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## Clinical Practice Guideline Development Manual

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## 1. Background

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The Clinical Practice Guidelines (CPG) Committee was established by the Renal Association in 1995 to prepare guidelines for the management of patients with renal disease and help identify the data to be collected by the UK Renal Registry. This aims to ensure up-to-date and safe practice, with the ultimate aim of improving patient outcomes.

The RA Clinical Practice Guidelines are not funded by any external organisation, commercial company or charity. Although reviewed by its members, the guidelines are editorially independent from the Renal Association. In 2013 it was agreed that for appropriate topics The Renal Association would produce joint adult and paediatric guidelines with the British Association for Paediatric Nephrology.

Full Committee membership can be found at [www.renal.org/guidelines/clinical-practice-guidelines-committee](http://www.renal.org/guidelines/clinical-practice-guidelines-committee)

The CPG Committee is responsible for the following areas of work:

- Continuous updating of the Clinical Practice Guidelines posted on the Renal Association website
- A rolling review programme to ensure the revision of all guidelines at intervals of no greater than five years
- The preparation of collaborative guidelines with other specialist societies e.g. the British Association for Paediatric Nephrology. The British Transplantation Society
- The Preparation of commentaries, on behalf of the Renal Association, on guidelines produced by other organisations.
- Ensuring that all new and revised guidelines are prepared using the process outlined in the policy manual published on the Renal Association website
- Ensuring that all guidelines follow the systems and processes to facilitate NICE accreditation
- Ensuring that patients are represented on each guideline development review group
- Maintaining an archive of historic guidelines of the Association

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## 2. NICE accreditation

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NICE accreditation helps health and social care professionals identify the most robustly produced guidance available, enabling them to deliver high quality care. More information on accreditation can be viewed at: [www.nice.org.uk/accreditation](http://www.nice.org.uk/accreditation)

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## 3. Patient Involvement

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Although the guidelines are mostly aimed at healthcare professionals, NICE accreditation requires lay involvement at both the CPG Committee level and for individual guideline development

Representation from specialist patient groups, as well as input from individuals with personal experience of chronic kidney disease (CKD), dialysis (haemodialysis or peritoneal), kidney transplantation or acute kidney injury (AKI) would be welcome. Reasonable travel expenses incurred during this work will be reimbursed by the Renal Association.

## 4. Paediatric Involvement

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In 2013 CPG Committee agreed that, for appropriate topics, The Renal Association would produce joint adult and paediatric guidelines with the British Association for Paediatric Nephrology. Relevant guidelines should therefore have a Paediatric Lead author who will play a key role in the guideline development.

## 5. Selection and Planning of Guideline Topics

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Topics for the Renal Association guidelines are selected to cover all of the main areas of clinical management of patients with renal disease.

The guideline recommendations and audit measures serve to define the dataset collected by the UK Renal Registry as well as for local and regional audit. The close links with the UK Renal Registry promote implementation of the guideline recommendations and the achievement of performance indicators. The main objective of the Clinical Practice Guidelines is to improve clinical practice in renal services nationwide

Consideration will be given to guidelines produced by other bodies such as NICE or KDIGO in order to avoid duplication.

The Renal Association Clinical Practice Guidelines Committee will suggest topics for guidelines and this will be considered and ratified by the Renal Association Clinical Affairs Board.

In the case of collaborative guidelines with other organisations, agreement will be reached at the outset as to whether the Renal Association is leading on guideline development and if the guideline is being produced according to this manual.

## 6. Standardised Format

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In order to ensure standardisation across the guidelines, authors are asked to use the format below. The language used in the guideline will be appropriate for the target audience, which will be stated in the introduction. This may include technical language if the target audience includes healthcare professionals.

Importantly, a summary of the recommendations will appear immediately after the introduction. These will therefore be easily identifiable, and must be made specific and unambiguous by using standard and up-to-date-vocabulary. Detailed notes regarding guideline development are contained in appendix A.

### Title Page

- Guideline Title
- Date of Draft Version (superseded by final version date following review)
- Date of Guideline review (maximum of five years from final version date)
- Authors, with designations (see appendix B)

### First Page

- Endorsements (e.g. RA/NICE)
- Method used to arrive at a recommendation - insert the following statement: "The recommendations for the first draft of this guideline resulted from a collective decision reached by informal discussion by the authors and, whenever necessary, with input from the Chair of the Clinical Practice Guidelines Committee. Where no agreement was reached on the appropriate grading of a recommendation, a vote was held and the majority opinion was carried. "

If no vote was required, edit the statement to: “The recommendations for the first draft of this guideline resulted from a collective decision reached by informal discussion by the authors and, whenever necessary, with input from the Chair of the Clinical Practice Guidelines Committee. If no agreement had been reached on the appropriate grading of a recommendation, a vote would have been held and the majority opinion carried. However this was not necessary for this guideline.”

- Conflict of Interest statement for all authors (see appendix C)

## Contents Page

### Guideline text

- Introduction - including background, aims, scope, search strategy and dates that each database search is performed.
- Summary of Clinical Practice Guideline Recommendations
- Summary of Audit Measures (link with UKRR)
- Summary of Research Recommendations (if applicable, 5 maximum, consider a link with UKKRC CSG)
- Rationale for Clinical Practice Guidelines (concise)
- Lay summary
- Acknowledgements – Include the following statement: “This document has been externally reviewed by key stake holders according to the process described in the Clinical Practice Guidelines Development Policy Manual.” If applicable, then also add: “In addition we are particularly grateful to the following individuals for their comments ...”
- Appendix

Authors are also asked to submit a JPEG photo of themselves along with a short paragraph on the aims and objectives of the guidelines, for publication on the Renal Association website.

## 7. UK Renal Registry Support

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The UK Renal Registry is currently providing administration support to the CPG Committee to help manage the guideline development process. For any queries or for more information on how the UKRR team can assist with the Guideline development process, please contact: **Melanie Dillon (Melanie.Dillon@renalregistry.nhs.uk)**

## Appendix A – Notes for Guideline Development

### 1. Background

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Consider the frequency of condition, associated morbidity/mortality, existing evidence/guidance

### 2. Aims

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State the overall aims of the guidelines e.g. improve quality of care and reduce variation in practice

### 3. Scope

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State the Population/Groups that will be covered by the guidance: e.g. adults and children with acute kidney injury

State the Population/Groups that will be not be covered by the guidance: e.g. neonates, patients with existing chronic kidney disease

State the Setting: e.g. wards, outpatient areas, GP practices, walk-in centres

State the Target Audience and Intended Users of the guideline: e.g. nephrologist, paediatric nephrologists, general practitioners, Specialist trainees, nurses, patients, carers, relatives).

Note that every effort should be made to include representatives from the target audience / intended during scoping and users as guideline authors. It is also essential that they are consulted during feedback on the draft guideline.

State the Clinical Issues that will be covered: (e.g.: diagnosis and management of acute kidney injury)

State the Clinical Issues that will **not** be covered: e.g.: patients receiving plasma exchange for Haemolytic uraemic syndrome

A decision on the relevant issues for each guideline will be based on clinical priorities, knowledge of the available literature, the range of treatment and interventions in this field and outcomes which are important to patients. On this basis several criteria will be used to decide which topic areas within each module merit inclusion in the guidance. These include:

- a. areas of variation in clinical practice
- b. areas of variation in patient outcomes
- c. resources to provide high quality patient care
- d. interventions, procedures and drug management which influence patient morbidity and/or mortality
- e. patient safety and avoidance of preventable complications.

Issues for each guideline may also be informed and modified by feedback from peers and stakeholders.

## 4. Search Strategy

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Authors for each new or updated guideline conduct a systematic search of the literature immediately prior to starting work on the guideline. Details will be included in the Introduction to the Guideline itself.

The dates covered by the literature search will be stated along with details of the search strategy and search terms used. As a minimum, sources searched should include PubMed or Medline, using key search terms agreed by the authors.

The co-authors also assess other related nephrology guidelines issued by national and international organisations such as the Kidney Disease Improving Global Outcomes (KDIGO), European Renal Best Practice (ERBP) and NICE.

## 5. Inclusion criteria for evidence

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The authors will critically appraise any eligible papers to decide which to include and exclude. Any disagreements will be resolved through discussion by the authors. Articles are considered of particular relevance if they are describing prospective randomised or quasi-randomised trials, controlled trials, meta-analyses of several trials or systematic reviews. Authors should usually exclude studies with significant methodological flaws or bias, case reports or case series reporting less than 20 subjects, and studies not reported in English.

## 6. Appraising the evidence and developing recommendations

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The modified GRADE system will be used. It provides an informative, transparent summary for clinicians, patients and policy makers by combining an explicit evaluation of the strength of the recommendation with a judgment of the quality of the evidence for each recommendation.

There is a two-level grading system for the strength of recommendations.

A Grade 1 recommendation is a strong recommendation to do (or not do) something, where the benefits clearly outweigh the risks (or vice versa) for most, if not all patients.

A Grade 2 recommendation is a weaker recommendation, where the risks and benefits are more closely balanced or are more uncertain. Two levels facilitate a clear interpretation of the implications of strong and weak recommendations by clinicians. Explicit recommendations are made on the basis of the trade-offs between the benefits on the one hand and risks, burden and costs on the other.

Standard wording is used to indicate the strength of each recommendation. It is desirable to provide clinicians with a standard terminology to aid interpreting the strength of recommendations. When making a strong recommendation guideline authors are encouraged to use 'We recommend...' and when making a weak recommendation authors should use 'We suggest...' The use of the active voice attributes responsibility for the recommendations to the guideline authors and their supporting organisation. For example 'We recommend that specialist trainees in renal medicine should sit the Knowledge Based Assessment examination before the last two years of training' (1D). An alternative would be 'We suggest that specialist trainees in renal medicine should become members of the RA to enhance their continuing medical education and support their professional development (2C).'

Explicit methodology is used to describe the quality of evidence.

Grade A evidence means high-quality evidence that comes from consistent results from well-performed randomised controlled trials, or overwhelming evidence of some other sort (such as well-executed observational studies with very strong effects).

Grade B evidence means moderate-quality evidence from randomised trials that suffer from serious flaws in conduct, inconsistency, indirectness, imprecise estimates, reporting bias, or some combination of these limitations, or from other study designs with special strength.

Grade C evidence means low-quality evidence from observational studies, or from controlled trials with several very serious limitations.

Grade D evidence is based only on case studies or expert opinion.

There is an ability to upgrade and downgrade the quality of evidence. GRADE can appraise all relevant study data to upgrade or downgrade the overall quality of evidence. RCTs are high initial grade. Observational studies are low initial grade. Other evidence is very low initial grade. *Reduce grade* if study limitations, inconsistency between studies, surrogate outcome but no direct patient outcomes, bias. *Raise grade* if confounders would have reduced the observed effect, strong association without plausible confounders or if there is a large dose-response effect.

Changes to the grading of the recommendations may be considered after feedback from the drafts of the guidance (see external review below).

## **7. Method used to arrive at a recommendation**

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The recommendations for the first draft result from a collective decision reached by informal discussion by the authors and, whenever necessary, with input from the Chair of the Clinical Practice Guidelines Committee. The number of expert co-authors of each guideline is too small to support formal consensus methods such as the Delphi technique. Where no agreement is reached on the appropriate grading of a recommendation, a vote is held and the majority opinion is carried. If a majority cannot be reached, this is stated in the Guideline.

Changes to the grading of the recommendations may be considered after feedback from the draft of the guidance.

## **8. Benefits compared with side effects and risks of all possible treatment options**

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Treatments for renal patients have side effects and risks. For example, immunosuppressive medication used in transplantation and autoimmune renal disease has the risk of infection, and surgery (transplantation, vascular access) has the risk of complications. Dialysis may prolong and improve life in most but not all patients. The benefits of treatment will be weighed against the risk/side effects, and against the risks of not treating. These may differ for different patients depending on comorbidity. This will be made clear when applicable to specific recommendations, and may also be discussed in the introduction or rationale sections where appropriate. Guidelines will consider all possible treatment options, including conservative management. The benefits and potential risks will be clearly stated. Where appropriate this will refer to specific patient groups, and flow charts may be used.

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## 9. Organisational and financial barriers to implementing recommendations

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The authors should draft and agree the recommendations within each module based primarily on clinical effectiveness but the use of resources and cost effectiveness should also be taken into account. For example, a recommendation may state that an expensive drug should be given, that additional staff are needed, or expensive equipment is necessary. Guideline authors should include a discussion of any organisational or financial barriers. This may either be within the rationale for a particular recommendation, or as an appendix to the guideline.

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## 10. Audit Measures

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Each guideline contains a number of audit measures to assist with implementation of the guidance, promote an improvement in the quality of care and allow comparative audit. The audit measures should be measurable, achievable and serve as evidence-based criteria for continuing quality improvement. A summary of all of the audit measures in each module is included before the rationale section of all of the recommendations.

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## 11. External review

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A draft version of the guideline will be available on the Renal Association website for a minimum period of 4 weeks.

Feedback is invited from RA members, non RA members, patients and any other relevant stakeholders.

The Clinical Practice Guidelines Committee will oversee the process of external review and ensure that the comments are addressed by the guideline authors, and will approve the final version.

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## 12. Dissemination

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The final approved guideline, including the lay summary, will be disseminated by publication on the Renal Association website and via stakeholders, as well as dissemination via society presidents, etc.

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## 13. Project Governance

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The guidelines will be owned by the Renal Association who will be responsible for keeping the document up to date.

For guidelines produced in collaboration with other organisations, it will be clarified if the Renal Association is the lead and owner of the guideline, or if another organisation has taken this role.

For collaborative guidelines, both parties may use each other's logos for the purposes of delivering and promoting the best practice guide, provided such use is in line with the owner's policies. Any other use of the logo or other intellectual property rights will require express permission in writing from the owner. Intellectual Property arising from development shall belong to the Renal Association. This will also apply where collaborative guidelines are lead and owned by the Renal Association.

Guidelines will be due for review no later than five years after publication.

## 14. Timeline

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A planned publication date will be agreed at the outset, based on the anticipated start date.

The work to develop the best practice guides will begin once the author group, scope and methodology is agreed. It is anticipated to take 9 months to complete.

## APPENDIX B: Guideline Authors and Responsibilities

### 1. Guideline authors

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The guideline authors will include a chair who will normally be consultant nephrologist but in some cases could be another suitably qualified member of the multi-disciplinary team (MDT).

The guideline authors will always include a lay member who may be a kidney patient.

The guideline authors will include at least one other nephrologist or MDT member.

Inclusion of trainees, and members who are not nephrologists is encouraged.

The target audience or intended users of the guideline (see appendix A) should be considered and included as authors if possible.

The guideline authors will be agreed by the Clinical Practice Guidelines Committee

### 2. Author responsibilities

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#### Chair

- Confirms how the group will operate including abiding by confidentiality rules
- Ensures the group follow the RA Clinical Guidelines process (contained within this manual) for developing high quality guidelines
- Assists with the planning of the meetings
- Ensures all members have an opportunity to contribute to discussions
- Chairs meetings and teleconferences
- Ensures all members have declared conflicts
- Summarises the key actions at each meeting
- Ensures the guidelines are completed according the timeline in this manual
- Communicates with the Clinical Practice Guidelines committee regarding the progress of developing the guideline

#### All authors

- Attend group meetings and participate in teleconferences
- Ensure the guidelines are completed according the timeline in this manual
- Contribute to all stages of guideline development
- Complete actions as agreed at meetings
- Providing a response to any stakeholder comments
- Undertake to contribute to updates to the guideline if significant new evidence emerges prior to a formal review of the guideline. The authors may become aware of new evidence through their own knowledge of current research or by communication from other colleagues and/or Renal Association Members. The Renal Association Clinical Practice Guidelines Committee will decide if an update to the guideline is necessary, and this will be considered and ratified by the Renal Association Clinical Affairs Board.

## Appendix C – Conflict of Interest Policy

All authors should declare all commercial interests and remuneration from the biomedical industry when approached to be on the committee. The time period for relevant interests is 12 months before starting work on a guideline, and those anticipated for the duration of the guideline development.

Declarations of interest will be reviewed by the Chair of the Clinical Practice Guidelines Committee to ensure that there are no grounds to expect a conflict of interest.

Copies of Declaration of Interest forms for group members will be kept on file by the Renal Association for the duration of the work of the Guideline Group (and then for the subsequent period of time that the Guideline remains valid).

The Chairs of guideline authors should not have shares in a biomedical company or be retained as a consultant with a company.

‘Shares’ refers to any shares in the biomedical industry, excluding Unit Trusts, and it refers to shares held by a member or a close family member. A consultancy refers to a paid retainer or agreement between a Renal Association member and a company with respect of one drug or device, or more generally, usually with a contract for a specific period of time. Consultancy will include ongoing attendance at Advisory Board meetings but would not normally include a situation where an individual is paid for a specific item or for attending or speaking at an occasional meeting. If there is doubt, interests should be declared.

Interests should include shares and consultancies, commercial sponsorship for the member and for the people for whom they are responsible, e.g. Research Fellows, and support for research within their Department. In the case of uncertainty the interest should be declared.

Authors who have shares or a general consultancy agreement with a biomedical company should not normally take part in discussions about any product from that company, or a main competitor, and should leave the room when such discussions occur. Members receiving a consultancy retainer for a specific product should leave the room when that product or a direct competitor is being discussed.

A statement should be included in each Guideline when published to confirm that the authors adhered to this policy for the Declaration of Interests. An example of such a statement is as follows: **“All authors made declarations of interest in line with the policy in the Clinical Practice Guideline Development Manual. Further details can be obtained on request from the Renal Association.”**

## Appendix D – Conflict of Interest Declaration Form

The time period for relevant interests is 12 months before starting work on a guideline, and for the duration of the guideline development.

If in doubt declare all interests.

**I confirm that I have read the Conflicts of Interest Policy contained in the current Renal Association Guideline Development Manual and declare the following interests.**

**I will update this form if new interests arise.**

|                                  |                             |
|----------------------------------|-----------------------------|
| <b>Name:</b>                     | <b>Guideline Committee:</b> |
| <b>Interests to be declared:</b> |                             |
| <b>Signature</b>                 | <b>Date:</b>                |