-existing national data collections with overlapping datasets which might provide an appropriate source of data for the audit.

2.4 Data Quality
Tenderers must illustrate how they will ensure that the highest standards of data quality and completeness, including mechanisms to check inter-rater reliability and identify missing data.

2.5 Linkage to Other Databases
Tenderers must consider in detail how linkages to other national databases including HES, PEDW, and other national audits, registries and databases will be used to enhance the audit. Consideration
must also be given, from the outset, of the related information governance requirements for such linkage.

2.6 Data Security
Comprehensive measures must be developed and implemented to mitigate the risk of loss of data. Tenderers must be able to show a full understanding of the Data Protection Act and its relevance to national clinical audit processes, as well as all other relevant security policies and legislation.

2.7 Confidentiality and Consent
A comprehensive information governance policy must be developed for application to this audit. Tenderers must state clearly whether any patient-identifiers will be extracted for central processing or linkage purposes and their proposed mechanism for gaining the required permissions.

3 Communications, Reports and Change Initiatives

Comprehensive information about the audit including the commissioning body, audit aims and objectives, design, geographical cover, timelines, and audit tools / data set (including terms and conditions of their use) must be publically accessible via a dedicated section of the supplier’s website, with links wherever possible from relevant stakeholders’ websites.

A comprehensive communications plan will form part of the audit delivery and must be provided for review by HQIP during the first six months of the contract. Dissemination of audit results are expected to be to the full range of interested parties including clinical service providers; service commissioners; patients, carers and the public; policymakers and regulators. Dissemination should take place through a variety of formats and activities appropriate to the needs of the target audience. All reports produced under this contract must be publically accessible unless they are reporting pilot or developmental work. Adaptations may be required to remove the risk of patients being individually identifiable. The HQIP document ‘Policy on public reporting for the National Clinical Audit and Patient Outcomes Programme (NCAPOP)’ is included in the tender pack and should be consulted for further information.

All national comparative reports will be subject to HQIP’s Standard Reporting Procedure (SRP) and comprise a major deliverable for the Audit. Early in the contract, a progress report may be relevant rather than publication of comparative data, and in this case the requirement to follow the SRP may be waived.

3.1 Professional Audiences
It is expected that the audit supplier will ensure that comparative data are presented to the relevant professional and commissioning groups in a timely manner and via a format which is clear, informative and appropriate to the needs of the group concerned. Each unit’s own data should be extractible locally and supported by appropriate tools to facilitate its use in relevant local activities such as for presentations or for comparisons with other local data sources.
3.2 Public Audiences
The needs of patients and the public must be fully assessed and appropriate activities undertaken. All annual public reports containing audit results should be made available in a public-friendly format. Additionally, audit data in the public domain is expected to be made available to relevant organisations such as NHS Choices.

3.3 Management of Outliers
For all NCAPOP audits, it is expected that DH guidance on the detection and management of outliers will be adopted for English organisations, and equivalent Welsh Government guidance adopted for Welsh participants. Should an alternative approach be considered, the reasons and details should be fully explained by the Tenderer.

4 Uses of the Data
4.1 Incorporation in NHS Outcomes Framework, Quality Accounts and on Data.gov.uk
The programme is expected to align where appropriate with the NHS Outcomes Framework, including the collection of data for relevant Framework Indicators and / or contributing to the development of new Indicators if required. In addition, participation rates and patient recruitment rates (at the level of granularity by which they appear in the annual reports) will be made available to HQIP in accordance with the Standard Reporting Procedure to facilitate inclusion in Quality Accounts. Finally, CSV versions of data, once published, are also required to be made available via the supplier’s website under the government’s transparency agenda for inclusion on the Data.gov.uk website.

4.2 Revalidation of Professionals
HQIP supports the expectation that individual clinicians may use provider-level audit data as part of their revalidation portfolios.

4.3 Regulation of Organisations
The audit supplier will be required to make available aggregate data for regulatory bodies e.g. The Care Quality Commission and Monitor, subject to appropriate data sharing agreements.

4.4 International comparisons
It is expected that the supplier will take into account the potential for ongoing international comparisons of care quality and form appropriate links with those developing and leading relevant overseas projects if appropriate.

4.5 Research
HQIP encourages the use of the data for epidemiological studies and health services research. Such requests must be the subject of an appropriate data sharing agreement and information governance support.