



Database of Cancer Uncertainties (DoCU)

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*National Institute for
Health and Clinical Excellence*

CoCanCPG Symposium

European Network on Clinical Guidelines Development



SIXTH FRAMEWORK
PROGRAMME

Introduction

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Aim(s) of the project

General aims (as per the proposal for the database):

- To focus new cancer research on uncertainties that have been identified as high priority across Europe.
- To create a European Network to accelerate the commissioning process, overcome fragmentation and avoid duplication of effort.

Specific aim (as per the database development specification):

- To develop a database of uncertainties in the management of cancer that have been identified during guideline development



Objectives

- Objective 1: To harness the guideline development process to identify uncertainties
- **Objective 2: To create a web-based European-wide relational database to facilitate the collation and tracking of the uncertainties**
- Objective 3: To establish a process to allow the uncertainties to be prioritised
- Objective 4: To translate uncertainties into research recommendations
- Objective 5: To promote the research recommendations to potential researchers and funders of research
- Objective 6: To establish a process to track the status of the identified uncertainties



Release of the database

- CoCanCPG Database of Cancer Uncertainties was released on Tuesday 20 October 2009
- Went live on the NICE website:

<http://www.nice.org.uk/aboutnice/howwework/researchanddevelopment/cocancpg.jsp>



Statistics in the first few weeks

Site and page visits:		
No. of times people have visited the site:		890
No. of times people have visited the search page:		641
No. of searches carried out by:	free text:	11
	topic/sub-topic:	20
	search all:	34
No. of people who have visited 'submit an uncertainty' page:		112



The uncertainty life-cycle



Step 1: Identify uncertainty

- Definition of Uncertainty:
‘an absence of certainty: a state of having limited knowledge where it is impossible to exactly describe existing state or future outcome.’
- Identify ‘raw’ uncertainties
- Apply manual searching technique



Examples of common terminology

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



Step 2: Collate uncertainties

- Extract identified uncertainties

An example:

‘Future research based on randomised controlled trials is needed to compare the effectiveness and cost-effectiveness of different follow-up strategies. The studies examined follow-up of lung cancer patients only after resection. There was no evidence on follow-up after chemotherapy, radiotherapy, combination therapy or palliative care.’

- Populate template as guide to data collection
- Long list generated



Data collection template

Template for DoCu data collection																									
ID	Source				Origins			Location		Record							Research Question					Metadata	Priority		
ID No.	Guidance	Guidance ID	Guidance Type	Guidance Version	Issue Date of Guidance	Country	Partner Organisation Name	Page no. or /Link	Paragraph heading	Identified 'uncertainty'	Type of uncertainty	Why is there uncertainty?	Why is it important to support this uncertainty for research?	Topic	Sub-topic	Submission date of uncertainty first on website	Suggested study type	Population	Intervention	Comparator	Outcomes	Formulated research question	Metadata	Is this a priority?	Why is this a priority?
	The Diagnosis and Treatment of Lung Cancer	CG024	Clinical Guideline	Full	Feb-05	NICE	UK	115	11.6.2.1	Studies conducted during the 1970s and 1980s on the effectiveness of PCI provide limited data due to the lack of statistical power of the randomised data. In addition, these studies were based on patients with complete response judged by chest x-ray. A systematic review was retrieved and there were no RCTs to update this evidence.	Uncertainty	No evidence	Clinical effectiveness	Lung	Lung	Automated	randomised controlled trials	patients with complete response	PCI	chest x-ray	effectiveness of PCI		No		
	The Diagnosis and Treatment of Lung Cancer	CG024	Clinical Guideline	Full	Feb-05	NICE	UK	111	1.8.3	Further research is needed into whether the use of low-dose CT in early diagnosis of patients at high risk of developing lung cancer has an effect on the mortality of lung cancer. A randomised trial should compare no intervention with low-dose CT performed at baseline and then annually for 5 years.	Research recommendation	Uncertain Existing evidence	prognosis	Lung	Lung	Automated	randomised controlled trials	patients at high risk of developing lung cancer	low-dose CT	none	effect on mortality of lung cancer		No		



Step 3: Sift uncertainties

- Remove duplicates from long list
- Break uncertainty down in PICO format
- Review uncertainty for completeness of PICO
- Shortlist will contain full PICO breakdown



Step 4: Submit uncertainties via web entry form into DoCU – registration and log-in



- Register to NICE website
- Log-in using registration details
- Apply for access to the Database of Cancer Uncertainties
- Complete form with details and save
- Await automated email confirmation or directly from DoCU administrator
- Logout and log-in again
- Should be taken straight to the 'Submit an uncertainty' form



Step 4: Submit uncertainties via web entry form into DoCU



CoCanCPG DoCU Submission - Windows Internet Explorer provided by NICE

http://www.nice.org.uk/aboutnice/howwework/researchanddevelopment/cancer.jsp

NICE NHS Evidence

Submit an uncertainty

Please complete the form shown to submit a new uncertainty to the Database of Cancer Uncertainties. Incomplete submissions may be rejected by the database administrator. Please provide all available details. All submissions are subject to approval prior to being shown on the web site. An incomplete uncertainty may be 'saved' for further editing prior to final submission by clicking the 'Save this form for later' button at the bottom of the screen.

Items shown with an asterisk (*) are required.

ID 19

Submission date Oct-09

* Guidance

* Issue date of guidance (October-09)

* Country (Please select one)

* Partner organisation name (Please select one)

* Page/Link

* Paragraph no. or heading

* Identified uncertainty

* Type of uncertainty (Please select one)

CoCanCPG DoCU Submission - Windows Internet Explorer provided by NICE

http://www.nice.org.uk/aboutnice/howwework/researchanddevelopment/cancer.jsp

Quality and Outcomes Framework

Quality standards

NICE International

* Type of uncertainty (Please select one)

* Why is there uncertainty?

No evidence available:

- No research has been identified

Uncertain existing evidence:

- The publication contains insufficient information due to inadequate reporting
- The research has been undertaken but is not methodologically robust
- 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)
- Research has been undertaken into a related but different question (for example the comparator differs)
- The research is out of date - for example a systematic review needs updating with recent trials, or clinical practice has changed
- The research cannot be understood - due to inappropriate reporting or language difficulties.

Other reasons for why there is uncertainty

* Why is it important to support this uncertainty for research? (Please select one)

Supporting information



Step 4: Submit uncertainties via web entry form into DoCU

A screenshot of a web browser window titled "CoCanCPG DoCU Submission - Windows Internet Explorer provided by NICE". The address bar shows the URL "http://www.nice.org.uk/about/nice/howwe/work/researchanddevelopment/cancer.jsp". The form contains several fields: "Topic" (dropdown menu), "Sub-topic" (dropdown menu), "Suggested study type" (text input), "Population" (text area), "Intervention" (text area), "Comparison" (text area), and "Outcome" (text area). The browser's taskbar at the bottom shows the Windows Start button and several open applications including "User IDs - Micros...", "Appendices", "Microsoft PowerP...", "CoCanCPG DoCU...", and "Draft DoCU proce...".A screenshot of the same web browser window, showing the final part of the form. It includes a "Formulated research question" text area, a "Is this a priority" dropdown menu, and a "Why is this a priority" text area. At the bottom of the form, there are two red buttons: "Submit" and "Save this form for later". Below the buttons, there is a "Data protection" section with a link to "Back to CoCanCPG home". At the very bottom of the page, there is a footer with links for "Accessibility", "Cymraeg", "Freedom of Information", "Data Protection", "Copyright", "Disclaimer", and "NHS Choices", along with a copyright notice: "Copyright © 2009 National Institute for Health and Clinical Excellence. All rights reserved." The browser's taskbar is identical to the previous screenshot.

Step 5: Quality assurance of submitted uncertainties



- Email alerts notify CoCanCPG DoCU administrator:
 - New registered users
 - New submitted data (completed forms)
 - New comments about uncertainties
- CoCanCPG DoCU administrator:
 - Checks details of registered users before acceptance
 - Checks details of new uncertainties (for completeness of form population) for acceptance or return to contributor
 - Checks content of comments for acceptance or rejection
 - Publishes uncertainties and comments on the website

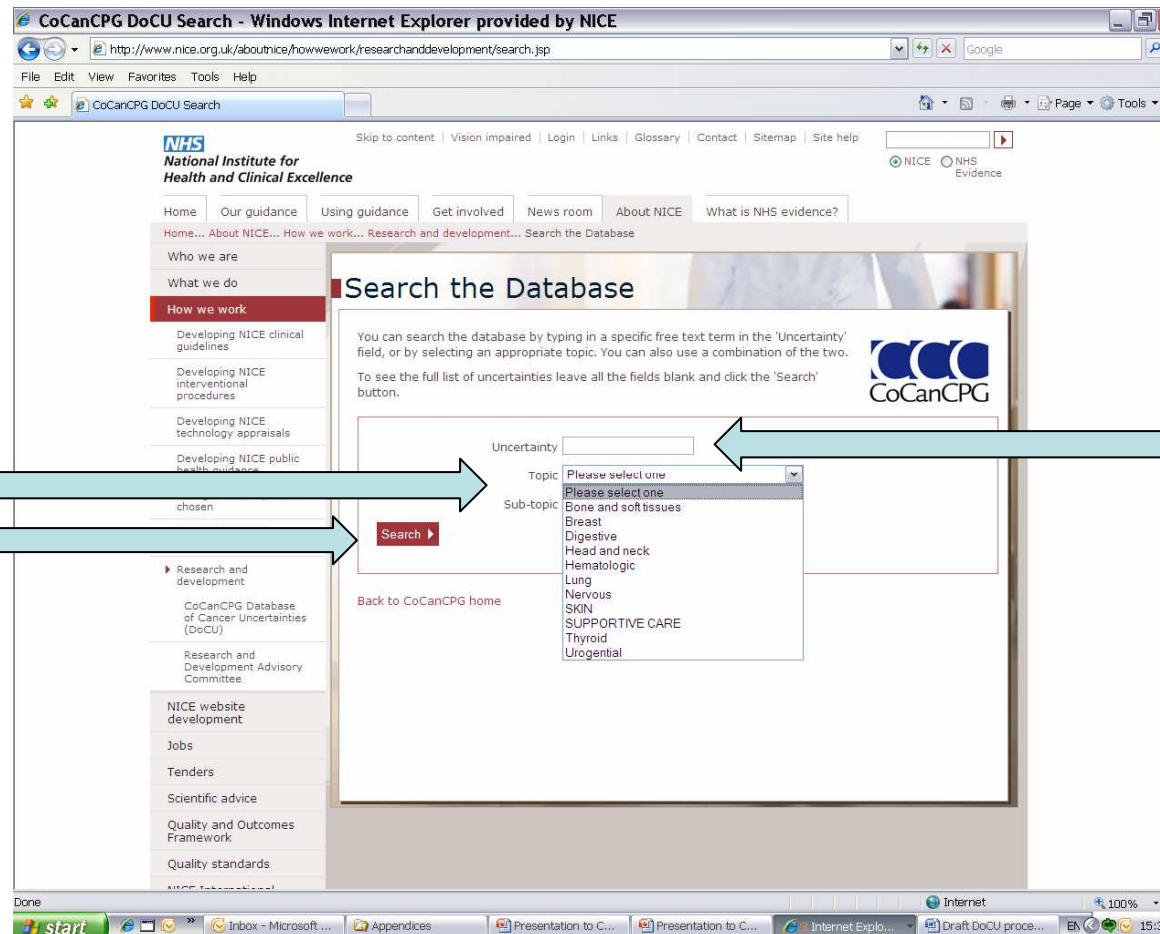


Steps 6 to 9: In development

- Step 6: Prioritisation of submitted uncertainties
- Step 7: Formulate and promote
- Step 8: Research accepted by research funder/
research collaboration
- Step 9: Check status of uncertainty



Search the database



By: free-text

By: topic/sub-topic filters

By: search all



Search results

List of results:

- ID
- Issue date of uncertainty
- Topic
- Identified Uncertainty
- Why is there uncertainty?
- Why is it important to support this uncertainty for research?

CoCanCPG DoCU Search - Windows Internet Explorer provided by NICE

http://www.nice.org.uk/aboutnice/howwe/work/researchanddevelopment/search.jsp

CoCanCPG DoCU Search

Search results

Results 1-10 of 18

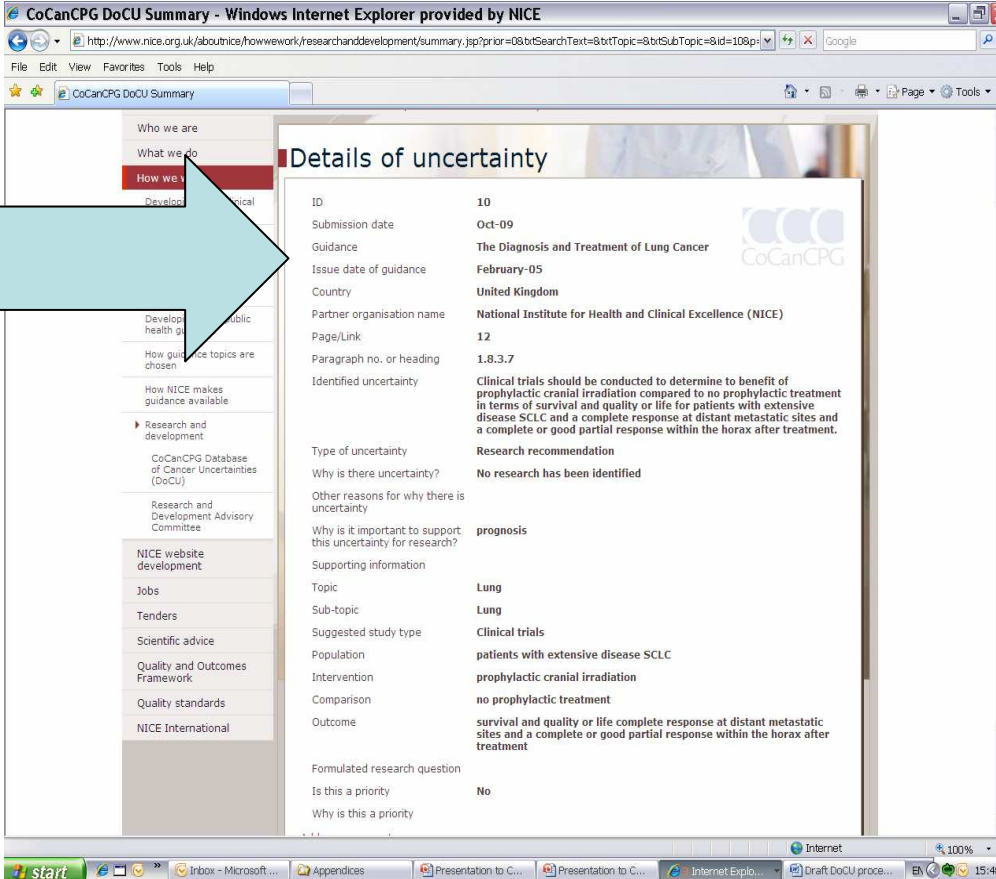
ID	Issue date of uncertainty	Topic	Identified uncertainty	Why is there uncertainty	Why is it important to support this uncertainty for research?
10	February-05	Lung	Clinical trials should be conducted to determine to benefit of prophylactic cranial irradiation compared to no prophylactic treatment in terms of survival and quality of life for patients with extensive disease SCLC and a complete response at distant metastatic sites and a complete or good partial response within the horax after treatment.		
12	February-05	Lung	For patients who have had attempted curative treatment and have completed their initial follow up, trials should examine the duration of follow-up and whether regular routine follow up is better than symptom-led follow-up in terms of survival, symptom control and quality of life.	The research has been undertaken but is not methodologically robust	clinical effectiveness
8	February-05	Lung	Further large-scale prospective trials should be conducted into the effect on survival and quality of life of postoperative radiotherapy compared to surgery alone in the treatment of completely resected stage III NSCLC patients.	The research has been undertaken but is not methodologically robust	prognosis
3	February-05	Lung	Further research is needed into whether chemotherapy or active supportive care result in better symptom control, quality of life and survival for patients with advanced NSCLC of performance status 2.	The research has been undertaken but is not methodologically robust	clinical effectiveness
16	February-05	Lung	Further research is needed into whether chemotherapy or active supportive care result in better symptom control, quality of life and survival for patients with advanced NSCLC of performance status 2.	The research has been undertaken but is not methodologically robust	clinical effectiveness
2	February-05	Lung	Further research is needed into whether the use of low-dose CT in early diagnosis of patients at high risk of developing lung cancer has an effect on the mortality of lung cancer. A randomised trial should compare no intervention with lowdose CT performed at baseline and then annually for 3 years.	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)	prognosis

Filter:
'Identified uncertainty'



Details of individual record

Output screen:

ID	10
Submission date	Oct-09
Guidance	The Diagnosis and Treatment of Lung Cancer
Issue date of guidance	February-05
Country	United Kingdom
Partner organisation name	National Institute for Health and Clinical Excellence (NICE)
Page/Link	12
Paragraph no. or heading	1.8.3.7
Identified uncertainty	Clinical trials should be conducted to determine to benefit of prophylactic cranial irradiation compared to no prophylactic treatment in terms of survival and quality of life for patients with extensive disease SCLC and a complete response at distant metastatic sites and a complete or good partial response within the horax after treatment.
Type of uncertainty	Research recommendation
Why is there uncertainty?	No research has been identified
Other reasons for why there is uncertainty	
Why is it important to support this uncertainty for research?	prognosis
Supporting information	
Topic	Lung
Sub-topic	Lung
Suggested study type	Clinical trials
Population	patients with extensive disease SCLC
Intervention	prophylactic cranial irradiation
Comparison	no prophylactic treatment
Outcome	survival and quality of life complete response at distant metastatic sites and a complete or good partial response within the horax after treatment
Formulated research question	
Is this a priority	No
Why is this a priority	



Launch of the database

- Press release prepared
- Each partner can take away and apply to own organisation/country
- NICE preparing official launch at its annual conference in December 2009



What next?

- Steps 6-9 are in development and being progressed
- More uncertainties will be added to the database from:
 - NICE Prostrate Cancer Clinical Guideline
 - NICE Research Recommendations on Cancer topics
- Consortium partners to confirm their contributions and add directly to database via the web entry form

