

Database of Cancer Uncertainties (DoCU)

DRAFT PROCESS MANUAL

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Introduction

This draft process manual has been developed to support CoCanCPG members to identify uncertainties for submission into DoCU.

The draft manual describes a step-by-step approach to identifying uncertainties; capturing them; reviewing the list of uncertainties; and populating the DoCU through formal contributions on a web form. It also outlines the subsequent steps in development for prioritisation and promotion.

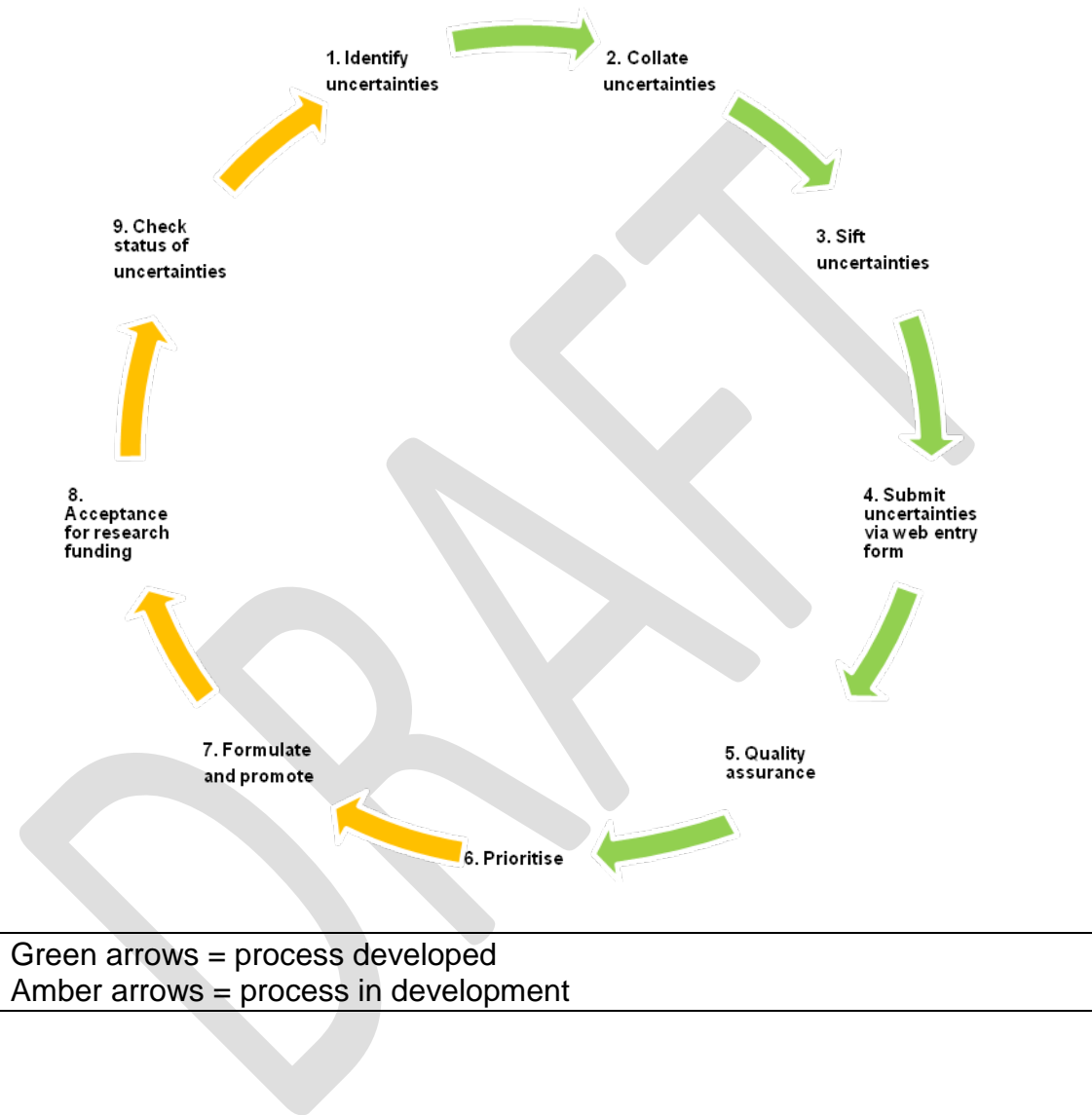
A published NICE clinical guideline for lung cancer¹ was used as an example to develop the manual.

This draft process incorporates all objectives described in the database proposal paper that were agreed by consortium members (see Appendix 1).

The uncertainty life-cycle

The process that we are aiming for with this project is illustrated in Figure 1.

Figure 1: Complete life-cycle in identifying uncertainties



Step 1: Identify uncertainty

- Step 1 involves reviewing the cancer guidance in full, to identify uncertainties or research recommendations arising from them. Experience has indicated that it is unlikely that all the uncertainties will have been translated into research recommendations.
- The uncertainties may be related to any aspect of cancer management and there are different types of uncertainties. Examples are provided in Boxes 1 and 2.
- Uncertainties may be identified during the process of healthcare by patients, carers and clinicians, or during primary research (for example a clinical trial may raise more research questions). Uncertainties may also be identified during secondary research, for example during guideline development, systematic reviewing or economic modelling.
- Either a manual or electronic search process can be used to identify the uncertainties but they may yield different results. The electronic search strategy is in development and therefore in the interim period a manual search strategy is preferred. There are a number of common phrases which may indicate an uncertainty (for a full list see Appendix 2).

Box 1: Example sources of uncertainty¹

Uncertainties that can arise include:

- clinical effectiveness
- cost effectiveness
- diagnosis
- implementation
- appropriate outcome measurement
- accuracy of a test
- clinical prediction rules
- prognosis
- identification/attribution of adverse events
- patients' experiences
- service delivery

Box 2: Examples of different classes of uncertainty

Class 1: There is no evidence available because:

- a. the relevant research has not been done
- b. the relevant research has been done but not published
- c. the relevant research has been done but the searches have failed to identify it.

¹ This list is not exhaustive and will be developed further

Class 2: Existing evidence is available but:

- a. the publication contains insufficient information due to inadequate reporting
- b. the research has been undertaken but is not methodologically robust
- c. the research has been undertaken but the results were inconclusive
- d. the research has been undertaken but the study enrolled too few patients to be sure statistically that the results were not due to chance
- e. research into the question has been undertaken but the results cannot be applied to the population in question (for example, the setting is not comparable, the patient population differs, a different dosage of drug has been used)
- f. research has been undertaken into a related but different question (for example the comparator differs)
- g. the research is out of date – a systematic review needs updating with recent trials, or clinical practice has changed for example
- h. the research cannot be understood due to inappropriate reporting or language difficulties.

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Table 1: Examples of common phrases that may indicate uncertainties

Text from guideline
'further research is needed'; 'research is required'; 'research should be conducted' ...
'we identified no evidence'; 'there is no evidence'; 'inconsistent evidence'...
'few studies have been published in this area'; 'none of the studies considered'; 'too few studies'...
'we identified no trials'; 'be informed by later trials'; 'there are few...trials'
'no data'; 'there is little data'; 'data is at times conflicting'
'no conclusions can be made'; 'no conclusions can be drawn'
'did not break down the results sufficiently' ; 'due to inconsistency of the results'

Step 2: Collate uncertainties

- Extract all identified uncertainties/research recommendations from the cancer guidance.
- Put all identified uncertainties/research recommendations into a table. The suggested format for the data collection table is provided in Appendix 3 for this exercise. Supporting text for the field names are provided to enable the correct information to be placed under each field heading (see Appendix 4).
- The activities from Step 2 should generate a long list of all cancer uncertainties from the guidance document.

Step 3: Sift uncertainties

- From the list remove duplicates.
It may be necessary to rephrase some uncertainties if they do not indicate a clear standalone uncertainty (i.e. if supporting text from different parts of the guidance is required).
- Go through each uncertainty that remains on the long list and where possible break them down based on the PICO formula (Population; Intervention; Comparison; Outcome) formula.
- Review all uncertainties according to completeness of the PICO formula.

Further input may be required from the guideline developers for those uncertainties that do not have a full PICO breakdown.

- From the long-list, a short-list of uncertainties should be produced for entry into the database. This short list should contain those uncertainties that have a complete PICO breakdown.

Step 4: Submit uncertainties via web entry form into DoCU

- The shortlist of uncertainties should be transferred (i.e. copy and pasted) from the data collection table to the web entry form on the NICE website.
- For the purposes of the pilot, to do this you must:
 - Be an existing member of the CoCanCPG. If not, you must go through to the coordinating organisation within your country (i.e. CoCanCPG member (see Appendix 5). If there is no coordinating organisation within your country, contact the CoCanCPG DoCU administrator (NICE).
 - Register/log-in to the contributors section of the online DoCU, through 'Submit an uncertainty' link..
 - Add uncertainty, and then 'save this form for later' (if incomplete) or 'submit' (completed form).

Step 5: Quality assurance of submitted uncertainties

- Email alerts notify the DoCU administrator of new uncertainties that have been submitted.
- Each uncertainty will be checked for completeness by the database administrator. If necessary, the administrator may contact individual who submitted the uncertainty for further information.
- Once accepted, the uncertainties will become live to view on the website.

Step 6: Prioritisation of submitted uncertainties

- The prioritisation process is in development.

Step 7: Formulate and promote

- Once the uncertainty has been identified as a priority by the collaboration it will need to be formulated into a coherent recommendation for research. Potential funders will need to be identified and the research recommendations will need to be promoted to the funders.
- This process is in development.

Step 8: Research accepted by research funder/ research collaboration

Step 9: Check status of uncertainty

- In order to ensure that DoCU is kept up to date it will be necessary to ensure that there is a process established to track the status of the prioritised uncertainties and to ensure these uncertainties are re-assessed in guidance review. It is anticipated that this will include literature searching/review of ongoing research databases and communication with the contributor organisation.

References

1. National Collaborating Centre for Acute Care. The diagnosis and treatment of lung cancer. London: National Collaborating Centre for Acute Care, 2005.

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Appendices

Appendix 1: CoCanCPG DoCU proposal

Appendix 2: Common phrases indicating uncertainty

Appendix 3: Template for DoCU data collection

Appendix 4: Database fields

Appendix 5: CoCanCPG members

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Glossary

Uncertainty: an absence of certainty: a state of having limited knowledge where it is impossible to exactly describe existing state or future outcome.

Research recommendations: all unanswered research questions that emerge during the development of guidance, developed into recommendations for further research.

Relevant research: can include any primary or secondary research, which will include clinical trials, literature/systematic reviews.

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