

Development of
**The Database of Uncertainties about the Effects of
Treatments (DUETs)**
A resource to help prioritise new research
September 2004 – January 2006

**Mark Fenton, Editor,
Hazim Timimi, Systems Developer
Iain Chalmers, Coordinator**

Background

There are many important uncertainties about the effects of treatments. Some of these uncertainties are inevitable: for example, it is very rarely possible to be absolutely certain what the effects of a particular treatment will be in a particular patient. Sometimes uncertainties about the likely effects of treatments can be reduced by systematically reviewing relevant research. Often, however, either no relevant up-to-date systematic reviews exist, or such reviews make clear the existing evidence leaves room for unacceptable uncertainty. To help ensure that treatments are likely to do more good than harm, it is this last category of uncertainties that need to be identified and considered for further research.

Not infrequently, however, research on the effects of treatments fails to address questions that matter to patients and those who care for them - lay and professional. For example, when patients, rheumatologists, physiotherapists and general practitioners were asked to identify their priorities for research on the management of osteoarthritis of the knee, there was little enthusiasm for the studies of drugs that the pharmaceutical industry typically supports. Instead, patients and clinicians wanted more rigorous evaluation of the effects of physiotherapy and surgery, and better assessment of the educational and coping strategies that might help patients to manage this chronic, disabling and often painful condition (Tallon et al. Lancet 2000; 355: 2037-40).

The Database of Uncertainties about the Effects of Treatments (DUETs) has been established to help those prioritising new research to take account of those patients', carers' and clinicians' questions about the effects of treatments which cannot be answered by referring to up-to-date systematic reviews of existing research evidence. Access to the Database is at <http://www.duets.nhs.uk>.

DUETs was conceptualised during the summer of 2004, after a decision had been taken to establish the James Lind Alliance (JLA), to encourage patients and clinicians to work together to identify and prioritise unanswered questions about the effects of treatments (see <http://www.lindalliance.org>). The James Lind Initiative (JLI) provides the Secretariat for the James Lind Alliance at the Summertown Pavilion in Oxford, and the JLI responded to an invitation from the National Knowledge Service to apply for funding to help develop DUETs (**Annexe 1**). The JLI convened a Development Group, with wide representation, to guide the development of DUETs, and this group met for the first time on 23 September 2004 (**Annexe 2**).

At this and subsequent meetings on 13 December 2004, 11 April 2005 and 16 January 2006, the DUETs Development Group established and received reports from working groups (i) to guide the formulation of questions about the effects of treatments for inclusion in DUETs; and (ii) to develop guidelines for improving the presentation of proposals for further research in systematic reviews and clinical guidelines. The membership of the working groups and the reports they prepared for consideration at the April 2005 meeting of the DUETs Development Group are at **Annexes 3 and 4**.

Funding received through the National Knowledge Service permitted commissioning of software development by Update Software (Hazim Timimi) and the appointment of a part-time editor for DUETs (Mark Fenton) from May 2005 until 31 March 2006. A request for extension of this support until 31 December 2006 has been submitted (**Annexe 5**).

The Welsh Office for Research and Development has indicated some interest in supporting the development of DUETs. After discussions in Cardiff and Oxford involving members of the DUETs editorial team and co-applicants in Wales, several applications were submitted or drafted during 2005 (**Annexe 6**). WORD is currently considering a bid for a development officer to work on developing DUETs as part of a proposed programme of work from the Mental Health Research Network Cymru.

Identifying unanswered questions about the effects of treatments

Although many organisations exist to provide information for patients and clinicians about the effects of treatments, it is important to note that admission of uncertainties about the effects of treatment among information providers is uncommon. We have not encountered any example of enquirers being referred to ongoing clinical studies addressing unanswered questions of interest to them.

Our operational definition of uncertainty is either that no up-to-date systematic review exists, or that an up-to-date systematic review shows that uncertainty still exists. A systematic review is considered to be up to date if it has been published or updated within the previous two and a half years.

Questions from patients and carers are identified from information helplines. These provide answers to enquiries about clinical uncertainties of treatment, or the effects of treatment, to patients or carers.

Uncertainties from clinicians are identified from clinical guidelines where recommendations for further research have been made, indicating continuing uncertainty, or from Clinical Question and Answering Services (CQASs). Where questions have been asked of a CQAS, we used our previously stated operational definition of uncertainty to decide if a question was eligible for entry onto DUETs.

Research recommendations, or calls for submission of research proposals for example by NICE and The NHS Health Technology Assessment Programme, are used to identify uncertainties from research. Uncertainties from systematic reviews are also included in this section of DUETs. An uncertainty in a systematic review is

identified by a confidence interval which includes the value of one, or of an outcome the systematic review reported that it wished to answer but found no evidence to either confirm or refute effectiveness of an intervention.

Searches are also undertaken to identify any relevant ongoing studies which may be addressing the uncertainty.

Content (December 2005)

DUETs currently contains unanswered questions about the effects of treatment contributed from several sources. The current content of DUETs mainly reflects the first JLA Working Partnership, which involves Asthma UK and the British Thoracic Society, and concerns the identification of priorities about treatments for asthma (**Annexe 7**). Currently we have questions from:

Patients: Asthma UK Adviceline; NHS Direct (Wales).

Carers: Asthma UK Adviceline

Clinicians: ATTRACT; National Library for Health Primary Care Question Answering Service; Department of General Practice, University of Groningen, The Netherlands

Uncertainties identified in clinical guidelines and systematic reviews: Scottish Intercollegiate Guidelines Network (SIGN)/British Guideline on the Management of Asthma; BMJ Clinical Evidence; Cochrane Airways Group; National Institute for Health and Clinical Excellence.

Questions being addressed in ongoing research: Current Controlled Trials

Each question entered in DUETs is assigned to one of following categories:

- No systematic reviews identified
- Relevant, up-to-date systematic reviews do not address continuing uncertainties about treatment effects
- Existing relevant systematic reviews need updating
- Up-to-date systematic reviews have revealed important continuing uncertainties about treatment effects

Recommendations in DUETs are thus for (i) new systematic reviews; or (ii) extending or updating existing systematic reviews; or (iii) further research. Examples of questions and recommendations currently in DUETs are shown in **Annexe 8**.

Database development

The software for assembling and interrogating DUETs has been developed by Hazim Timimi at Update Software, who has had frequent meetings with the DUETs editorial group, as well as with some members of DUETs Treatment Questions Working Group. The design of the database reflects input from discussions at these meetings. Although we do not now envisage any major change in the current content and format of the database and website, DUETs will continue to evolve in the light of

feedback, and Update Software will continue to provide programming and maintenance for the website, at least until 31 March 2006.

Members of DUETs Working Group 1 have formally appraised DUETs and their helpful feedback has been taken into account.

Future development of DUETs

A major challenge in identifying patients' questions about the effects of treatments is the widespread unwillingness to admit uncertainties about treatment effects. For example, contrary to our initial expectations, NHS Direct may not be a ready source of unanswered patients' questions about the effects of treatments. People who contact NHS Direct because they need advice on how to respond to symptoms are advised by clinicians following protocols. Other enquirers may be passed onto a Health Information Specialist, and it was questions posed by this group that we had envisaged as a source of patients' questions for inclusion in DUETs. Having worked closely with NHS Direct (Wales), however, it is becoming clear to us that this may not be a good source of unanswered questions after all. The Information Specialists working with NHS Direct see their role as providing information, not admitting uncertainty and acknowledging that there is inadequate information on which to base confident advice.

The initial model for populating DUETs with unanswered questions has been for the Editor (a mental health nurse with substantial informatics experience) to seek out what were initially thought to be 'low hanging fruit' – through NHS Direct, clinical question answering services, and existing patient help lines. Although this model of development has helped to populate DUETs with questions about the treatment of asthma - the focus of the first attempt to establish a James Lind Alliance (JLA) Working Partnership - it has limitations. In particular, although the DUETs Editor can provide methodological and information searching skills, he is necessarily hampered by his lack of specialist clinical knowledge of asthma.

Extending the content of DUETs

Other JLA Working Partnerships will provide the opportunity to test other models for populating DUETs. As part of the development of DUETs, and as a pilot project to establish the most productive model of populating the database, the JLA Asthma Working Partnership is reviewing the most recent asthma treatment guidelines to establish the best way to improve on their current content. As currently conceptualised, clinical guidelines exist to make treatment recommendations, not to identify treatment uncertainties or recommend research priorities for addressing these uncertainties.

To pilot methods for developing and managing a DUETs module in a field in which he has specialist knowledge, Mark Fenton will work with others to develop a DUETs module for schizophrenia. This work will be done in collaboration with colleagues in the Mental Health Research Networks in England and Wales (**Annexe 9**), Rethink (formerly the National Schizophrenia Fellowship), HAFAL, Mind Cymru, the Sainsbury Centre for Mental Health, and those involved in developing a lay-friendly register of clinical trials in mental health (**Annexe 10**).

We have also had relevant discussions with the NICE Guidelines Team, the NHS Health Technology Assessment Programme, and some of the emerging National Clinical Research Networks, all of which have identified uncertainties through their research prioritisation processes.

These experiences will make clearer what resources are needed to populate and manage each module in the DUETs database. Current suggestions are that at least three editors should assume responsibility for ensuring the relevance and currency of the content of each DUETs module, endeavouring to ensure that the interests of patients, clinicians and health service management are all taken into account.

Devolving the management of DUETs

DUETs has attracted considerable interest, not to say enthusiasm, in spite of the fact that little has been done to draw attention to its existence. This suggests that, although only currently in a pilot phase, it is wise to consider now how the management, editing and updating of the database as it expands might be integrated with other initiatives of the National Knowledge Service. It should certainly continue to be developed in close association with the National Clinical Question Answering Services, and it may be that the responsibility for managing DUETs modules should be assumed by other groups, for example, the Specialist Libraries in the National Library of Health.

**Annexes to Report of the Development of
The Database of Uncertainties about the Effects of Treatments (DUETs)**
A resource to help prioritise new research

- Annexe 1:** National Knowledge Service Project Brief
- Annexe 2:** DUETs Development Group meeting 23 September 2004
- Annexe 3&4:** DUETs Development Group meeting and papers presented April 2005
- Annexe 5:** National Knowledge Service Project Brief Extension Dec 2006
- Annexe 6:** Welsh Office for Research and Development applications 2005
- Annexe 7:** James Lind Alliance Asthma Working Partnership
- Annexe 8:** Examples of questions and recommendations currently in DUETs
- Annexe 9:** Welsh Mental Health Research Network
- Annexe 10:** Database of Lay friendly trials in Mental Health Minutes of Meeting

NKS PROJECT BRIEF

Programme Title	Database of Uncertainties about the Effects of Treatments (DUETs)		
	<i>Section 1.01</i>		
Objectives	The Database of Uncertainties about the Effects of Treatments (DUETs) is being created to capture and classify questions about the effects of treatments which cannot currently be answered satisfactorily (using existing systematic reviews), and to provide links to information about ongoing studies addressing these questions.		
Scope	Sources of unanswered questions about the effects of treatments include NHS Direct/NHS Direct Online, ATTRACT, question-answering services for patients in national voluntary organisations, Patient Advice and Liaison Services (PALS), Cochrane Review Groups, the Centre for Reviews and Dissemination, National Institute for Clinical Excellence, and the NHS Health Technology Assessment Programme. A meeting on 23 September 2004 brought together people who can contribute to the conceptualisation and development of DUETs, and working groups were established to develop more detailed plans addressing the following issues (i) Formulating questions about the effects of treatments and other data items for inclusion in DUETs; (ii) Assessing ways of identifying and classifying patients' questions; and (iii) Identifying unanswered questions from systematic reviews and improving the presentation of proposals for further research in reviews. A further meeting has been arranged for 13 December at which more detailed plans for DUETs will be discussed and agreed.		
Description / Purpose	DUETs is being created particularly to help patient and clinician organisation partnerships to identify and prioritise shared uncertainties about the effects of treatments. There will be open access to DUETs through the NHS National Knowledge Service, the website of the James Lind Alliance (JLA), and other gateways.		
	Deliverables / Milestones	Dates	Cost
	1. Outline plans for development of DUETs	31/01/05	None
	2. Specification for pilot version of database	31/03/05	£10,000
	3. Software development	30/06/05	£10,000
	4. Data collection on unanswered questions, prioritizing health problems for James Lind Alliance meetings	30/09/05	£10,000
	5. Public access to DUETs arranged through JLA website and NeLH	Dec 2005	

Benefits / OBC	Existing research information systems do not capture unanswered questions efficiently, leading to unnecessary and unrecognised duplication of research applications and assessment. The information in DUETs will be accessible to question-answering services for patients, clinicians and researchers, and will link to information about relevant ongoing research.
Project Lead & Organisation	Iain Chalmers, James Lind Alliance Secretariat Mark Starr, Update Software Jon Brassey, ATTRACT Paul Glasziou, Dept of Public Health and Primary Care
Funding to be Allocated to	James Lind Initiative (supported by the MRC and the R&D Programme of the Department of Health).
Interfaces	National electronic Library for Health; National Knowledge Service.
Dependencies	Willingness of sources of unanswered questions to co-operate.
Constraints	No technical problems foreseen.
Acceptance Criteria	The database should be searchable by NHS-wide search engines.
Risks	No significant risks identified.
Signed Date	 8 November 2004

DUETs Report Annexe 2

Meeting to discuss a Database of Uncertainties about the Effects of Treatments (DUETs)

A resource to help patients and clinicians identify shared uncertainties
about the effects of treatments

2-4 pm Thursday 23 September 2004

James Lind Initiative (1st floor meeting room)
Summertown Pavilion, Middle Way, Oxford OX2 7LG

Uncertainties about the effects of treatments are reflected in the questions that patients and clinicians bring to question answering services such as NHS Direct and ATTRACT. Some of their questions can be addressed by reference to up-to-date, systematic reviews of reliable research studies. For many other questions, however, information is not readily available. Sometimes this is because no systematic reviews of the relevant evidence have been prepared; sometimes it is because existing systematic reviews have not been kept up to date; and sometimes it is because systematic reviews have shown that uncertainties about treatment effects will not be reduced without further research.

The Database of Uncertainties about the Effects of Treatments (DUETs) is being created to capture and classify questions about the effects of treatments which cannot be addressed satisfactorily using existing systematic reviews. DUETs is being created particularly as a resource to help the patient and clinician organisation partnerships who will identify and prioritise shared uncertainties about the effects of treatments within the context of the James Lind Alliance. However, there will be open access to DUETs through the NHS Natiopanl Knowledge Service, the website of the James Lind Alliance and other gateways.

Actual and potential sources of unanswered questions about the effects of treatments include NHS Direct/NHS Direct Online, ATTRACT, Question-answering services for patients in national voluntary organisations, Patient Advice and Liaison Services (PALS), Cochrane Review Groups, Centre for Reviews and Dissemination, National Institute for Clinical Excellence, and the NHS Health Technology Assessment Programme. This meeting has been convened to bring together people who can contribute to the conceptualisation of how best to develop DUETs.

Meeting agenda

1. Welcome and Introductions
2. Background and James Lind Alliance: Iain Chalmers
3. Clinical Question Answering Services: Paul Glasziou
4. Harvesting unanswered questions about the effects of treatments: Jon Brassey
5. Technical issues in developing DUETs: Mark Starr
6. Potential contributors to a Database of Uncertainties about the Effects of Treatments: All
7. Next steps: Iain Chalmers

Pre-circulated papers

- Introduction, agenda, and list of participants
- Travel directions for Summertown Pavilion
- BMJ editorial on informed uncertainty (Chalmers BMJ 2004)
- Introduction to the James Lind Alliance
- National Clinical Question Answering Services (Glasziou and Rozmovits)
- Just in time information for clinicians (Brassey et al. BMJ 2001)

Participants

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DUETs Report Annexe 3

Report of DUETs Treatment Questions Working Group, April 2005

Jon Brassey (co-convenor), *NLH Question Answering Service & ATTRACT*

Jackie Wickham (co-convenor), *Frances Chinemana, NHS Direct Online*

Paul Glasziou, *Centre for Evidence-Based Medicine*

Nick Hicks, Heather Paisley, *Milton Keynes Primary Health Care Trust*

Katie Sheppard, *Asthma UK*

Mark Starr, *Update Software*

Working group 1 met on 22nd February to take forward and combine the previous work of working groups 1 and 2.

In attendance:

Jackie Wickham

Mig Muller

Mark Starr

Jon Brassey

Apologies received from Paul Glasziou

The group felt that the primary concern of the new group was to combine the previous efforts of the separate groups (group 1 – clinician, group 2 – patient) in relation to classifying the evidence used in answering a question.

We felt that the following was a suitable answer classification system

- 1) SR clear result
- 2) SR unclear result
- 3) RCTs but no SR
- 4) Other relevant evidence
 - a. Consensus/expert opinion
 - b. Dated research
 - c. Non-systematic secondary review
 - d. Other peer-reviewed research
 - e. Other
- 5) No evidence
- 6) Unreferenced guideline

We also felt that each of the above points could be given a 'close but no cigar' assignment. In other words if the question said "I have an 11 year boy with measles should I give drug X" and we found a trial in 12-16 years old we felt that was potentially a pertinent bit of research (ATTRACT would certainly use it!).

Aside from the actual classification we raised a number of other issues:

- 1) We discussed the proposed data fields needed for the actual database. This will need some discussion in order to finalise and actually design the database.
- 2) The issue of how to best handle multiple 'evidence' sources for a particular question. For instance an SR will answer part of the Q and an RCT another part. It had been discussed creating 2 PICOs – we felt this needs some further discussion to clarify exactly how this would work.
- 3) Another discussion point related to how NHS Direct questions might populate DUETs. The primary concern being the unknown potential scale of questions. For instance it appears that NHS Direct get 500,000 contacts per month. Of these 100,000 go through to the health information staff (ie not handled by nurses). Of these around 2-3,000 are sent through to specific information experts who then do a search.

We felt it was sensible to try and pilot any NHS Direct involvement. We're hopeful of securing funding (from the Wales Office for Research and Development) and as such we're hoping to start a pilot shortly (involving NHS Direct Wales).

Another issue that needs resolving is an agreement around any methodology for the pilot.

DUETs Report Annexe 4

Papers prepared by DUETs Research Recommendations Working Group, April 2005

Janet Moody (convenor), Lyn Kerridge, Liz Payne *National Coordinating Centre for Health Technology Assessment*

Klara Brunnhuber, Polly Brown, *BMJ Knowledge*

Kalipso Chalkidou, Jeremy Wyatt, *National Institute for Clinical Excellence*

Mike Clarke, *UK Cochrane Centre*

Julie Glanville, *Centre for Reviews and Dissemination*

Sara Twaddle, *Scottish Intercollegiate Guidelines Network*

Paper 1: Update from group participants on generic guidance to authors on recommendations for further research

1. CRD - update

CRD is planning to update its document '**Undertaking Systematic Reviews of Research on Effectiveness: CRD's Guidance for those Carrying Out or Commissioning Reviews**' (known as CRD report 4 <http://www.york.ac.uk/inst/crd/report4.htm>) during 2005, with a view to publish in 2006. Our section on writing the final report will include guidance on how to write research recommendations. Given the current timetable I would expect that guidance to be very much informed by the work of the DUETS working group, and to take account of the requirements of funding programmes such as the HTA programme, and recommendations from working groups in this area.

You have already abstracted the information from our current report which we are happy to have included in any document you produce. The only other information that I can provide that might help is that DARE abstractors are encouraged to report the review authors' recommendations for research as in the text of the document. If the implications expressed by the authors appear to be inappropriate given the evidence presented in the review the abstractor may point this out. If authors do not make research recommendations we enter the following statement: "The authors do not state any implications for further research". As you probably know this was developed to assist NCCHTA in its research message assessment exercises (many years ago now!).

Julie Glanville

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2. SIGN - *update*

SIGN and Research Recommendations

The evidence-based guidelines developed by SIGN are derived from a systematic review of the scientific evidence. Where there is insufficient evidence to make a recommendation, this is identified in the text. For example, in the recently published SIGN 80 (Management of lung cancer), section 4.1 states that '*no evidence was identified supporting the use of blood tests, eg tumour markers, in the diagnosis of lung cancer*'. This is by no means an unusual situation – many of our guidelines have several unanswered questions even after extensive systematic review.

In addition, all SIGN guidelines include a section on research recommendations. For an example of research recommendations included in our guidelines published during 2003 see <http://www.sign.ac.uk/methodology/ressum2003.html>. We recognise, however, that the choice of research recommendations may be influenced by the views of the guideline development group members and some guidance around this area would be welcomed.

During 2004 the Chair and Director of SIGN met with the Chief Scientist at the Scottish Executive Health Department to discuss ways of linking SIGN research recommendations to funding of research in Scotland. The attached paper from SIGN Council shows the outcome of these discussions.

SIGN would be happy to update its research recommendations document and identify the areas where no recommendations were able to be made.

Sara Twaddle

Director – SIGN

New address from 4 April 2005: 28 Thistle Street, Edinburgh EH2 1EN

Please note new email: sara.twaddle@nhs.net

Paper presented to SIGN Council, November 10 2004

SIGN GUIDELINES - INFLUENCING THE RESEARCH AGENDA

As discussed at SIGN Council on 10th June 2004 (sign-06/04-11.2), SIGN guidelines since 1995 have included a section on recommendations for further research. It was agreed that SIGN should pursue the question of “what happens following these recommendations” with research commissioners and funders, starting with the Chief Scientist Office.

On 24/08/04 the Chair and Director of SIGN met with the Chief Scientist and Director, CSO, to discuss this and other matters. It was agreed that the best way forward was for representatives of SIGN Guideline Development Groups (e.g. GDG Chair and Programme Manager Co-chair) to liaise with the recently-established CSO Portfolio Advisory Groups. These have been established to provide CSO with more specific advice on future investments in priority areas. They have been established in Cardiovascular disease (including diabetes) and Stroke, Cancer, Mental Health and Public Health; 75% of SIGN guidelines currently fall within these 4 NHS Scotland priority areas.

On 27/08/04 the Chair of SIGN attended a meeting of the Cardiovascular and Stroke Portfolio Advisory Group. It was agreed to pilot SIGN/CSO liaison with this group, which is timely because in 2005-6 SIGN's Cardiovascular Guidelines on CHD, PAD and one of the 3 areas of Stroke are being reviewed. Representatives of these GDGs would liaise with the Portfolio Advisory Group during 2005, when the SIGN Guideline research recommendations are drafted. A further meeting between SIGN and CSO (including the Chair of the Cardiovascular Portfolio Advisory Group, Professor David Webb) will be held during 2004 to develop this project.

GDO Lowe
Chair, SIGN

3. NICE - *unchanged*

Dr Kalypso Chalkidou advises: The information contained in the report to the December 2004 DUETs meeting summarises our policy around research recommendations in terms of identifying evidence gaps and formulating research questions. Obviously we have not got that far yet but we are currently waiting to assess the results of this effort from our GDG groups; a rather lengthy process.

NICE has been working closely with the HTA and SDO Programmes to promote NICE research recommendations (RRs).

NICE have developed a Guide and additional checklists to assist guidance authors, particularly in guidelines, in their task of turning evidence gaps they have identified during the systematic review of the evidence base into research recommendations. NICE have been working closely with the Methodology lead in Guidelines on this. A draft of the Guide and checklists are currently under consultation by the national collaborating centres and might change in the near future.

Encouraging research that will reduce uncertainties is required to allow the development of evidence-based guidance in the future. Unfortunately, NICE do not issue our guidance developers with explicit instructions on how to identify these gaps and translate them into RRs or "only in research" recommendations. This is something worth considering introducing in our technical manual. For the time being, they count on the skills of the systematic reviewers in the National Collaborating Centres to identify areas of low quality or no evidence. The results are then presented to their specialists (e.g. clinicians) who with the help of the NCC develop RRs where needed.

From 1 December 2004 NICE launched a Topic suggestion website, providing open access for submitting suggestions of topics for NICE technology appraisal and clinical guidelines work programmes. **Technology appraisals** are recommendations on the use of new and existing medicines and treatments within the NHS, such as medicines, medical devices, diagnostic techniques, surgical procedures and health promotion activities. **Clinical Guidelines** are recommendations on the appropriate treatment and care of people with specific

disease and conditions within the NHS, These are based on best available evidence.

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4. Clinical Evidence – update: See Paper 2, below

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5. Cochrane – update

The relevant guidance on the content of the Implications for research section in Cochrane reviews is very brief. It is in the Cochrane Reviewers Handbook in a couple of places. The Handbook is available within The Cochrane Library and on the internet (from <http://www.cochrane.org/resources/handbook/hbook.htm>).

Relevant excerpts from the current version of the Handbook:

From Alderson P, Green S, Higgins JPT, editors. Cochrane Reviewers' Handbook 4.2.2 [updated March 2004]. In: The Cochrane Library, Issue 4, 2004. Chichester, UK: John Wiley & Sons, Ltd.

Section 9.4 Adverse effects

"Reviewers may wish to comment on how adverse effects should be further investigated in their Implications for Research section."

Appendix 2a

Abstract, Reviewers' conclusions:

".... Important conclusions about the implications for research should be included if these are not obvious."

Main text, Reviewers' conclusions:

"The primary purpose of the review should be to present information, rather than to offer advice. Implications for practice and Implications for research are subheadings in this section. The implications for practice should be as practical

and unambiguous as possible. They should not go beyond the evidence that was reviewed. 'No evidence of effect' should not be confused with 'evidence of no effect'. The implications for research should not include vague statements such as 'more research is needed'. Reviewers should state exactly what research is needed, why and how urgently. Opinions on how the review might be improved with additional data or resources might also be included here."

Suggestions for changes have been made to the Handbook editors and these will be considered during April and May 2005. The draft wording provided for the editors is:

"This section of Cochrane reviews is used increasingly often by people making decisions about future research. You should try to write something that will be useful for this purpose. As with the Implications for Practice, the content of this section should be based on what has gone before within your review and should avoid the use of information that you have not included or discussed within the review.

In preparing this section, consider the different aspects of research, perhaps using types of study, participant, intervention and outcome as a framework. Try to distinguish the implications for how research might be done and reported (for example, the need for randomised trials rather than other types of study, for better descriptions of studies in the particular topic of the review or for the routine collection of specific outcomes), from the implications for what future research should be done (for example, the lack of a continuing need for a comparison with placebo if there is an effective and appropriate active treatment, or the need for comparisons of specific named interventions, or for research in specific types of people.

It is important that this section is as clear and explicit as possible. General statements that contain little or no specific information, such as 'Future research should be better conducted.' or 'More research is needed.' are of little use to people making decisions, and should be avoided."

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Paper 2: BMJ *CLINICAL EVIDENCE*

***Compiled by:* Polly Brown, Publishing Manager, Klara Brunnhuber, Clinical Editor, and David Tovey, Editor, *Clinical Evidence*, BMJ Knowledge, London WC1H 9JR**

Many systematic reviews and guidelines regard it as a low priority task to formulate proposals for further research and either fail to do it altogether or present it in an inconsistent and incomplete way. Assessing these publications for the creation of research syntheses, members of the DUETs Working Group 3 have recognised this problem and are well placed to develop standards and guidance for the analysis and presentation of research gaps, for the benefit of the research community and research funding organisations.

NCCHTA and Clinical Evidence – identifying gaps in the evidence and standardising research proposals

A natural fit exists between the work of the NCCHTA and *Clinical Evidence: Clinical Evidence* systematically assesses the evidence for, and rates the effectiveness of important health technologies, and the NCCHTA requires and takes forward research proposals on health technologies with uncertain effectiveness.

The two organisations have a successful record of collaboration over the last year, with *Clinical Evidence* regularly supplying the NCCHTA with suggestions for future primary research and soon also systematic reviews.

The HTA

The HTA Programme is a national programme aiming to respond to the information needs of all people who use, manage and provide care in the NHS. The programme is dedicated to evaluation and receives its funding from the National Health Service Research and Development Section. It works alongside the Service Delivery and Organisation (SDO) and New and Emerging Applications of Technology (NEAT) Programmes.

The National Coordinating Centre for Health Technology Assessment (NCCHTA), based at the University of Southampton, manages and develops the HTA Programme through five key functions:

- Identifying possible topics for health technology assessment
- Prioritising these
- Commissioning research to meet the priorities
- Monitoring research in progress and assessing reports
- Communicating openly about the processes and publishing products of the programme.

In addition, the NCCHTA continually reviews the programme to make the process of needs-led health technology assessment more effective and efficient.

Clinical Evidence

Clinical Evidence aims to help health professionals and patients make informed decisions about the benefits and harms of preventive and therapeutic interventions. Because its methodology relies on systematically researching the literature in identified clinical areas, it can also highlight areas where more research is needed. For clinical decision-making, *Clinical Evidence* highlights treatments that work, and for which the benefits outweigh the harms, especially those interventions that may currently be underused. It also states which treatments where evidence of benefit is lacking, or for which the harms outweigh the benefits. For the research community, *Clinical Evidence* highlights the gaps in the evidence - areas that currently do not have sufficient good quality randomised controlled trials (RCTs), or lack RCTs that deal with important patient outcomes or populations.

Clinical Evidence is one of a growing number of sources of evidence-based information for clinicians. But it has several features that make it unique.

1. Its contents are driven by questions rather than by the availability of research evidence. Rather than start with the evidence and summarise what is there, it identifies important clinical questions, searches for, and summarises the best available evidence to answer them.
2. It identifies but does not try to fill important gaps in the evidence. In a phrase used by Jerry Osheroff, who has led much of the research on clinicians' information needs, *Clinical Evidence* presents "the dark as well as the light side of the moon". It is helpful for clinicians to know when their uncertainty stems from gaps in the evidence rather than gaps in their own knowledge.
3. It is continuously updated, with full literature searches in each topic every 12 months.
4. The summary page for each topic presents the questions addressed, some key messages, and a list of the interventions covered (in alphabetical order), categorised according to whether they have been found to be effective or not. The categories of effectiveness were developed from one of the Cochrane Collaboration's first and most popular products 'A guide to effective care in pregnancy and childbirth'.

The categories used for effectiveness ratings are explained in the table below:

Intervention	Icon	Description
Beneficial		for which effectiveness has been demonstrated by clear evidence from RCTs, and for which expectation of harms is small compared with the benefits.
Likely to be beneficial		for which effectiveness is less well established than for those listed under “beneficial”.
Trade off between benefits and harms		for which clinicians and patients should weigh up the beneficial and harmful effects according to individual circumstances and priorities.
Unknown effectiveness		for which there are currently insufficient data or data of inadequate quality.
Unlikely to be beneficial		for which lack of effectiveness is less well established than for those listed under “likely to be ineffective or harmful”.
Likely to be ineffective or harmful		for which ineffectiveness or harmfulness has been demonstrated by clear evidence.

Interventions that cannot be tested in an RCT for ethical or practical reasons are sometimes included in the categorisation table and are identified with an asterisk.

Searching and appraising the literature

For each question, the literature is searched using the Cochrane Library, Medline, Embase and, occasionally, other electronic databases, looking first for good systematic reviews of RCTs; then for good RCTs published since the search date of the review. Where no good recent systematic reviews are found, individual RCTs are searched for back to 1966. The date of the search is recorded in the methods

section for each topic. Of the studies that are identified in the search, only a small proportion is summarised. The selection is done by critically appraising the abstracts of the studies identified in the search, a task performed independently by information scientists using validated criteria similar to those of Sackett et al and Jadad. Where the search identifies more than one or two good reviews or trials, those judged to be the most robust or relevant are selected. Where few or no good reviews or trials are identified, other studies are included but their limitations highlighted. Contributors, chosen for their clinical expertise in the field and their skills in epidemiology, review the selection of studies and justify any additions or exclusions they wish to make.

Summarising the evidence, peer review, and editing

The contributors summarise the evidence relating to each question. Each topic is then peer reviewed by the section advisors, by at least two external expert clinicians, and by an editorial committee, including external expert clinicians and epidemiologists. The revised text is then extensively edited by editors with clinical and epidemiological training, and data are checked against the original study reports.

What do we know?

What can *Clinical Evidence* tell us about the state of current evidence-based medical knowledge? What proportion of commonly used treatments is supported by good evidence? What proportion should not be used or used only with caution, and how big are the gaps in our knowledge? An analysis of the 2329 treatments covered in Issue 12 of the printed edition shows that

- 358 (15%) are rated as 'Beneficial',
- 498 (21%) as 'Likely to be beneficial',
- 170 (7%) as 'Trade off between benefits and harms',
- 115 (5%) as 'Unlikely to be beneficial',
- 91 (4%) as 'Likely to be ineffective or harmful',
- 1097 (48%), the largest proportion, as 'Unknown effectiveness' (see figure 1).

Dividing treatments into categories is never easy. It always involves a degree of subjective judgement and is sometimes controversial. *Clinical Evidence* does it because users find it helpful, but judged by its own rules the categorisation itself is certainly of unknown effectiveness and may well have trade offs between benefits and harms. **However, the figures above suggest that the research community has a large task ahead and that most decisions about treatments still rest on the individual judgements of clinicians and patients.**

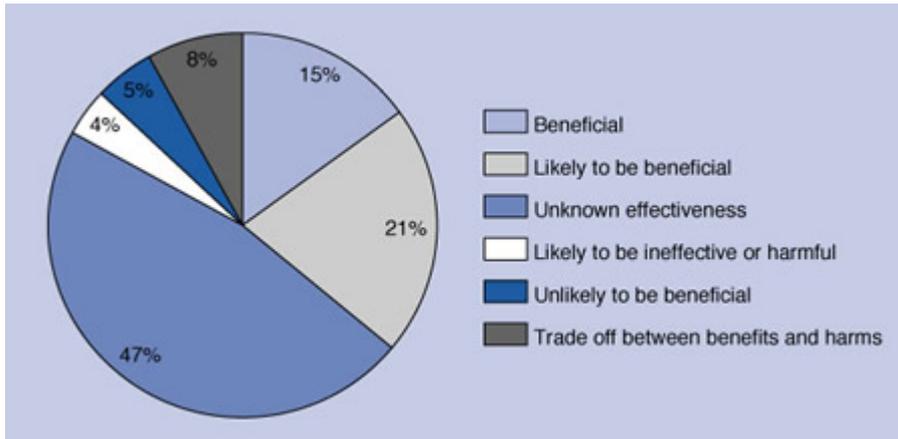


Figure 1.

Flow of knowledge

In a truly knowledge based health system, the flow of knowledge would form a virtuous circle or (as characterised in Figure 2.) a figure of eight. Healthcare providers and patients generate questions during consultations. If there aren't ready answers in evidence based guidelines or handbooks, questions should be assessed by systematic review of the literature. Systematic reviews may identify good evidence to support clinical decisions, in which case this can be fed into practice. If a systematic review finds insufficient evidence to support a clinical decision, this represents a gap in our knowledge base, which should be fed into the research agenda. Ultimately, new research should be incorporated into further systematic reviews and the results of these used to guide practice. And so the cycle continues. The quality of information available at each stage depends on the quality of the information provided by the stage before.

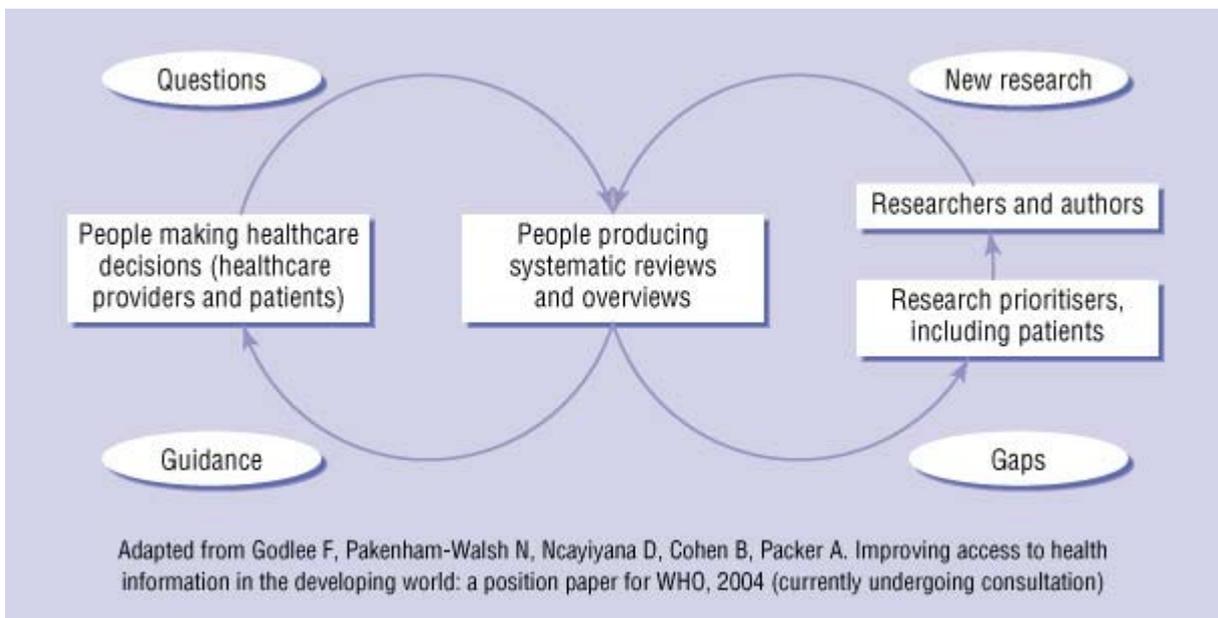


Figure 2.

What is presented in the figure as a unidirectional flow is in reality much more complex. Information flows within and between groups in ways that are now being

characterised as local information cycles. Complete, sustainable information cycles are those in which readers/users are also writers/contributors. Contributions include feedback that can impact on the information. A completely inclusive information cycle exists within the world of academic research, where all authors are readers and all readers potential authors. But information cycles also exist, or can be established, between researchers, systematic reviewers, funders of research, healthcare providers, and patients. These information cycles have the potential to greatly increase the relevance and reliability of information about health care, and to build skills, understanding, and “buy in” that will encourage the use of that information. *Clinical Evidence* and the HTA have been strengthening such information cycles feeding the gaps in the evidence back into the research agenda.

Making suggestions to the HTA

The HTA provides users of its site with excellent guidance about the type of information to be included with a research proposal. The following example demonstrates how existing *Clinical Evidence* content lends itself to covering all areas in a systematic and comprehensive way:

1. The technology or topic you are suggesting

HTA comment:

“Technology” is broadly defined to include diagnostic and screening tests and interventions, new and existing drugs for particular conditions, surgical techniques, therapeutic interventions and specific aspects of nursing clinical care. Your suggestion should be as specific as you can make it.

How Clinical Evidence answers:

Extracorporeal shockwave lithotripsy (ESWL)

2. The patient group and clinical setting

HTA comment:

Give a brief description of the patient group(s) that may benefit from this clinical intervention (technology) and the patient setting(s) where the technology will be used.

How Clinical Evidence answers:

People with asymptomatic renal or ureteric stones

3. Importance to the NHS

HTA comment:

This information is VERY INFLUENTIAL. Prioritisation decisions are made on the basis of clinical indication for the intervention, severity of the condition, epidemiology (incidence, prevalence) and the cost of the technology / intervention.

How Clinical Evidence answers:

Nephrolithiasis is the presence of stones within the kidney; urolithiasis is a more general term for stones anywhere within the urinary tract. A third of all kidney stones become clinically evident; typically causing pain, often severe in nature; renal angle

tenderness; haematuria; or digestive symptoms (e.g. nausea, vomiting, or diarrhoea).[1] The onset of pain is usually sudden, typically felt in the loin, and radiating to the groin, and genitalia (scrotum or labia). People are typically restless, finding the pain excruciating and describing it as the worst pain ever experienced. Severe ureteric obstruction may cause [hydronephrosis](#) or infection. Infection may also occur after invasive procedures for stone removal. Urolithiasis is usually categorised according to the anatomical location of the stones (i.e. renal calyces, renal pelvis, ureteric, bladder, and urethra). Ureteric urolithiasis is described further by stating in which portion (proximal, middle, or distal) the stone is situated. Kidney stones develop when crystals separate from the urine and aggregate within the kidney papillae, the renal pelvis, or the ureter. The most common type of stone contains varying amounts of calcium and oxalate, whereas “struvite” stones contain a mixture of magnesium, ammonium, and phosphate. Struvite stones are associated almost exclusively with infection with urease producing organisms, whilst calcium oxalate stones have several aetiologies. Rarer stones include those formed from uric acid, cysteine, and xanthine, although this list is not exhaustive. The aetiology and chemical composition of a stone may have some bearing on its diagnosis, management, and particularly on prevention of recurrence. Although the choices for surgical management in general remain the same for all types of stone disease, the recognition of a specific cause, such as recurrent infection with a urease producing organism for struvite stones, or cysteinuria for cysteine stones, will inform further management. Diagnosis is usually based on clinical history, supported by investigations with diagnostic imaging. Bleeding within the urinary tract may present with identical symptoms to kidney stones, particularly if there are blood clots present within the renal pelvis or ureter. Several other conditions may also mimic a renal colic and need to be considered for differential diagnosis. These include urinary tract infection (and indeed the two conditions may coexist), analgesic abuse (either renal damage from excessive ingestion of analgesics, or in people with a history of opiate abuse, who may feign a renal colic in an attempt to obtain opiate analgesia). Rarely, people with sickle cell disease may also present with severe abdominal pain, which needs to be distinguished from a renal colic. This chapter assesses the effects of treatments only for the removal of renal and ureteric stones. It excludes pregnant women, in whom some forms of diagnostic procedures and treatments for stone removal are contraindicated, and people with significant comorbidities (including severe cardiovascular and respiratory conditions) who may be at increased risk when having general anaesthesia.

The peak incidence for stone disease occurs at the ages of 20–40 years, although stones are seen in all age groups.[2] There is a male to female ratio of 3 : 1. Calcium oxalate stones, the most common variety, have a recurrence rate of 10% at 1 year, 35% at 5 years, and 50% at 5 years after the first episode of kidney stone disease in North America.

In many otherwise healthy people the aetiology is uncertain.[3] However, incidence is higher in people with hyperparathyroidism and people with disorders including small bowel dysfunction, urinary tract infection (in particular caused by urease producing organisms) and structural/anatomical abnormalities of the kidney and ureter (including obstruction of the pelviureteric junction, hydronephrotic renal pelvis or calyces, calyceal diverticulum, horseshoe kidney, ureterocele, vesicoureteral reflux, ureteric stricture, or medullary sponge kidney). Other conditions associated

with the development of renal stones include gout (especially leading to uric acid calculi) and chronic metabolic acidosis (typically resulting in stones composed of calcium phosphate). Women with a history of surgical menopause are also at higher risk because of increased bone resorption, and urinary excretion of calcium. Drugs, including some decongestants, diuretics, and anticonvulsants are also associated with an increased risk of stone formation.

Most kidney stones pass within 48 hours with expectant treatment (including adequate fluid intake and analgesia). Others may take longer to pass and the observation period can be extended to 3–4 weeks where appropriate. Ureteric stones less than 5 mm in diameter will pass spontaneously in about 90% of people, compared with 50% of ureteric stones between 5 mm and 10 mm.[4] Expectant management is considered on a case to case basis, and only in people with stones which are asymptomatic or very small (although stone size may not correlate with symptom severity), or both, and in people with significant comorbidities (including severe cardiovascular and respiratory conditions, who may be at increased risk when having general anaesthesia), in whom the risks of treatment may outweigh the likely benefits. Stones may migrate regardless of treatment or after treatment for their removal, and may or may not present clinically once in the ureter. Stones blocking the urine flow may lead to [hydronephrosis](#) and renal atrophy. They may also result in life threatening complications including urinary infection, [perinephric abscess](#), or urosepsis. Some of these complications may cause kidney damage and compromised renal function.[5] Eventually, 10–20% of all kidney stones need treatment.

1. Glowacki LS, Beecroft ML, Cook RJ, et al. The natural history of asymptomatic urolithiasis. *J Urol* 1992;147:319–321.
2. Uribarri J, Oh MS, Carroll HJ. The first kidney stone. *Ann Intern Med* 1989;111:1006–1009.
3. Menon M, Parulkar BG, Drach GW. Urinary lithiasis: etiology, diagnosis and medical management. In: Walsh PC, Retik AB, Vaughan ED, et al, eds. *Campbells urology*. 7th edition. Philadelphia: WB Saunders Company, 1998.
4. Segura JW, Preminger GM, Assinos DG, et al. Ureteral Stones Clinical Guidelines Panel summary report on the management of ureteral calculi. *J Urol* 1997;158:1915–1921.
5. Blandy JP, Singh M. The case for a more aggressive approach to staghorn stones. *J Urol* 1976;115:505–506

4. The current evidence base (if known)

HTA comment:

Prioritisation decisions are also informed by existing evidence (or lack of evidence), so any details that you can provide of important (recent) studies or systematic reviews would be helpful.

How Clinical Evidence answers:

Versus conservative management (defined as observation, usually with serial imaging): We found no systematic review but found one RCT (228 people with asymptomatic renal stones < 15 mm in diameter) comparing prophylactic extracorporeal shockwave lithotripsy [ESWL] versus conservative management.[1] People were followed annually for up to 5 years (mean follow up 2.2 years). At the

“most recent” follow up (minimum 1 year of follow up, mean: 1.29 years with ESWL v 1.2 years with conservative management), the RCT found no significant difference in the stone free rate between ESWL and conservative management (28/101 [28%] with ESWL v 16/99 [17%] with conservative management; P = 0.06). It gave no results on outcomes at 5 years. **Versus percutaneous nephrolithotomy:** We found no systematic review or RCTs comparing ESWL with percutaneous nephrolithotomy in people with asymptomatic kidney stones. **Versus ureteroscopy:** We found no systematic review or RCTs comparing ESWL with ureteroscopy in people with asymptomatic kidney stones.

References:

1. Keeley FX Jr, Tilling K, Elves A, et al. Preliminary results of a randomized controlled trial of prophylactic shock wave lithotripsy for small asymptomatic renal calyceal stones. *BJU Int* 2001;87:1–8.

Steps forward

- *Clinical Evidence* to work together with others on developing guidelines and standards for formulating research suggestions based on the EPICOT (evidence, population, intervention, comparison, outcome, timeline) structure
- *Clinical Evidence* to use their contacts and work together with others to identify and collaborate with other research funding organisations
- *Clinical Evidence* to continue supplying the NCCHTA with regular primary research suggestions on relevant interventions categorised as ‘Unknown effectiveness’
- *Clinical Evidence* to supply the NCCHTA with regular research suggestions on relevant interventions that are covered by extensive RCT evidence but no systematic review
- *Clinical Evidence* to explore and develop a ‘Suggestions for further research’ feature for all its topics

PAPER 3: INFORMATION WHICH RESEARCH FUNDERS REQUIRE THE HTA PROGRAMME INFORMATION NEEDS

Compiled by: Janet Moody, NCCHTA, J.Moody@soton.ac.uk, Tel: 023 8059 5756

As a research funder, NCCHTA has many years experience of retrieving recommendations for further research from various sources, including Cochrane reviews and the DARE database.

The NCCHTA webform has been designed to capture information in areas which map fairly closely onto the PICO principle.

NCCHTA webform	PICO
Describe the patient group and health care setting	Patient, Population
Describe the health technology where further evidence or guidance is needed	Intervention or Indicator or Problem
Provide any information you can on existing evidence	Comparison or control
State why this research or evidence is important to the NHS	Outcome

Attached describes potentially useful information from which to make recommendations for further research – using Cochrane and DARE as examples.

1	Highest need	Most likely to be completed
2		
3		
4		
5	Lowest need	Least likely to be completed

The information required has been ranked according to need and the likelihood of information being provided.

Definition of Ranking *

COCHRANE REVIEWS

Would be useful for people who weigh up research recommendations	Currently extracted and entered on HTA webform	Where in Cochrane do we source this data
	Title of review	Title of review
	Research recommendations	Reviewer's conclusions (<i>research implications</i>)
	Author's conclusions from the review	Abstract (<i>conclusions</i>)
	Main results of the review	Normally from Abstract (<i>main results</i>), but may be taken from results in main body of review
	Dates of search for the review	Abstract (<i>search strategy</i>)
	Patient group	Criteria (<i>types of participant</i>) included in the review
	Number of studies in review	Description of studies or Abstract (<i>NB. start and finish dates of searches do not always appear</i>)
	Cochrane Library number	Cover Sheet (<i>Cochrane</i>

Would be useful for people who weigh up research recommendations	Currently extracted and entered on HTA webform	Where in Cochrane do we source this data
		<i>Library number)</i>
BACKGROUND INFO *		
1 how many people affected in the UK		Many reviews include some of this info. in Background, but it is very variable
2 definition 2 causes 2 age-group		
3 rate of increase or decrease of condition		
2 Current practice		May be touched on
4 Suggested outcome measures		
5 impact on QoL		
5 Relative cost info. of eg. different treatments		Sometimes appears in review
5 Likely impact of technology		
5 Research design issues including ethics, plus any controversy in the field		

DARE

DARE records are summaries with a critical commentary on their quality, of systematic reviews published in journals and elsewhere. They are produced by the CRD in York.

Would be useful for people who weigh up research recommendations	Currently extracted and entered on HTA webform	Where in DARE record do we source this data
	Title of review	Title of review or Author's objective
	Research recommendations	What are the implications of the review? <i>(Research)</i>
	Patient group	Participants included in the review
	Conclusions of the review	Author's conclusions
	Results of the review	Results of the review
	Number of studies in review	Number of studies included
	Dates of search for the review	What sources were searched to identify primary studies? <i>(NB. start and finish dates of the searches do not always appear)</i>
	CRD database number	CRD database number
BACKGROUND INFO *		

1 how many people affected in the UK		Can exist in the original publication, but varies considerably (<i>DARE records are summaries with critical commentary about the original publication</i>)
2 definition 2 causes 2 age-group		
3 rate of increase or decrease of condition		
5 impact on QoL		
2 Current practice		May be mentioned in some original publications
4 Suggested outcome measures		
5 Relative cost info. of eg. different treatments		Cost info. not often included – because not often discussed in the original publication
5 Likely impact of technology		
5 Research design issues including ethics, plus any controversy in the field		

DUETs Report Annexe 5

NKS PROJECT BRIEF

Programme Title	Database of Uncertainties about the Effects of Treatments (DUETs)	
Objectives	<p>Request for extension of funding (from 1 April 2006 to 31 December 2006) of the DUETs project brief agreed in December 2004</p> <p>The Database of Uncertainties about the Effects of Treatments (DUETs) has been created to capture and classify questions about the effects of treatments which cannot currently be answered satisfactorily (using up-to-date systematic reviews), and to provide links to information about ongoing studies addressing these questions.</p>	
Scope	<p>Sources of unanswered questions about the effects of treatments include NHS Direct/NHS Direct Online, ATTRACT, question-answering services for patients in national voluntary organisations (eg Asthma UK), question-answering services for clinicians, Cochrane Reviews, the Centre for Reviews and Dissemination, National Institute for Clinical Excellence, NHS Health Technology Assessment Programme and clinical guidelines (eg those prepared by the British Thoracic Society) . Meetings have been held with representatives from the above organisations, who have contributed to the development of DUETs. A further meeting has been arranged for 16 January 2006 at which DUETs will be reviewed, and future development discussed.</p>	
Description / Purpose	<p>DUETs has been created particularly to help patient and clinician organisation partnerships to identify and prioritise shared uncertainties about the effects of treatments. There is already open access to DUETs through the NHS National Knowledge Service (www.duets.nhs.uk) and the website of the James Lind Alliance (www.lindalliance.org).</p> <p>This request to extend funding to cover a further period of 9 months is principally for salary support for the Editor of DUETs, Mark Fenton, so that he can extend the content of DUETs beyond asthma to schizophrenia, and to roll out to others (initially in epilepsy) the methods used for harvesting and incorporating questions in during the pilot phase of DUETs. Some additional support is also requested for software support and modification if necessary.</p>	
	Breakdown of costs	Cost

	1. Salary for DUETs Editor	£17,000
	2. Software development and maintenance	£12,000
	3. Accommodation	£5,000
	4. Stationery, telephone, equipment and IT support and Travel	£3,000
Benefits / OBC	Existing research information systems do not capture unanswered questions efficiently, leading to unnecessary and unrecognised duplication of research applications and assessment. The information in DUETs will be accessible to question-answering services for patients, clinicians and researchers, and will link to information about relevant ongoing research.	
Project Lead & Organisation	Iain Chalmers, Coordinator, James Lind Initiative Mark Fenton, Editor DUETs Hazim Timimi, Update Software Jon Brassey, ATTRACT Paul Glasziou, Dept of Public Health and Primary Care	
Funding to be Allocated to	James Lind Initiative (supported by the MRC and the R&D Programme of the Department of Health).	
Interfaces	National electronic Library for Health; National Knowledge Service.	
Dependencies	Willingness of sources of unanswered questions to co-operate.	
Constraints	No technical problems foreseen.	
Acceptance Criteria	The database is searchable by NHS-wide search engines.	
Risks	No significant risks identified.	
Signed		
Date	November 2005	

DUETs Report Annexe 6a

1 Title of investigation (not exceeding 120 characters including spaces)

Building an evidence base to lay questions about treatment – with respect to asthma, epilepsy and schizophrenia

2 Lay summary (not exceeding 250 words)

A principle aim of NHS Direct Wales/ Galw Iechyd Cymru is ‘to provide advice and information about health, illness and the NHS, so that everyone is better able to care for themselves and their family’ (<http://www.nhsdirect.wales.nhs.uk/>). In many cases users require advice and information about treatment. Such questions are most commonly dealt with by Health Information Advisors. However, a small proportion of such questions are problematic to those who seek to answer them and such questions are usually passed on to health informaticists who use medical search engines to find appropriate answers. Unfortunately the evidence for responses to these ‘problematic’ questions is not always robust.

This project focuses on questions of treatment with respect to three conditions; Epilepsy, Asthma and Schizophrenia. They are ‘patient driven’ questions that originate with the public who contact NHS Direct Wales. We aim to harvest (over a 6 month period) all problem questions relating to the aforementioned conditions that cannot be answered by highest level of evidence (i.e systematic review). After validating that such questions cannot, indeed, be answered using current databases and feeding back all results to NHS Direct, we aim to develop a bank of unanswered questions for lodgement in a central database at DUETS (Database of Uncertainty of the Effects of Treatment). The latter is located at the James Lind Alliance in Oxford. By lodging unanswered questions in the database we identify areas for future research using the highest levels of evidence. We aim to complete this work by March 31st 2006.

3 Start date: October 1st 2005 **End date:** March 31st 2006

4 Relevance to priority policy areas

4a Please indicate whether this proposal is relevant to (i) health or (ii) social care or (iii) both

Health

4b Please indicate which of the priority policy areas (refer to application guidance notes) this proposal addresses

Chronic Disease Management

4c Describe briefly (in no more than 500 words) how this research addresses the priority policy areas that you have indicated above

Asthma, Epilepsy and Schizophrenia are chronic conditions that affect (in varying degrees) members of the Welsh population. Indeed, prevalence rates for asthma are particularly high in Wales and Asthma UK Cymru has suggested that the condition causes almost 30% more hospital cases in Wales than elsewhere. It is clear that all three conditions affect the quality of life of those affected and all three are open to aspects of self-care. Self-care is integral to government health strategy to empower patients to take greater control of their health and well-being. In the realm of chronic disease there are moves to encourage and develop a cadre of ‘expert’ patients. This changes the culture of the NHS from a paternalistic approach to a collaborative approach with doctor and patient being partners in care. This not only relieves demand on scarce resources but benefits patients by improving quality of care. However, for patients to become ‘expert’ they need a strong evidence base and high quality research about all aspects of their condition. This includes evidence about treatment.

As is indicated in *Improving Health in Wales* and *Well Being in Wales* there is a need for evidence-based responses to the management of ill-health, and whilst those documents focus primarily on the evidence base of health professionals the general thrust of the claims apply to patients as much as to professionals. This proposal is aimed at integrating lay knowledge into the research infrastructure. It seeks to do so by integrating patient queries about aspects of treatment – for asthma, epilepsy and schizophrenia – into a database that can, in turn, constitute a valuable resource for those who seek to research and answer questions about treatment using the highest levels of evidence. In that respect, the proposal fits into various strategies for integrating patient interests into the medical research agenda, as well as strategies for lay management of chronic disease. The three conditions that are to be focussed on are intended as a pilot. The researchers expect that after developing a protocol for handling data on epilepsy, asthma and schizophrenia that the strategy can be extended to deal with a far wider range of conditions.

5 Details of Lead Applicant

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Note: All correspondence will be directed to this address

6 Details of Co-applicants (there should be no more than three co-applicants)

Name: Jon Brassey
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Telephone: Fax: Email: ichalmers@jameslindlibrary.org

Name:
Job Title:
Address:
Telephone: Fax: Email:

7 Outline description of project (no more than 1,000 words) - please include title, objectives, methodology, outcomes and staff (refer to application guidance notes for assessment criteria).

Title: Building an evidence base to lay questions about treatment – with respect to asthma, epilepsy and schizophrenia.

Background

Self-care is integral to government health strategy to empower patients to take greater control of their health and health care. As an active, rather than passive process, self-care refers to self-monitoring, self-treatment, and self-management of illness. Such care not only relieves demand on scarce resources but benefits patients by improving quality of care. However, to achieve this requires a strong evidence base and high quality research. The need for a strong evidence base is all the more important in the light of the concept of the expert patient. The Expert Patients Programme (EPP) is based on self management techniques developed by Kate Lorig of Stanford University in the early 1970s and is being introduced into all Primary Care Trusts in England by 2007. A similar programme of lay-led generic self

management courses is being introduced in Wales based on the LHB structure. Two pilot sites were set up in Gwynedd and Swansea LHBs, and the programme is now being rolled out to the rest of Wales.

The engagement of lay people into medical care requires not only expertise but also resources on which to base such expertise. The provision of NHS Direct Wales forms part of such provision, and in most cases the queries that are presented to NHS Direct Staff can be answered with a high degree of confidence and certainty. In some case, however, the queries that arise out of exchanges with the public pose difficulties. This project is directed toward a study of patient driven questions about treatment that cannot be easily answered because of lacunae in the evidence base.

Uncertainties about the effects of treatments are reflected not only in the questions that patients bring to question answering services such as NHS Direct, but also to answering services dealing with questions from health professionals such as ATTRACT (<http://www.attract.wales.nhs.uk>), and the NLH. In many cases questions that come into these services can be addressed by reference to up-to-date, systematic reviews of reliable research studies. For many other questions, however, information is not readily available. Sometimes this is because no systematic reviews of the relevant evidence have been prepared; sometimes it is because existing systematic reviews have not been kept up to date; and sometimes it is because systematic reviews have shown that uncertainties about treatment effects will not be reduced without further research.

Database of Uncertainties about the Effects of Treatments (DUETs) is being created to capture and classify questions about the effects of treatments that cannot be addressed satisfactorily using existing systematic reviews. DUETs is being created particularly as a resource to help the coalitions of patient and clinician organisations identifying and prioritising shared uncertainties about the effects of treatments within the context of the James Lind Alliance. To assemble this database, work is being undertaken with representatives of patients and clinicians representing people with asthma, epilepsy and schizophrenia. The aim in populating the DUETs database is to include data from several sources to identify the most frequently asked questions. This project aims to collect and integrate appropriate questions about treatment from NHS Direct Wales into that database.

Objectives:

1. Collect unanswered questions about treatment (relating to asthma, epilepsy and schizophrenia) from NHS Direct Wales.
2. Integrate such questions into the DUETs database.
3. Report findings back to NHS Direct Wales and patients.

Methods

1. Identify variables to be collected from NHS Direct Wales. These may include:
 - a. Gender of the person whom the question is being asked for.
 - b. Age
 - c. Health care condition
 - d. Intervention being asked about
 - e. Any comparison in question
 - f. Any outcomes from question
 - g. Details of search undertaken to answer question to ensure a full attempt at an answer has been made (including data sources checked)
 - h. Answer provided.
 - i. Does the enquirer wish to be contacted further if any new information is found in the near future? If so, contact details.
2. Pilot above collection and amend in light of pilot outcomes.
3. Test completeness of previous searches against 10% of previous searches to identify robustness of this being an unanswerable question.

- a. Undertake electronic search of identical data sources. Identify most appropriate data sources and undertake new search.
- b. Appraise results
4. Match patients condition, intervention and outcome from question and enter into DUETs database
5. Provide SNOWMED coding, and group similar questions, matching the Patient, Intervention Comparison and Outcome headings.
6. Pilot presentation/structure of DUETs to allow greatest use.

Resources:

The principal resource will be to cover salary and other associated costs. The main roles of a researcher will be to process the relevant NHS Direct data, undertake relevant searches and integrate the data into the DUETs database. The appointee to be based at Cardiff University School of Social Sciences.

Outcomes:

An improved database that identifies areas of uncertainty with respect to treatment and areas where further research is needed in order to answer patient-led questions. Feedback to NHS Wales Direct on the status of unanswered queries.

8 Resources

8a Outline description of resources

	£s		
	Year 1	Year 2	Total
Staff costs RA @ point 9 on RA scale for 6 months	150 70		
Overheads			
Consumables & expenses	None		
Equipment	None		
Grand Total			
VAT (if applicable)			

8b Has funding been sought for this, or a similar, project elsewhere?

~~Yes~~/No (if yes, please give details)

9 Personal statement (no more than 100 words)

Lindsay Prior is a medical sociologist (based at Cardiff University) with an interest in self-care, the expert patient, and lay expertise. He was recently involved in a WORD funded scoping

exercise on self-care and the expert patient (led by Dr C. Shaw). His interests extend to investigating how lay people use expert knowledge and decision-aids to manage their health. He has worked with the co-applicant (Jon Brassey, Director of ATTRACT) for some years.

10 Please give details of the ethical considerations of this project

The project would not involve access to patients nor to patient records, nor to data relating to NHS employees. No identifiable details of people who ask questions of NHS Direct Wales would be handled by the researchers. It would not therefore be necessary to gain Medical Research Ethics approval for this work.

DUETs Report Annexe 6b

Proposal for DUETs work in Wales developed by Glyn Elwyn, Summer 2005

Background

The involvement of patients is becoming a guiding principle for both the delivery and design of healthcare systems. This trend is the result of many converging processes, including the prominence given to the ethic of individual autonomy and the realisation that participation in healthcare interactions increases safety, quality, patient satisfaction and other outcomes, such as compliance with treatments. There is also a substantial body of evidence on the development of self-care, self-management and self-monitoring – exemplified by the ‘expert patient’ programme.¹ There is also interest in shared decision making² and on the involvement of patients in service design and policy making, ensuring that decisions are sensitive to patients needs and reflect their priorities and values.

An area where patient involvement has been neglected however concerns research prioritisation and research design³, probably because it is so difficult, given the range of stakeholders (government bodies, industrial organisations, higher education establishments, and so on). Although there may be an implicit wish to support research that reflects patients interests, questions and treatment outcomes of interest to patients are only very rarely actively solicited, as noted in recent editorials in the BMJ and Lancet^{4,5}.

This proposal aims to establish and evaluate a method of developing a system for collecting questions that patients ask about the effects of treatments which have not been adequately addressed by researchers, and which should be taken into account in the prioritizing proposal for additional research.

There is growing acknowledgement that most healthcare interventions have not been well evaluated and that ‘uncertainty’ about the balance of harms and benefits is common. While individual professional judgement is valid at the individual level, it is increasingly realised that evidence to guide practice should result from systematic appraisal processes⁶. If, however, systematic evidence is lacking and both clinicians and patients face residual uncertainty, what should be done? As Chalmers and others have argued, the solution may often be to insist on choosing treatments in ways that will reduce uncertainty, for example, within the context of a controlled trial^{7,8}. Although the case for addressing therapeutic uncertainties is logical, there is currently no agreement about how these “informed” uncertainties should be identified and prioritised.⁹

It is also clear that although research may sometimes have addressed questions of importance to patients, it has too often failed to address them in ways yielding information that matters to patients, and to the clinicians to whom they turn for help. Questions both parties consider important are not being addressed by researchers. For example, when patients, rheumatologists, physiotherapists and general practitioners were asked to identify their priorities for research on the management of osteoarthritis of the knee, there was little enthusiasm for the studies of drugs that the pharmaceutical industry typically supports. Instead, patients and clinicians wanted more rigorous evaluation of the effects of physiotherapy and surgery, and better assessment of the educational and coping strategies that might help patients to manage this chronic, disabling and often painful condition¹⁰. Although the pharmaceutical and medical technology industries play an essential role in developing new treatments, their commercial interests often influence research agendas. For this reason many areas of potentially valuable research are neglected. Furthermore, it should not be assumed that patients and clinicians will always have the same research priorities, unless a process to assess their priorities – like that used for osteoarthritis - has shown that they do¹¹.

After a series of consultations, focused ultimately in a seminar in Wales in August 2004 (participants: Iain Chalmers, Adrian Edwards, Glyn Elwyn, Alessandro Liberati, Andy Oxman, Paul Glasziou, Malcolm Rigler, David Sackett, Hazel Thornton,), a decision was made to establish a *Database of Uncertainties about the Effects of Treatments* (DUETs), and the National Knowledge Service subsequently provided funds to support this. DUETs aims to identify and publish those patients' and clinicians' questions about the effects of treatments that cannot be answered by referring to up-to-date systematic reviews of existing research evidence. This is a key definition and it is recognised that ‘raw’ patient questions will need to be assessed in order to judge whether they fit this definition, and could be integrated into the database. Although DUETs gives priority to identifying and publishing unanswered questions asked by patients and clinicians, it also notes uncertainties about the effects of treatments that have been identified by the authors of systematic reviews and clinical guidelines.

DUETs is a web-based searchable database which can be viewed at www.update-software.com/DUETs. There is open access to DUETs through the NHS National Knowledge Service, the website of the James Lind Alliance and other gateways. Actual and potential sources of unanswered questions about the

effects of treatments include NHS Direct and NHS Direct Online, the National Knowledge Service's question-answering service for general practitioners, question-answering services for patients in national voluntary organisations, answering services dealing with questions from health professionals such as ATTRACT (<http://www.attract.wales.nhs.uk>), and the National Library for Health, Patient Advice and Liaison Services (PALS), Cochrane Review Groups, the Centre for Reviews and Dissemination, National Institute for Clinical Excellence, and the NHS Health Technology Assessment Programme. The database has been placed under the aegis of the James Lind Alliance (JLA) <http://www.lindalliance.org/> - an alliance of patients and clinicians convened jointly by INVOLVE (formerly Consumers in NHS Research) and the Royal Society of Medicine to identify and prioritize unanswered questions about the effects of treatments.

This research proposal focuses on one of the potential data sources for DUETs, specifically the questions posed by patients to NHS Direct organisations in the UK. Queries that are presented to NHS Direct Staff can in most cases be answered with a high degree of confidence. In some cases, however, the queries that arise out of exchanges with the public pose difficulties, and it is in these areas that 'uncertainties' are likely to be located. This study aims to analyse these patient questions and make them explicit and publicly available through the *Database of Uncertainties about the Effects of Treatments*. In order to limit the scope of the work involved, a decision was taken to focus on involving chronic diseases in three clinical areas, namely asthma within the respiratory field, epilepsy within neurology and schizophrenia in the area of mental health. To assemble this database, work is being undertaken by the James Lind Alliance with representatives of patients and clinicians representing people with asthma, epilepsy and schizophrenia.

Aims, objectives and purpose

This study aims to work with three NHS Direct services to collect, analyse and integrate within DUETs patients' questions '*about the effects of treatments that cannot be answered by referring to up-to-date systematic reviews of existing research evidence*', starting with the service in Wales and extending to two other NHS Direct organisations in the East Midlands and Thames Valley & Northamptonshire.

The objectives are to:

1. Collect unanswered questions about treatment (relating to three specific areas, asthma, epilepsy and schizophrenia) from three NHS Direct organisations.
2. Analyse the structure and validity of the uncertainty implicit in these patient originated questions and integrate them into the DUETs database.
3. Liaise with the James Lind Alliance, the National Knowledge Service in the UK (led by Sir Muir Gray) and the national research networks in Wales and England, so that unanswered questions asked by patients can be taken into account when priorities for new research are being considered.

Design and methodology

The study is a cross-sectional survey and analysis of the questions posed by patients to a selected sample of NHS Direct organisations, leading to a synthesis of 'informed uncertainties' and contributing to the development of the Database of Uncertainties about the Effects of Treatments (DUETs). Pilot work conducted by the applicants has revealed that NHS Direct organisations currently adopt a number of ways to document and report patients' 'questions'. Guided by this pilot experience, the work in the study proposed here would be conducted in two phases. The initial phase involves consultation with three NHS Direct organisations (one in Wales, the other two in England) to assess and analyse the information currently available (historical data) and liaison to arrive at an agreed method of prospective documentation of patients' questions. The second phase is to operationalise the method for prospective documentation of unanswered patients' questions, and for forwarding them to DUETs database for synthesis and dissemination. In this phase the reports from the study (relating to asthma, epilepsy and schizophrenia) will be analysed and form the basis for work relating to other health problems.

Settings: Contact has been established with three NHS Direct organisations, namely NHS Direct Wales (Contact: Fiona Dennis), NHS Direct East Midlands (Contact: Jackie Wickham) and NHS Direct Thames Valley & Northamptonshire (Contact: Mig Muller). Applicants have established working relationships with these three organisations and a meeting has been arranged in Wales on 31 August 2005.

Phase 1: Operationalisation of the data structures at NHS Direct organisations.

Exploratory work by Mark Fenton, Editor of DUETs, has established that NHS Direct could be a valuable source of patient questions about treatment 'uncertainties'. However, existing data capture systems at NHS Direct were

designed to be reactive to active or symptomatic concerns. Although these NHS Direct organisations recognise that many patient questions match the definition of ‘treatment uncertainties’ sought for inclusion in DUETs, recording of data about these more ‘complex’ questions needs further development in order to provide data for efficient extraction and analysis. Furthermore, data systems vary to some extent across NHS Direct organisations, and liaison is required to arrive an agreed reporting structure capable of being automated.

Pilot work has also already established that NHS Direct receives very large numbers of questions. For the purposes of this study, they can be categorised into two groups. The core work of NHS Direct concerns questions by or on behalf of symptomatic patients who need advice, reassurance, and/or management by the NHS. NHS Direct also receives patient questions that are more difficult to answer, which do not involve dealing with an acute problem, and information specialists are employed to address these, using a range of methods and information sources. It is these questions that are of direct interest and potential relevance for inclusion in the DUETs database. It has been estimated by one NHS Direct organisation that at least 19 of these questions arise per month.

It is likely that these more complex questions are under reported, however. Existing systems vary in the amount of information that is recorded about the origin, nature and clinical details of such questions and there is no established method of managing the queries. A typical response is that the patient is advised that their question will be investigated by an information specialist in NHS Direct and that they will be contacted as soon as is feasible. Although the nature of these questions is not known and it is likely that many will not fit the exact definition of the type of patient question that defines a ‘treatment’ uncertainty, we intend investigate to possibility of exploiting this source of patients’ questions about the effects of treatments. For an example of the ideal ‘end product’, see Table 1:

Table 1 An example of patient question where ‘informed uncertainty’ exists (taken from existing DUETs database)

Is it safe to use steroids in children under the age of two, who have asthma. What are the side effects and will I damage my child in the long term?	
Who asked the question?	Carer
Why did they ask the question?	To inform treatment decisions
Why is there uncertainty about the effects of treatment?	No systematic review(s), that is, there has been no search for and systematic review of any evidence that may be available to address the question
What is needed?	Systematic reviews
References to relevant ongoing research:	In the UK: McKean M, Ducharme F. Inhaled steroids for episodic viral wheeze of childhood. The Cochrane Database of Systematic Reviews 2000, Issue 1. Art. CD001107. DOI: 10.1002/14651858.CD001107 . Elsewhere: <i>None identified</i>

During this first phase of the study the research officer will visit each of the NHS Direct organisations to map how they respond to ‘complex’ patient questions, and will set up a working group within each organisation to explain the aims of the DUETs data study. Permissions and research governance procedures will be established and completed. Existing data (historical for the last 3 or 5 years) will be sought and analysed for patient questions that required the response of information specialists, concentrating on asthma, schizophrenia and epilepsy. In addition, by conducting interviews with the relevant NHS Direct management and information specialists (estimated maximum of six interviews per NHS Direct organisation) an in depth understanding of how ‘complex’ patient questions are managed will be developed. The aim of this initial phase is to develop a process whereby each NHS Direct organisation provides an initial assessment of whether the complex question fits the definition of one in which ‘treatment uncertainty’ exists, and if so, to obtain the data needed for inclusion in DUETs (see Table 2). In summary, the initial phase of this project is designed to operationalise prospective data collection on patient questions where ‘treatment uncertainties’ exists, concentrating on unanswered questions about the effects of treatment for asthma, epilepsy and schizophrenia

Table 2 Variables to be collected from NHS Direct Wales

Variables	Notes
Gender	Of the person whom the question is being asked for.
Age	(in years or months) i.e. not the date of birth
Health care condition	Categorisation by clinical area and where possible diagnosis or problem
Intervention being asked about	A description of the treatment or procedure where uncertainty is raised
Any comparison in question	Is there a comparator suggested? e.g. compared to using drug X or doing nothing.
Any outcomes from question	What end point is of interest to the patients?
Details of search undertaken to answer question to ensure a full attempt at an answer has been made (including data sources checked)	How did the information specialist manage the query and specifically, did they manage to locate a relevant high quality systematic review.
Answer provided.	Details

(a) Phase 2: Prospective patient question collection, analysis and synthesis

After the data structuring process of phase 1 (using a mix of consultation, in-depth qualitative interviews and ‘existing data’ analysis), phase 2 will involve implementing and evaluating a structure for prospective data collection of the variables outlined in Table 2. Agreement will be reached with all three NHS Direct organisations and support provided to allow their data collection systems to be modified. The work will then proceed to pilot the collection of data, and DUETs will undertake to test the retrieval system, checking the completeness of searches in a random 10% of ‘patient questions’ reported as being *about the effects of treatments that cannot be answered by referring to up-to-date systematic reviews of existing research evidence*. Coding structures will be considered and modified in line with current thinking about the use of SNOMED CT and other options considered by the Connecting For Health and Informing Healthcare Agencies, in addition to the use of ‘free text’ search engines. Advisers from the three clinical areas have agreed to collaborate and guide the synthesis of ‘patient questions’: they are - for schizophrenia - Professor Keith Lloyd, Swansea University; ,for asthma - Dr Colin Gelder, NHS Wales; and for epilepsy - Professor Mike Kerr, Cardiff University and Dr Philip Smith.

Resources

The principal need for the resource requested is to cover the salary and travel of a research officer for one year, and support for a small number of Steering Group meetings and resources for the three NHS Direct organisations to cover their data modification requirements (although it may be possible to recover these costs from the Support for Science budget). The main roles of the researcher will be to liaise with the relevant NHS Direct organisations and with the editor of DUETs, analyse and synthesise the data, assist in integrating the work within DUETs provide a report, write peer reviewed publications, and disseminate the work. The appointee to be based at Cardiff University Centre for Health Science Research.

Dissemination

The resources of the JLA and their associated support organisations in the UK (MRC, INVOLVE etc) as well as the normal channels will be used to disseminate the work.

Outcomes and impact

An improved database making explicit areas of uncertainty about the effects of treatment that matter to patients, to help prioritise further research.

Feedback to NHS Wales Direct and NHS UK on the status of unanswered queries.

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DUETs Report Annexe 6c

Mental Health Research Network Cymru Rhwydwaith Ymchwil Iechyd Meddwl Cymru

14. Use of additional funding The James Lind Alliance research fellow

It is proposed to seek funding for a researcher to work with these organisations to populate the DUETs databases in these areas. In the case of mental health we would then seek external funding to run this project UK wide on the UK MHRN. We would also seek to pilot in Wales the patient-clinician working partnerships proposed by the James Lind Alliance. In mental health the partnerships would be with the Wales Collaboration for Mental Health and the Welsh Psychiatric Society (www.wps.swan.ac.uk).

This fellowship would be shared with the respiratory medicine network for whom this individual would work on a DUETs database for asthma. Two early priorities for the James Lind Alliance in the development of a Database of Uncertainties about the Effects of Treatments (DUETs) are asthma and schizophrenia. Uncertainties about the effects of treatments are reflected in the questions that patients and clinicians bring to question answering services such as NHS Direct, Hafal, Mind Cymru) and ATTRACT. Some of their questions can be addressed by reference to up-to-date, systematic reviews of reliable research studies. For many other questions, however, information is not readily available. Sometimes this is because no systematic reviews of the relevant evidence have been prepared; sometimes it is because existing systematic reviews have not been kept up to date; and sometimes it is because systematic reviews have shown that uncertainties about treatment effects will not be reduced without further research.

The proposed networks in respiratory medicine and mental health therefore propose to collaborate in giving Wales a UK lead in the establishment of DUETs in these respective areas. Work is also proposed in primary care with NHS Direct Wales to use information gleaned from routine calls to that service, to generate questions about treatment uncertainties. In the mental health field, Hafal and Mind Cymru are two national organisations that regularly field calls from people with schizophrenia Both are members of the Wales Collaboration for Mental Health and are co applicants on the Mental Health Research Network Cymru network application.

It is proposed to seek funding for a researcher to work with these organisations to populate the DUETs databases in these areas. In the case of mental health we would then seek external funding to run this project UK wide on the UK MHRN.

DUETs Report Annexe 7

JLA Partnership Asthma UK (AUK) and British Thoracic Society (BTS)

Background paper of summary of progress

January 2006

- Asthma is the first pilot JLA Working Partnership
- Interest started in April 2004 at a meeting on asthma in the *RSM Medicine and Me* series, at which Stephen Holgate (professor of respiratory medicine at Southampton) and Philippa Major (assistant research director at Asthma UK) both expressed enthusiasm to John Scadding for establishing a JLA Partnership in Asthma.
- An exploratory meeting in July 2004 established the levels of interest from the two partnership organisations; and their respective interests in working in partnership. The possibility of Allergy UK and the British Society of Allergy being involved was also discussed.
- Following a decision to convene a partnership of AUK and the BTS an ‘orientation’ meeting in March 2005 was held so that partners could get to know each others’ organisations and discuss the JLA objectives.
- A planning meeting in 2 months later addressed the asthma DUETs and recruiting a full planning group.
- Two key staff changes occurred at AUK, thus breaking continuity for a while.
- In July 2005 concern was expressed at a meeting of the JLA Development Group at the lack of visible progress, so Sally Crowe wrote to Asthma UK and the British Thoracic Society to ask whether they still regarded the proposed partnership as worthwhile
- AUK and BTS have responded positively: AUK they have made good progress in identifying patients’ questions for inclusion in DUETs, and they were considering how best to consult with their “members”, the new staff in place were enthusiastic and committed.
- Both groups recruited 6 or so members each, to attend a planning meeting in December, hosted by BTS at their Winter Clinical Meeting
- Colin Gelder, lead physician in a bid to establish a research network for respiratory disease in Wales is keen to help and has been involved in the research side of the BTS
- The DUETs database is now populated with unanswered questions on treatment uncertainties in asthma – these need adding to and refining by asthma specialists.

More detail and a chronology of events

April 2004

At the *Medicine and Me* meeting on asthma at the Royal Society of Medicine involving Professor Stephen Holgate (AIR Division, Southampton General Hospital) and Philippa Major (Assistant Research Director AUK) expressed enthusiasm to Prof John Scadding (Associate Dean RSM and co-convenor of the JLA) about establishing a JLA partnership in asthma. These discussions continued in parallel with the formation of the JLA

July 2004

A scoping meeting was held at the RSM, between Stephen Holgate, representatives of Asthma UK, Nick Partridge and John Scadding. Enthusiasm for a Working Partnership in asthma was again expressed. Further background about the formation of the JLA and its rationale was presented. There was discussion about the various patient and clinician organisations, which have an interest in asthma, and it was concluded that a partnership between the British Thoracic Society and Asthma UK was appropriate to consider questions about a wide range of important treatment uncertainties. Tentative arrangements for a priority-setting meeting were made for 1 November 2004, though it was recognised that much planning was needed and that this

Patricia Atkinson	James Lind Alliance Secretariat
Karen Bowler	Living with asthma, Spokesperson
Sarah Buckland	INVOLVE support unit
Sally Crowe	Director, Crowe Associates (Chair)
Amelia Curwen	Director of Policy, Services and Research, Asthma UK
Sheila Edwards	Chief Executive, BTS
Lester Firkins	Consultant, MRC
Dr Bernard Higgins	Consultant Respiratory Physician,
Prof Stephen Holgate	AIR Division, Southampton General Hospital
Liz Johnson	Living with asthma, spokesperson
Philippa Major	Assistant Research Director, Asthma UK
Veronique Moodie	Academic Conference Department, RSM
Dr Sophie Petit-Zeman	Director of Public Dialogue, AMRC
Dr John Scadding	Associate Dean, RSM
Katie Shepherd	Care Development Manager, Asthma UK

timescale might not be realistic

March 2005

An “orientation” meeting for the Asthma partnership was hosted by the JLA at the RSM. The **objectives** were:

- For the JLA Working Partnership of Asthma UK and the BTS to have had an opportunity to hear about the JLA in more detail and ask questions of some members of the JLA Steering Group
- For both working partners to have considered the added value of participation in a JLA Working Partnership to the asthma research agenda
- For both working partners to have explored and agreed (via action points) a way of working together within the context of a JLA planning meeting

This was very much an “exploratory” meeting for everyone concerned given the “Pilot” nature of this for the JLA.

Cornerstone to the meeting was an interactive session on how the proposed process and structure of the JLA could apply to the Asthma Partnership

Agreed **actions** were

1. BTS to formally agree the concept proposed at an Executive meeting in either March or May (depending on agendas) and agree who would engage with the DUETs group.
2. Asthma UK to discuss and agree a workable process for capturing the views of patients and the public and report back to the BTS and the JLA secretariat in about 4 weeks. Sarah Buckland and Lester Firkins offered to help in this aspect of the partnership work.
3. The JLA secretariat to keep an active hand in proceedings to ensure that the actions are done and that a formal agreement for a working partnership programme can be made by the end of May 2005.
4. Information about DIPEX to be sent to Asthma UK and BTS.

March 2005

Annual Accounts for AUK and BTS were reviewed by Jenny Hirst on behalf of the JLA for evidence of institutional influence or dependence and were found acceptable – although some small but helpful recommendations were made.

May 2005

A planning meeting for the partnership was hosted by the JLA at the RSM

The **attendees** were;

Patricia Atkinson
Sarah Buckland
Sally Crowe
Mark Fenton
Lester Firkins
Dr Bernard Higgins
Liz Johnson

James Lind Alliance Secretariat
INVOLVE support unit
Director, Crowe Associates (Chair)
Editor, DUETS, JLA
Consultant, MRC
Consultant Respiratory Physician,
Living with asthma, spokesperson

Philippa Major
Dr Sophie Petit-Zeman
Dr John Scadding
Katie Shepherd
Jenny Versnal

Assistant Research Director, Asthma UK
Director of Public Dialogue, AMRC
Associate Dean, RSM
Care Development Manager, Asthma UK
Assistant Research Director, Asthma UK

Apologies:

Karen Bowler
Sheila Edwards
Prof Stephen Holgate
Veronique Moodie

Living with asthma, Spokesperson
Chief Executive, BTS
AIR Division, Southampton General Hospital
Academic Conference Department, RSM

Objectives were:

- For the two partners to agree (via action points and clear lines of responsibility) a way of working together
- To agree a date for a JLA Asthma prioritisation meeting
- To agree planning and preparation milestones including an interim planning meeting
- To agree who should be part of the interim planning group
- To start to discuss who should be at the JLA Asthma prioritisation meeting
- To receive an update on the asthma-specific questions for DUETs
- To discuss and agree support that is required from the JLA Secretariat and from JLA affiliates

Following this meeting a “Work in Progress” (WIP) tracking sheet was produced (instead of minutes) so that next steps and agreed actions could be tabulated, accepted and monitored by all parties. This is available on request from Sally.

May–July 2005

During this period both Philippa Major and Kate Shepherd left AUK. Jenny Versnal has replaced Philippa and is very keen to continue this initiative – but as could be expected, the break in continuity has brought its own difficulties.

July 2005

Despite the Work in Progress tracking sheet having been circulated twice for comment, the JLA Development Group was becoming increasingly concerned at the lack of visible activity. Sally Crowe sent a letter (Appendix B) to both AUK and BTS suggesting milestones that the Development Group felt needed to be in place. If these could be agreed, the JLA would be happy to continue to provide support. This proved helpful in airing issues, and Sally and Lester made visits to both partnership members.

August 2005

Sarah and Lester met with AUK – and AUK is to work further with their four volunteers and Mark to compile questionnaires **for** their website and newsletter aimed at further populating the DUETs database as appropriate

Further discussions about how AUK can continue to obtain the views of their members, will continue between AUK, the JLA and INVOLVE.

September 2005

A date and venue for the next planning meeting finalised and each partnership member to recruit a broad range of people with asthma (AUK) and interested respiratory clinicians (BTS)

October 2005

An agenda is drawn up and discussions on how to brief new members of the group. A separate meeting for the people with asthma (prior to the Dec meeting) is also being explored.

December 2005

A planning meeting was held at the BTS Winter Clinical Meeting in London. It was well attended by respiratory clinicians and people with Asthma, as well as staff from both partner organisations. Additional support was given by the editor of the Cochrane Airways Group, a member of INVOLVE and two staff from the Health Technology Assessment Programme. All have relevant experience in their fields to offer the group.

The following decisions were made:

1. A further refinement of the Asthma DUETs with input from BTS members
2. AUK to develop an online web questionnaire to garner more patient generated questions and also explore postings on their message boards (accessed by non members)
3. An initial process was decided for filtering these initial questions from DUETs with some of the planning group volunteering to undertake this task. Facilitators for this event were volunteered from the JLA and HTA.
4. A list of potential invitees for the main priority setting meeting were agreed
5. More information is required about the priority setting process before decisions are made; a paper is to be circulated for comments and discussion by the Asthma Working Partnership as well as the JLA Steering Group.
6. It was agreed that the full priority setting meeting could follow on relatively quickly after the 'first pass' filtering of the DUETs.

DUETs Report Annexe 8

This screen presents the search results in a tabbed format, allowing the database user to click on any of the tabs to see all those question by source of contributor.



Database of Uncertainties about the Effects of Treatments (DUETs)

- Home
- About uncertainties
- Contributors
- Feedback

Search for **asthma** (all of the words/phrases)
Search results categorised by who asked the question:

Patients (8) Carers (18) Clinicians (5) Publications (17) Research (0) Other (0)

Questions asked by patients: page 1 of 1

- Browse
- Quick search:

 [Tips](#)
- Advanced search
- How to search
- Words you can't search for

- [Are there any complementary therapies or supplements that help in asthma?](#)
- [What is the value of using inhaled steroids continuously, versus a short course of oral steroids when the need arises if one doesn't have regular asthma attacks?](#)
- [Is continuous medication beneficial for my asthma if I don't have symptoms?](#)
- [Is it really necessary to take preventative medication if I only have mild asthma?](#)
- [Is it better to inhale steroids rather than take them as tablets?](#)
- [Will exercise affect my asthma?](#)
- [What is the value of complementary medicines such as Buteyko method for people with asthma?](#)
- [Will how I position myself to get to sleep help improve my asthma?](#)

- For contributing organisations:
[Add a new question](#)
- [Editing system](#)

Result page: **1**

This is an example of a record which shows the question asked, the source of the question, and why there is uncertainty.



Database of Uncertainties about the Effects of Treatments (DUETs)

[◀ Back to search results](#)  [Printable version](#)

Home
About uncertainties
Contributors
Feedback

If doctors cannot diagnose asthma in children under 2, what is the most appropriate treatment?

Browse
Quick search: <input type="text"/>
<input type="button" value="Search"/> Tips
Advanced search
How to search
Words you can't search for

Who asked the question?	Carer
Source of question	Asthma UK Adviceline
Why is there uncertainty?	No relevant systematic reviews identified
What is needed?	Systematic reviews
Systematic reviews that need updating or extending	None identified
Systematic reviews in preparation	None identified
Ongoing controlled trials	None identified

For contributing organisations:
Add a new question
Edit this question
Editing system

Classification

Which health conditions?	Respiratory diseases: Asthma
What is person's age?	Child
Which types of treatments?	Complementary therapies, Devices, Diet, Drug, Education and training, Exercise, Physical therapies, Environmental
Which outcomes?	Asthma symptoms

Question added: 3 October 2005

Question last modified: 15 November 2005

Classification last modified: 5 October 2005

The DUETs team endeavours to ensure that information is correct at the time of data entry.

Produced by [Update Software Ltd](#)

This record demonstrates there are systematic reviews in preparation, which might answer the question.



Database of Uncertainties about the Effects of Treatments (DUETs)

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What is the optimum dosage of oral steroids in children with asthma?

Who asked the question?

Carer

Source of question

Asthma UK Adviceline

Why is there uncertainty?

No relevant systematic reviews identified

What is needed?

Systematic reviews

Systematic reviews that need updating or extending

None identified

Systematic reviews in preparation

Smith M, McLoughlin L. Oral and systemic steroids at different doses for acute asthma in hospitalised children. (Protocol) The Cochrane Database of Systematic Reviews 2004, Issue 3. DOI: [10.1002/14651858.CD004824](https://doi.org/10.1002/14651858.CD004824).

Ongoing controlled trials

None identified

Classification

Which health conditions?

Respiratory diseases: Asthma

What is person's age?

Child

Which types of treatments?

Drug

Which outcomes?

Adverse effects; asthma attacks; duration of attack.

Question added: 3 October 2005

Question last modified: 31 October 2005

Classification last modified: 5 October 2005

The DUETs team endeavours to ensure that information is correct at the time of data entry.

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This record shows there is an up to date review that demonstrates uncertainty, and that further research is required. It also displays that further research is ongoing, and there are hypertext links to the internet records of these.



Database of Uncertainties about the Effects of Treatments (DUETs)

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Will exercise affect my asthma?

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Who asked the question? Patient

Source of question Asthma UK Adviceline

Why is there uncertainty?

Up-to-date systematic reviews have revealed important continuing uncertainties about treatment effects

References to relevant up-to-date systematic reviews:

Holloway E, Ram FSF. Breathing exercises for asthma. The Cochrane Database of Systematic Reviews 2004, Issue 1. DOI: [10.1002/14651858.CD001277.pub2](https://doi.org/10.1002/14651858.CD001277.pub2).

What is needed?

Further research

Systematic reviews that need updating or extending

None identified

Systematic reviews in preparation

None identified

Ongoing controlled trials

Two Investigational Drugs in the Prevention of Airway Constriction Brought on by Exercise in Asthmatic Patients
[NCT00127166](#)

A Study Measuring Asthma Control In Pediatric And Adolescent Subjects Whose Asthma Is Worsened By Activity Or Exercise
[NCT00118690](#)

A Study Measuring Asthma Control In Pediatric And Adolescent Subjects Whose Asthma Is Worsened By Activity Or Exercise
[NCT00118716](#)

A Randomized Trial of Changing Exercise and Physical Activity Behavior in Asthma Patients
[NCT00195117](#)

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Classification

Which health conditions?

Respiratory diseases: Asthma

What is person's age?

Child

Which types of treatments?

Exercise

Which outcomes?

Asthma attacks.

Question added: 3 October 2005

Question last modified: 31 October 2005

Classification last modified: 5 October 2005

The DUETs team endeavours to ensure that information is correct at the time of data entry.

This record demonstrates that a systematic review needs extending.



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Mechanical ventilation versus no mechanical ventilation for people with severe acute asthma

Who asked the question?

Uncertainties identified in clinical guidelines and systematic reviews

Source of question

Clinical Evidence

Why is there uncertainty?

Relevant, up-to-date systematic reviews do not address continuing uncertainties about treatment effects

References to relevant up-to-date systematic reviews:

None identified

What is needed?

Extending existing systematic reviews

Systematic reviews that need updating or extending

Jones A, Peters J, Camargo C, Hammarquist C, Rowe B. Inhaled beta2-agonists for asthma in mechanically ventilated patients. The Cochrane Database of Systematic Reviews 2001, Issue 4. Art. No.: CD001493. DOI: [10.1002/14651858.CD001493](https://doi.org/10.1002/14651858.CD001493).

Systematic reviews in preparation

None identified

Ongoing controlled trials

None identified

Classification

Which health conditions?

Respiratory diseases: Asthma

What is person's age?

Any age

Which types of treatments?

Drug, Tender loving care only, Unclassified, Environmental

Which outcomes?

Death

Question added: 9 September 2005

Question last modified: 14 December 2005

Classification last modified: 9 September 2005

The DUETs team endeavours to ensure that information is correct at the time of data entry.

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This record demonstrates that a systematic review needs updating.



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Regular use of prophylactic medication for asthma

Who asked the question?	Uncertainties identified in clinical guidelines and systematic reviews
Source of question	British Guideline on the Management of Asthma
Why is there uncertainty?	Existing relevant systematic reviews are not up-to-date
References to relevant up-to-date systematic reviews:	<i>None identified</i>
What is needed?	Updating existing systematic reviews
Systematic reviews that need updating or extending	Calpin C, Macarthur C, Stephens D, Feldman W, Parkin P C. Effectiveness of prophylactic inhaled steroids in childhood asthma: a systematic review of the literature. <i>Journal of Allergy and Clinical Immunology</i> 1997;100(4):452-457.
Systematic reviews in preparation	<i>None identified</i>
Ongoing controlled trials	<i>None identified</i>

Classification

Which health conditions?	Respiratory diseases: Asthma
What is person's age?	Any age
Which types of treatments?	Drug
Which outcomes?	Minimal symptoms with minimal need for reliever medication; no exacerbations; no limitation on physical activity and normal lung function.

Question added: 2 December 2005

Question last modified: 14 December 2005

Classification last modified: 2 December 2005

The DUETs team endeavours to ensure that information is correct at the time of data entry.

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DUETs Report Annexe 9

Research Networks Cymru and Database of Uncertainties about the Effects of Treatments (DUETs)

Hafal National Resource Centre, Museum of Welsh Life,
St Fagan's, Cardiff, CF5 6DU

31 August 2005

AGENDA

11:00-11:30 Arrive & Coffee

1. Introductions
2. Mental Health Research Network – Keith Lloyd
3. Respiratory Disease Research Network – Colin Gelder
4. James Lind Alliance and Database of Uncertainties about the Effects of Treatments (DUETs) – Iain Chalmers, Mark Fenton
5. ATTRACT and the National Clinical Question Answering Service – Jon Brassey
6. Planned work with NHS Direct Wales – Jon Brassey, Fiona Dennis, & Adrian Edwards
7. General Discussion
8. Summary of agreed Action Points

13:30 Finish & Lunch

Mental Health Research Network Cymru Rhwydwaith Ymchwil Iechyd Meddwl Cymru

14. Use of additional funding

The James Lind Alliance research fellow

It is proposed to seek funding for a researcher to work with these organisations to populate the DUETs databases in these areas. In the case of mental health we would then seek external funding to run this project UK wide on the UK MHRN. We would also seek to pilot in Wales the patient-clinician working partnerships proposed by the James Lind Alliance. In mental health the partnerships would be with the Wales Collaboration for Mental Health and the Welsh Psychiatric Society (www.wps.swan.ac.uk).

This fellowship would be shared with the respiratory medicine network for whom this individual would work on a DUETs database for asthma. Two early priorities for the James Lind Alliance in the development of a Database of Uncertainties about the Effects of Treatments (DUETs) are asthma and schizophrenia. Uncertainties about the effects of treatments are reflected in the questions that patients and clinicians bring to question answering services such as NHS Direct, Hafal, Mind Cymru) and ATTRACT. Some of their questions can be addressed by reference to up-to-date, systematic reviews of reliable research studies. For many other questions, however, information is not readily available. Sometimes this is because no systematic reviews of the relevant evidence have been prepared; sometimes it is because existing systematic reviews have not been kept up to date; and sometimes it is because systematic reviews have shown that uncertainties about treatment effects will not be reduced without further research.

The proposed networks in respiratory medicine and mental health therefore propose to collaborate in giving Wales a UK lead in the establishment of DUETs in these respective areas. Work is also proposed in primary care with NHS Direct Wales to use information gleaned from routine calls to that service, to generate questions about treatment uncertainties. In the mental health field, Hafal and Mind Cymru are two national organisations that regularly field calls from people with schizophrenia Both are members of the Wales Collaboration for Mental Health and are co applicants on the Mental Health Research Network Cymru network application.

It is proposed to seek funding for a researcher to work with these organisations to populate the DUETs databases in these areas. In the case of mental health we would then seek external funding to run this project UK wide on the UK MHRN.