

Clinical Knowledge Summaries

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About CKS

In September 2012, Clarity Informatics Ltd (www.clarity.co.uk) was awarded a contract, commissioned and funded by NICE, to provide clinical content for a new Clinical Knowledge Summaries (CKS) service available through the NICE website and aimed at a primary and first contact care audience in the UK.

CKS topics provide primary care practitioners with concise, readily accessible summaries of the current evidence base and practical guidance and advice on best practice in respect of over 350 topics consisting of 1000 clinical presentations or patient scenarios. These topics cover the most significant and commonly occurring presentations in primary care and the clinical content is continually monitored and reviewed, supported by a network of over 6000 expert reviewers. More than 65 topics will be updated each year as significant new evidence emerges and up to 10 new topics will be added.

The service is 100% funded by NICE, independent of the pharmaceutical industry and is provided solely by NICE to users within the UK. CKS topics are written and updated by an expert multidisciplinary team within Clarity Informatics Ltd with experience of primary care, supported by a network of over 6000 specialist external reviewers. Updates are triggered by the publication of new or updated NICE guidance or other important new evidence, new or updated national policies, safety information and changes to product licenses and device availability

CKS provides detailed up-to-date clinical knowledge on common acute and chronic diseases and disease prevention, providing answers to clinical questions at the point of decision making, supporting continuous professional development and learning as well as the development of local protocols and care pathways.

The processes used to generate CKS topics [have been accredited by NICE](#)

[Feedback on published topics or to suggest a new topic](#)

[Express an interest in being involved in the development of CKS topics](#)

Governance

Editorial Policy

The editorial process used by Clarity to develop and maintain CKS topics aims to ensure that the content is accurate, up-to-date and of high quality. It provides an overarching authoring plan which defines topic selection, work programme planning, literature searching, evaluating and selecting evidence, expert and user review, and publishing. The editorial process is approved by the CKS Editorial Steering Group.

Editorial Steering group

The Editorial Steering Group approves the processes by which:

- New topics are identified and prioritized;
- Topics are developed, including
 - Identifying and gathering the evidence
 - Selecting the evidence
 - Appraising the evidence
 - Summarizing the evidence and developing recommendations
 - External review
 - Content is kept up-to-date.

In addition, the Editorial Steering Group will advise:

- On a course of action when specific clinical content or recommendations are contentious (for example when the views of experts are strong and polarized, or when service availability is an issue);
- On implementation and adoption of clinical topics.

The Editorial Steering Group is made up of members that are representative of the target audience and include GPs, pharmacists, nurses, healthcare librarians, patient representatives and lay members.

Declaration of interest policy

Clarity request that all those involved in the writing and reviewing of CKS topics, and those involved in the external review process to declare any competing interests. Signed copies are securely held by Clarity Informatics and are available on request with the permission of the individual. A copy of the declaration of interest form which participants are asked to complete annually is also available on request. A brief outline of the declarations of interest policy is described here and full details of the policy is available on the Clarity Informatics website (<https://cks.clarity.co.uk>).

Declarations of interests of CKS authors are not routinely published, however competing interests of all those involved in the topic update or development are listed in the *Declarations* section in *How this topic was developed?* for each topic.

Competing interests include;

- Personal financial interests
- Personal family interest
- Personal non-financial interest
- Non-personal financial gain or benefit

Although particular attention is given to interests that could result in financial gains or losses for the individual, competing interests may also arise from academic competition or for political, personal, religious and reputational reasons.

An individual is not obliged to seek out knowledge of work done for, or on behalf of, the healthcare industry within the departments for which they are responsible if they would not normally expect to be informed.

Who should declare competing interests?

Any individual (or organization) involved in developing, reviewing, or commenting on CKS clinical content, particularly the recommendations, should declare competing interests. This includes CKS authoring team members, expert advisers, lay members, external reviewers of draft CKS topics, individuals providing feedback on published CKS topics, and Editorial Steering Group members.

Declarations of interest are completed annually for authoring team and editorial steering group members, and are completed at the start of the topic update and development process for external stakeholders.

Work programme

An up-to-date programme of work is maintained to plan the specific activities of the authoring team and to inform external reviewers and stakeholders. This is refined and updated on a monthly basis and takes into account planned reviews of CKS topics and new topics for development.

Planning topic updates

Every CKS topic is fully reviewed and updated at least every 5 years which involves re-scoping, identifying and selecting the best available evidence and reviewing and updating recommendations and background information. Each updated topic is quality assured by an internal and external review process, and finally published on the NICE CKS website within 5-years of its creation or date of the last full review.

In the following circumstances a full review of a CKS topic is planned before 5 years:

- If the systematic literature surveillance process ('horizon scanning') identifies compelling clinical information that triggers a substantive review and update of the knowledge (for example newly published NICE guidance, NHS Health Technology Appraisals or national policy from the Department of Health).
- If specific enquiries or feedback trigger a substantive review and update of the knowledge.

To identify factors that will trigger an early full review we:

- Analyse and monitor the NICE guideline and technology appraisal programme to identify relevant topics and expected publication dates.
- Identify national policies or initiatives.
- Consider user feedback.

Developing new topics

New CKS topics are added in line with the contractual requirements with NICE which includes up to 10 new topics per year. Topics are selected, after discussion with NICE, to meet the requirements of users and to support national policies and initiatives. A series of

meetings are held by the Topic Development Panel to discuss the development of new topics each year which take into consideration the following;

- Enquiries sent to NICE CKS
- Hot topics
- GP curriculum
- New NICE clinical guidelines
- New pressures affecting primary care as highlighted by the Department of Health and Public Health England

The panel include members from NICE representing primary care, public health and pharmacy, as well as the medical director, project manager and senior pharmacist from Clarity Informatics. Areas of consideration include;

- Public health and social care
- Rare and significant conditions
- Clinical conditions where this is a shift towards management in primary care
- User feedback

In addition, new topics are added whenever there is capacity in the work programme to do so. A list of potential new topics is maintained which considers:

- Topics searched for on the NICE website for which there is no matching CKS topic.
- Primary care implementation of NICE guidance.
- Support of national policies (for example, identification of people with carbon monoxide poisoning by the DH).
- Requests received by users of the service.

Writing the clinical content

The clinical knowledge in each CKS topic is:

- Relevant to primary and first contact care.
- Provided at an appropriate level of detail for the key user groups.
- Presented through text that answers a set of clinical questions.
- Consistently structured in defined sections.
- Written in a consistent and professional style.
- Easily readable for healthcare professionals.

To ensure that the knowledge provided is relevant to - and at an appropriate level of detail for healthcare professionals working in primary and first contact care, Clarity:

- Scope each clinical topic using the clinical experience of the authoring team, feedback collected from users of the NICE CKS service and the current GP curriculum.
- Review each topic within the authoring team using GPs, pharmacists, lay members, and a Clinical Editor.
- Collate and assimilate comments received from external review of each CKS clinical topic by professionals that represent the community of users.

To ensure that the clinical topics are consistently structured in defined sections, Clarity:

- Have defined the structure of the topics in an XML schema and have represented this in the content management system to support authoring.
- Have defined what to write where in a number of easy to follow documents.

- Review each topic internally (i.e. within the authoring team) involving GPs, lay members, pharmacists, and a Clinical Editor.

To ensure that the text of each topic specifically answers the clinical questions, is written in a consistent and professional style, and is easily readable for a range of healthcare professionals working in primary and first contact care Clarity Informatics:

- Have developed and maintain the CKS writers' guide, a 'style' and 'effective writing' manual for authors to follow.
- Provide ongoing training in effective writing for the authoring team using alternate week 10 minute mini-sessions and formal training courses as required.
- Review each topic internally (i.e. within the authoring team) involving GPs, pharmacists, lay members and a Clinical Editor.
- Include proof-readers who undertake their own review and cross-checking process.

Topic development

Scoping

The content of each CKS topic aims to meet the knowledge needs of CKS users who are principally healthcare professionals in primary care (GPs, GP registrars, and nurses), pharmacists, and medical librarians. The purpose of the scope is to:

- Decide what the CKS topic will cover and what it will not cover. In particular:
 - Decide on the sex, age, and comorbidities of the population.
 - Identify key clinical issues.
 - Whether complementary and alternative therapies will be considered.
- Facilitate the development of the search questions for identifying the best available evidence.
- Outline the structure of the CKS topic by defining the set of scenarios and clinical questions that are relevant to the clinical practice of the CKS target audience.

The scope of each topic is defined by a meeting of the CKS authoring team which includes healthcare professionals with experience of primary care, lay members, and information specialists. To define the scope, the team considers:

- Their own experience of clinical practice.
- The previous scope of the topic (if the topic is 'time-expired' and being reviewed).
- Guidelines on which the CKS topic may be based.
- User/stakeholder feedback.
- The GP curriculum.
- Observations of primary care question and answering services.
- The time allocated in the work programme to develop or update a CKS topic.

Literature search

Clarity's approach to searching the literature employs a systematic, structured search protocol along with carefully developed search strategies and techniques in order to retrieve comprehensive, high quality information which form the basis of the CKS clinical recommendations.

A dynamic approach to searching is employed throughout the development, or updating, of each CKS topic so that the clinical author is able to request searches at any time to ensure that they are basing all recommendations on the best-available evidence.

The goal is to achieve a balance between sensitivity and precision, not aiming to replicate a conventional systemic review of all published material, rather to identify up-to-date, robust, high quality clinical evidence, which can be assessed by clinical authors to provide the best supporting evidence for best clinical practice.

Creating the clinical questions and scenarios

The content of CKS topics is presented to the users by posing and answering clinical questions which are grouped under scenarios. The authors use the information from the scoping meeting to:

- Define the scenarios and clinical questions that will form the framework on which the recommendations, basis for recommendations and supporting evidence will be presented to the users. These are then circulated for comments and agreed by the Clinical Editor.
- Develop clear and focused search questions that guide the information specialists in literature searching.

Specific clinical questions, particularly about management, are developed for each scenario in the clinical topic following the scoping meeting. Even then there is a framework for considering these questions which includes:

- Assessment
- Treatment, including in children or in pregnancy/breast feeding if appropriate
- Follow-up
- Referral/seek specialist advice
- Advice/self-care advice
- Treatments available in secondary care
- Use of complementary and alternative therapies
- Prescribing information Literature search

Developing the search questions

Appropriately detailed and specific search questions facilitate the process of identifying the evidence.

- The authors and information specialist assigned to the CKS topic use the clinical questions to develop detailed and specific questions that can be used for literature searching (the search questions).
- The search questions are developed using the PICOT framework — P (population), I (intervention) and C (comparison), O (outcome), and T (time: short-term or long-term).
- Associated synonyms and search terms for the search questions are also listed.
- A specifically designed form is used to facilitate and document the process.

Identifying the evidence

CKS clinical topics are developed and updated using the best available evidence. High quality secondary evidence from NICE accredited resources (for example, NICE guidance and Cochrane systematic reviews) is identified first, and primary research and expert opinion sought where necessary.

The CKS authors reliably assess the evidence identified by the structured literature review so that the recommendations can be formulated from the best available evidence and the

limitations of the evidence base are appreciated. To ensure that the CKS authoring team is appropriately skilled, Clarity:

- Encourage attendance at a formal critical appraisal training course as part of the induction process and at other times if appropriate.
- Provide in-house mini-training sessions every other week and longer training workshops as appropriate.
- Train some members of the team to 'expert' or tutor level.
- Encourage individuals to continually identify and address their own learning needs and professional development through an appraisal process.
- Provide easily accessible learning resources and appraisal checklists.

The best available evidence is selected to formulate recommendations and provide accurate background information (for example, on incidence and prevalence).

- Where available, CKS summarizes high quality guidance in which recommendations have been rigorously developed using appraised and synthesized studies (for example, NICE guidelines). Guidelines are assessed for quality by the clinical authors using the principles outlined by the AGREE II.
- Where high quality guidance is not available to answer a CKS clinical question, the best available evidence is selected by the clinical authors from the literature identified by the information specialists. The best available evidence for a CKS topic:
 - Depends upon the type of clinical question being answered.
 - Have outcomes that are clinically relevant and patient-centred rather than disease-centred.
 - Has the lowest risk of bias.
 - Is generalizable to the scenario/clinical question being answered.

Formulating recommendations and linking to the evidence

Each recommendation is based on an interpretation of the best available evidence and balances the health benefits against the risk of harm.

- Where NICE (or other) accredited guidance has been identified by the structured literature review, the recommendations from the source guidance are incorporated into CKS.
- Where high quality NICE accredited guidance is not available, recommendations are formulated by interpreting the best available evidence and balancing the benefits of an intervention with the risk of harm, noting that:
 - Ideally this should be done quantitatively, comparing the average expected benefit with the average expected harm
 - Where this information is not readily available from the literature and the effort to synthesize this information from a number of different sources will be resource intensive, balancing benefits and risks of harm is done qualitatively.
- The different options for management are presented to users in the recommendations. The preference of each option is indicated where possible (such as alternative, first-line, second-line) or advice to help users choose between the available options is provided where possible.
- Recommendations reflect known variability of service availability.
- Cost-effectiveness data from credible sources is used to formulate recommendations, but CKS does not undertake a formal economic analyses. Studies

However, studies are selected and evaluated on whether the intervention under investigation may have an impact on local clinical service provision or a national impact on cost for the NHS. The principles of clinical budget impact analysis are adhered to, evaluated and recorded by the author. The following factors are considered when making this assessment and analysis.

- Eligible population
 - Current interventions
 - Likely uptake of new intervention
 - Cost of the current or new intervention mix
 - Impact on other costs
 - Condition-related costs
 - In-direct costs and service impacts
 - Time dependencies
- The link between the evidence and the recommendation is made explicit in the *Basis of recommendation*. The Basis of recommendation outlines issues such as the type and quality of evidence, consistency of effects across studies, the degree to which the trial evidence is applicable and whether the recommendation is based on high quality guidance (such as NICE guidelines) or national policies and initiatives.
 - Each recommendation is reviewed internally by other CKS authors and the Clinical Editor to quality assure:
 - The link from the summarized trial evidence (where available) to the recommendation is rational and adequately described in the *Basis for recommendation*.
 - The recommendation is consistent with recommendations in other CKS topics of related subject areas.
 - Recommendations are reviewed externally by experts to ensure that the interpretation of the evidence and the balancing of benefits and risks of harms is accurate.
 - It will sometimes be necessary to seek the advice of experts to formulate a recommendation when the CKS authors do not have sufficient evidence or expertise to do so. This is most likely to occur when evidence is lacking or where there is uncertainty (e.g. where treatment effects are inconsistent across trials or the quality of the evidence is poor) and there is no published best practice or expert consensus to guide management.

Linking to the evidence

CKS recommendations are designed to be specific, unambiguous, easily identifiable, quick to read, easy to understand, and practical to follow. Each clinical question about management is answered by a clear recommendation (or set of recommendations), and it is clear to users:

- Why the recommendation was made (that is, the move from the evidence to the recommendation), and
- What is the quality of the evidence on which the recommendation is based, and
- What is the strength of the recommendation — would most healthcare professionals and patients choose to follow the intervention (strong recommendation), or are patient values likely to vary, or does service availability vary with geographical location (weak recommendation)?
- Each clinical question about management is answered by a clear recommendation (or a group of recommendations) that links to Basis of recommendation

- The structure of clinical questions and answers (recommendations, *Clarification/Additional information*, and *Basis of recommendation*) and the *Supporting evidence* sections are defined in an XML schema and represented in the CKS content management system to facilitate authoring.
- The link from each recommendation to the underpinning evidence is reviewed internally by CKS authors and a Clinical Editor (at an internal review meeting) to ensure that the step (or move) from the summarized trial evidence (where available) to the recommendation is logical and adequately described in the *Basis of Recommendation*.
- The links from the recommendations to the evidence are reviewed externally by experts.
- Professional copy-editors undertake their own review and cross-checking process of the links from the recommendations to the evidence.

Citing the evidence and linking to source documents

Recommendations and important factual information are clearly referenced in CKS topics. The Harvard style for citing references is used in CKS topics; as compared with other citation formats this provides the most information at the point of citation itself.

Where possible, a link to the full text of the source document is provided.

Editing and proofing

Each CKS topic is checked for clinical relevancy and accuracy, clarity, readability, typographical errors, and consistency with the CKS writers guide before it is sent for external consultation and before it is issued on to the website.

Clinical editing

For each clinical topic, the Clinical Editor reviews the set of clinical questions for relevancy and completeness. This is done before the authors of the clinical topic start writing the answer to these questions. The Clinical Editor suggests amendments and approves the final list.

The Clinical Editor and CKS authors review each topic at an internal review meeting when the draft is at an advanced stage, for clinical accuracy, clarity, style and structure. Following the internal review meeting the Clinical Editor checks the amendments before the topics are posted for external review.

Before issue onto the website, the Clinical Editor reviews each topic after it has been signed-off by the authors, for clinical accuracy, clarity, style and structure.

General editing and proofing

Each clinical topic is reviewed by non-clinical copy-editors with experience of medical writing to ensure a professional style that is consistent with the CKS writers guide and that the text is typographically correct, clear and easily readable.

Editing takes place after the CKS topic has been amended to incorporate the feedback from external reviewers (where appropriate).

Validation

Each CKS topic is validated from a clinical and technical perspective before being uploaded to NICE.

Validating the clinical content

- For new and substantively updated topics, the Clinical Editor considers the number and the quality of the comments received from the stakeholders that have participated in the external review, and the proposed response from CKS to each comment.
- Difficult or contentious comments are discussed between the Clinical Editor and the authors, and a decision is made whether to escalate specific issues to the Editorial Steering Group for a decision about what action should be taken.

Technical validation

- Each CKS topic is validated against the appropriate XML schema, classification, and container element structure.
- Prior to release, all topics are checked by an automated validator against a list of expression search strings and corrections made. Expressions relate to compliance with markup and presentation standards, as well as simple corrections recommended by the style guide.
- Manual checking of the work programme release set by the Technical Author in line with the style guide, technical standards and markup consistency takes place. A detailed process description outlines the verification and validation processes, and the technical means in which they are implemented. Manual checking takes place on a dedicated staging website.
- The Technical Author rereleases topics to implement corrections and re-runs the validator to verify all corrections.
- Detailed checklists of actions and quality assurance routines are executed for each clinical topic.
- The Technical Author communicates directly with the topic authors, and the Clinical Editor to resolve any outstanding issues.
- The Technical Author may present a post-release report to the Project Manager and Authoring team, to advise of any common errors and issues with the dataset.

Providing information on drugs

Clarity has a detailed CKS drug choice policy which outlines the process for including drug information in CKS topics.

Clarity selects and recommends drugs or devices, where appropriate, for the management of a condition and includes sufficient information to support the safe administration of, or writing of a prescription for, the selected drugs or devices. Prescribing details are not included for every possible product that might be appropriate to prescribe as (a) presenting a large number of possible products to prescribe can be overwhelming and as such does not support decision making and (b) these are listed in the BNF. The number of choices that the prescriber has is generally limited to five (maximum seven) at any one level of decision making.

- In each 'scenario' up to five (maximum seven) 'therapy groups' will be included.
- In each 'therapy group' up to five (maximum seven) 'prescriptions' will be included (for each age range).

In addition it is Clarity's policy to:

- Recommend generic products except where the Medicines and Healthcare products Regulatory Authority recommend the use of branded products, for example for modified-release products.
- Use the Recommended International Non-proprietary Name (rINN) (identical to the British Approved Name [BAN]), for drugs.
- Clearly indicate whether the use of the drug is licensed, off-label or unlicensed.
- Indicate if the drug or device is 'Black Triangle' (that is, under surveillance from the Commission on Human Medicines).
- Provide the NHS cost and an estimate of the over-the-counter cost of the prescription. This information is updated when the CKS topic is fully reviewed (It may be possible in future to automatically update this information using the Dictionary of Medicines + Devices (DM+D) database).

Providing prescribing information in CKS topics

- Detailed information to help healthcare professionals choose the most appropriate drug or device for an individual is included in the *Management* section of each CKS topic and is in a question and answer format with links to the evidence base.
- A *Prescribing information* section in each topic provides information about:
 - Which drug to choose if there is a range of drugs within a class that are potentially suitable
 - Dose — if the dose recommended is not the standard dose in the BNF.
 - How to administer or use the drug or device — if there is important information to highlight or if the information is not available in the BNF.
 - Formulation — if relevant to discuss.
 - How to manage important contraindications and cautions, adverse drug reactions, and drug interactions.
 - Safety warnings.
 - Drug monitoring.

Topic updates

The CKS service provides users with information and guidance that supports current best practice and national policy. Publication of new or updated NICE guidance and other key national policies, safety information and changes to the availability of recommended drugs and devices will trigger an update to CKS topics.

Note that evidence from primary research, particularly where only one trial is available will be handled with caution and only in compelling circumstances will it trigger an unscheduled update to the knowledge base. This caution is necessary because a significant number of clinical trials report results, or draw conclusions, that are found in subsequent trials to be exaggerated or invalid.

Triggers for updating

An update to a CKS topic can be triggered by:

- Publication of national guidance and 'secondary' evidence. This includes new or updates to existing NICE guidelines, Cochrane systematic reviews, NHS Health Technology Assessments or existing authoritative guidelines or systematic reviews produced by organizations other than NICE and Cochrane.
- Safety alerts for example from the Commission on Human Medicines.
- New national policies or changes to existing national policies for example, the introduction of a new test to diagnose heart failure (BNP or N-terminal pro-BNP).

- Publication of compelling new primary evidence. Each article is assessed for clinical relevance and each clinically relevant article is further assessed for validity.
- User or expert feedback on published CKS topics.
- The availability of drugs and devices.

To identify new evidence, new national policy, new safety alerts, and changes to product availability and licences, a group of individuals within the CKS authoring team have responsibility for:

- Scanning key journals regularly.
- Subscribing to relevant newsletters/bulletins, RSS feeds, and alerting services.
- Reviewing user or expert feedback on published CKS topics.
- Utilizing an external systematic literature surveillance service that continuously surveys more than 500 journals (directly or indirectly), 10 journal review services, the National Guideline Clearing House, the National Institute for health and Clinical Excellence, the Cochrane Database of Systematic Reviews, and the NHS Health Technology Assessment Programme.

Type of update

- A rolling programme for fully reviewing CKS topics every 5 years is maintained, with the exception of *Immunizations - seasonal Influenza* and *Influenza - seasonal* which are updated annually and where a NICE clinical guideline exists for a CKS topics - these are reviewed in line with the NICE Clinical Guideline update schedule.
- If a CKS topic requires updating ahead of schedule, the decision whether the update should be 'full' or 'interim' is made by the Clinical Editor and the CKS Update Group — a group of individuals (doctor, pharmacists, information specialists) from the CKS authoring team tasked to identify triggers for updates through a literature surveillance programme and manage minor updates.
 - An earlier, rather than a later, full review of a CKS topic is triggered when a substantive review of the evidence, and/or update of the recommendations, and/or change of scope is identified.
 - An interim update is appropriate if only a limited review of the evidence is required, and/or a small number of the recommendations require updating, and/or a specific key area (addressed by one or two clinical questions) needs to be covered by the update.
- Where an update to a CKS topic is not considered necessary, a reference to the article (with a hypertext link to the abstract or free full text) may be included in the Knowledge update section of a CKS topic.

Knowledge update

Each CKS topic provides a section that lists new evidence and information that has become available since the last full review and update of the topic.

- Systematic literature surveillance of journals, journal review services, The National Guideline Clearing House, NICE and the Cochrane Database of Systematic Reviews allows guidelines, systematic reviews, and primary research to be identified on a continuous basis. In addition availability of drugs and devices; licence changes to drugs and devices; safety alerts; and policies from the Department of Health and the Health Protection Agency are surveyed.

- Each item identified is screened by the Update team to see if it should trigger an update to the CKS topic. If an update is not necessary the Update team screen the item to see if it should be included in a Knowledge update.
- Articles included in a Knowledge update are not formally appraised for quality.
- Once a decision has been made to include an item in a Knowledge update the reference with hypertext links to the abstract or free full text is added under the following headings:
 - New evidence:
 - Evidence-based guidelines.
 - HTAs (Health technology assessments).
 - Economic appraisals.
 - Systematic reviews and meta-analyses.
 - Primary evidence.
 - New national policies.
 - New safety alerts.
 - Changes in product availability.

Timing of updates

- Scheduling of the update is determined by considering safety and clinical importance, the resources required (time and personnel), and on-going work.
- If there is an issue of safety about any CKS content, an update will be issued as soon as possible on the same day the problem was raised. If this is not practical, either the relevant clinical question and related information or the whole topic will be withdrawn.

Stakeholder involvement

External consultation

The external review process is an essential part of CKS topic development. Consultation with a wide range of stakeholders provides quality assurance of CKS topics in terms of:

- Clinical accuracy.
- Consistency with other providers of clinical knowledge for primary care.
- Accuracy of implementation of national guidance (in particular NICE guidelines).
- Usability.

Principles of the consultation process

- The process is inclusive and any individual may participate.
- To participate, an individual must declare whether they have any competing interests or not. If they do not declare whether or not they have competing interests, their comments will not be considered.
- External reviewers are not paid for commenting on the CKS draft topics.
- A guidance document is available to the external reviewers to aid the review.
- Discussion with an individual or an organization about the CKS response to their comments is only undertaken in exceptional circumstances (at the discretion of the Clinical Editor or Editorial Steering Group).
- All reviewers are given the opportunity to feedback about the CKS external review process, enabling improvements to be made where appropriate.
- External reviewers may also be asked specific questions about recommendations in the draft CKS topic.

- Questions to reviewers are posed when CKS authors do not have sufficient knowledge or expertise to make, or be reasonably confident about, a recommendation.
- Questions to reviewers are most likely to be posed when evidence is lacking or where there is uncertainty (because treatment effects are inconsistent across trials or the quality of the evidence is poor) and there is no published best practice or expert consensus to guide management.
- The questions are agreed during an 'internal' review of the draft CKS topic prior to the external review process and signed off by the Clinical Editor.
- The responses to the questions to reviewers are handled in a similar way to other comments that are received from external reviewers.
- Further consultation with external reviewers (limited to one or two recommendations) may be undertaken when reviewers have provided conflicting feedback or have raised important issues for which the evidence is lacking.
- Exceptionally, a CKS topic is so considerably amended following external review that a second 'full' consultation is undertaken. The decision whether to consult further with external reviewers is made by the authors and the Clinical Editor.
- Consultation with stakeholders lasts 4 weeks.
- Extensions to deadlines are accommodated whenever possible, particularly where a key professional organization is collating responses from a number of its members.

Stakeholders

- Key stakeholders identified by the CKS team are invited to comment on draft CKS topics. Individuals and organizations can also register an interest to feedback on a specific topic, or topics in a particular clinical area, through the Getting involved section of the Clarity Informatics website (<http://cks.clarity.co.uk/get-involved/>).
- Stakeholders identified from the following groups are invited to review draft CKS topics:
 - Experts in the topic area.
 - Professional organizations and societies (for example, Royal Colleges).
 - Patient organizations, Clarity has established close links with Age UK and the Alzheimer's Society specifically for their input into new topic development, review of current topic content and advice on relevant areas of expert knowledge.
 - Guideline development groups where the CKS topic is an implementation of a guideline.
 - The British National Formulary team.
 - The editorial team that develop MeReC Publications.
- Reviewers are provided with clear instructions about what to review, what comments are particularly helpful, how to submit comments, and declaring interests.

Lay member and patient involvement

Clarity has developed a literature search that is used to identify published studies, both qualitative and quantitative, that reflect patients' and carers' experiences and preferences in relation to the clinical topic. A number of sources of patient experiences is listed within the *Search Protocol* of each topic.

Clarity has enlisted the support and involvement of patients and lay persons at all stages in the process of creating the CKS content including;

- Topic selection

- Scoping of topic
- Selection of clinical scenarios
- First draft internal review
- Second draft internal review
- External review
- Final draft and pre-publication

Our lay and patient involvement consists of two elements;

- Expert patient groups and associations, currently Age UK and the Alzheimer's Society.
- A group of lay individuals who are completely independent of CKS to provide their insights and experience of healthcare.

These lay individuals are called upon at all stages noted above and their involvement is documented as part of the authoring process of all CKS topics. It is particularly important in the creation of the clinical scenarios within the CKS topics to ensure that we do not inadvertently omit questions or issues which are of key importance to a lay audience.

The Editorial Steering group includes of two patient representatives and a lay member who are involved in overseeing the processes used to develop and update CKS topics and available where contentious issues arise.