The role of the information specialist in supporting the production and review of technology appraisals at the National Institute for Health and Clinical Excellence (NICE)

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Key areas to address

- Background on NICE and the Information Services team
- Overview of:
    - Scoping a health technology appraisal
    - Reviewing a health technology appraisal

NICE

- The National Institute for Health and Clinical Excellence (NICE) is the independent organisation set up in 1999 based in England responsible for
  - providing national guidance on the promotion of good health and the prevention and treatment of ill health
  - setting quality standards
  - managing NHS Evidence
- NICE makes recommendations to the NHS on:
  - new and existing medicines, treatments and procedures
  - treating and caring for people with specific diseases and conditions.
- NICE makes recommendations to the NHS, local authorities and other organisations on:
  - how to improve people's health and prevent illness and disease.

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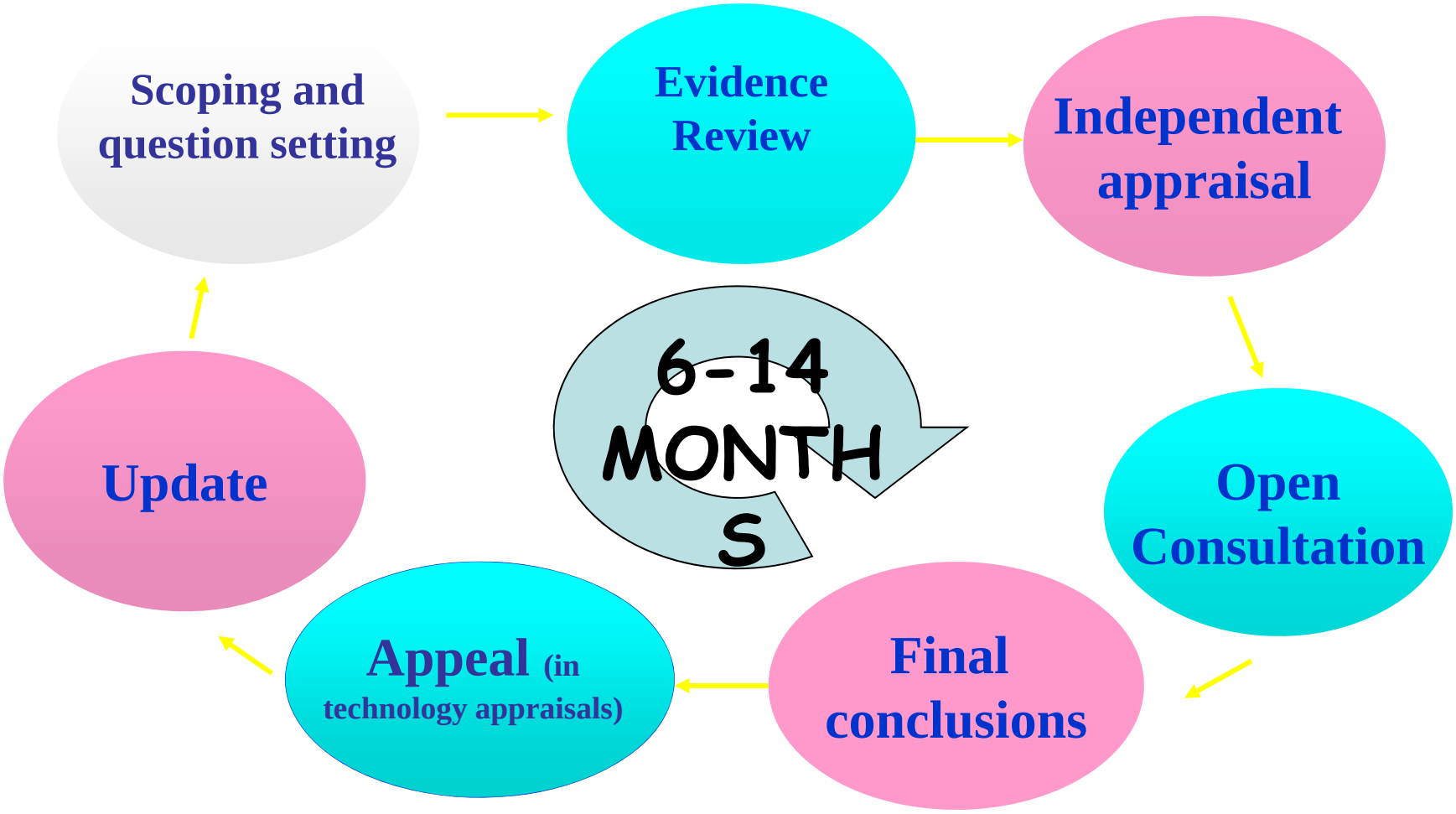
Information services team – who are we?

- A team of 20 information professionals based in London and Manchester
- Provide information support to meet the information needs of NICE staff and to help produce NICE guidance
- Support topic selection, appraisals scoping & reviews, short guidelines, interventional procedures, quality standards, quality & outcomes framework, devices & diagnostics, public health, NICE taxonomy etc
- Liaison leads for all teams in Institute
- Library resources – journals, databases, books, ILLs, information skills training, current awareness service

Health Technology Appraisals

- Health Technology Appraisals are recommendations on the use of new and existing drugs and medical devices
- Apply to England and Wales
- Developed by Centre for Health Technology Evaluation (CHTE) at NICE
- The appraisal process is divided into the following phases:
    - scoping the question
    - data collection and evidence review
    - appraisal recommendations

Technology appraisal process



Supporting the development of a draft scope

- Beginning of the appraisals process involves a scoping phase
- The scope will contain details of what a health technology appraisal will and will not cover
- The first step is to identify information relating to the technology – this task is carried out by the information specialist at NICE
- The information collected by the information specialist is made available via a page on the NICE intranet
- A technical analyst at NICE will write the draft scope

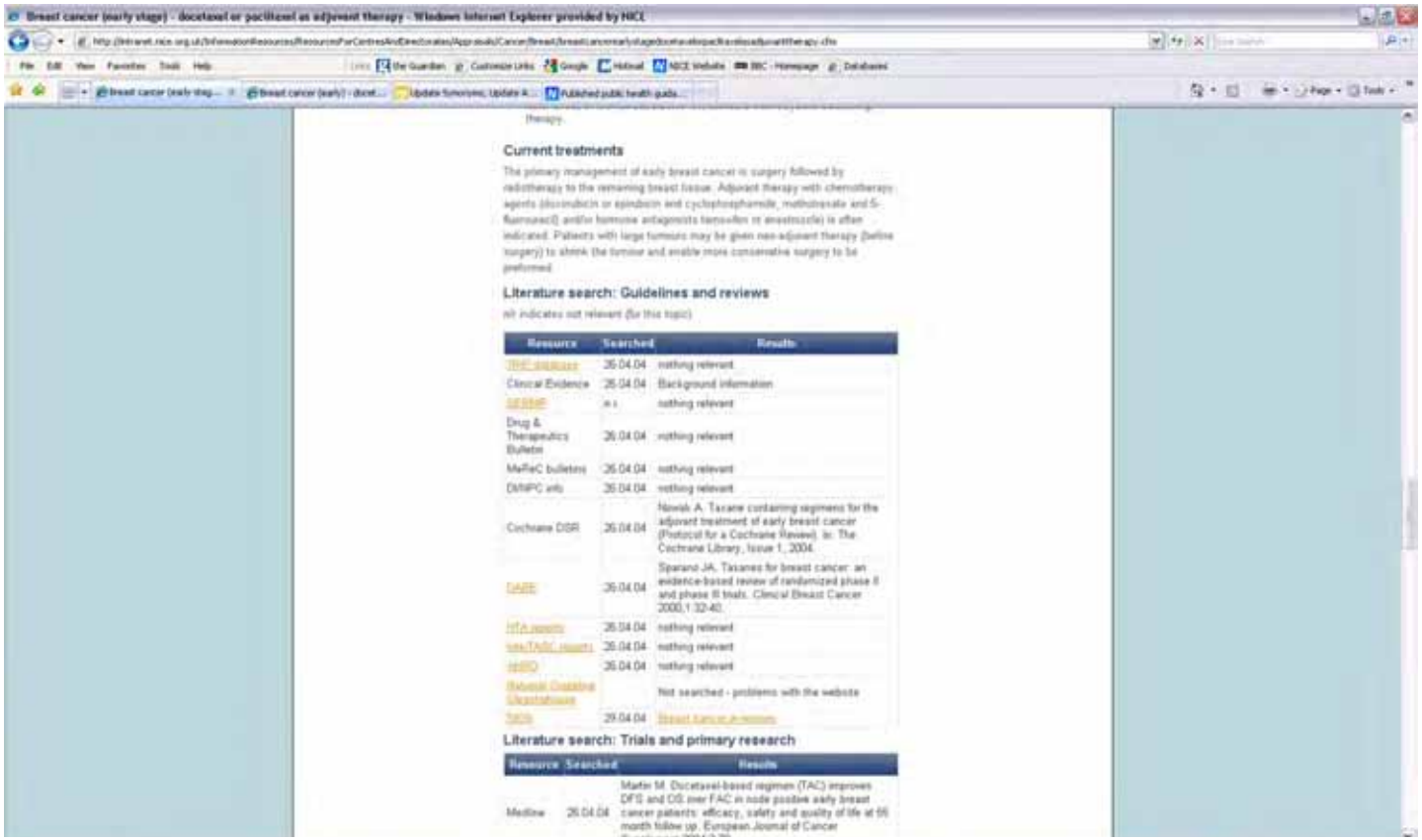
Gathering the evidence

- Information is gathered on the following areas:
  - the disease
  - the drug or device being appraised
  - the population
  - current treatments
  - the evidence
  - other considerations, including related NICE guidance and related policy developments

Monitoring the topic

- While the scope is being written the information specialist will monitor the topic through to publication
- Will monitor the progress of unlicensed drugs
    - when drug gained licence
    - did licence fail/get delayed
- Will also monitor the successful completion of key clinical trials.
- Once the scope has been written it goes out for consultation – this lasts for 20 days
- Scoping workshop
- NICE finalises scope and submits to the DoH

Example of a scoping page



Current treatments

The primary management of early breast cancer is surgery followed by radiotherapy to the remaining breast tissue. Adjuvant therapy with chemotherapy agents (doxorubicin or epirubicin and cyclophosphamide, methotrexate and 5-fluorouracil) and/or hormone antagonists (tamoxifen or anastrozole) is often indicated. Patients with large tumours may be given neo-adjuvant therapy (before surgery) to shrink the tumour and enable more conservative surgery to be performed.

Literature search: Guidelines and reviews

nlr indicates not relevant (for this topic)

Resource	Searched	Results
[illegible]	26.04.04	nothing relevant
Clinical Evidence	26.04.04	Background information
[illegible]	n.s	nothing relevant
Drug & Therapeutics Bulletin	26.04.04	nothing relevant
MeReC bulletins	26.04.04	nothing relevant
DMPC info	26.04.04	nothing relevant
Cochrane DSR	26.04.04	Nowak A. Taxane containing regimens for the adjuvant treatment of early breast cancer (Protocol for a Cochrane Review). In: The Cochrane Library, Issue 1, 2004.
DARE	26.04.04	Sparano JA. Taxanes for breast cancer: an evidence-based review of randomized phase II and phase III trials. Clinical Breast Cancer 2000;1:32-40.
HTA reports	26.04.04	nothing relevant
new/TARC reports	26.04.04	nothing relevant
NHSEED	26.04.04	nothing relevant
[illegible]		Not searched - problems with the website
TRIP	29.04.04	[illegible]

Literature search: Trials and primary research

Resource	Searched	Results
Medline	26.04.04	Martin M. Docetaxel-based regimen (TAC) improves DFS and OS over FAC in node positive early breast cancer patients: efficacy, safety and quality of life at 66 month follow up. European Journal of Cancer

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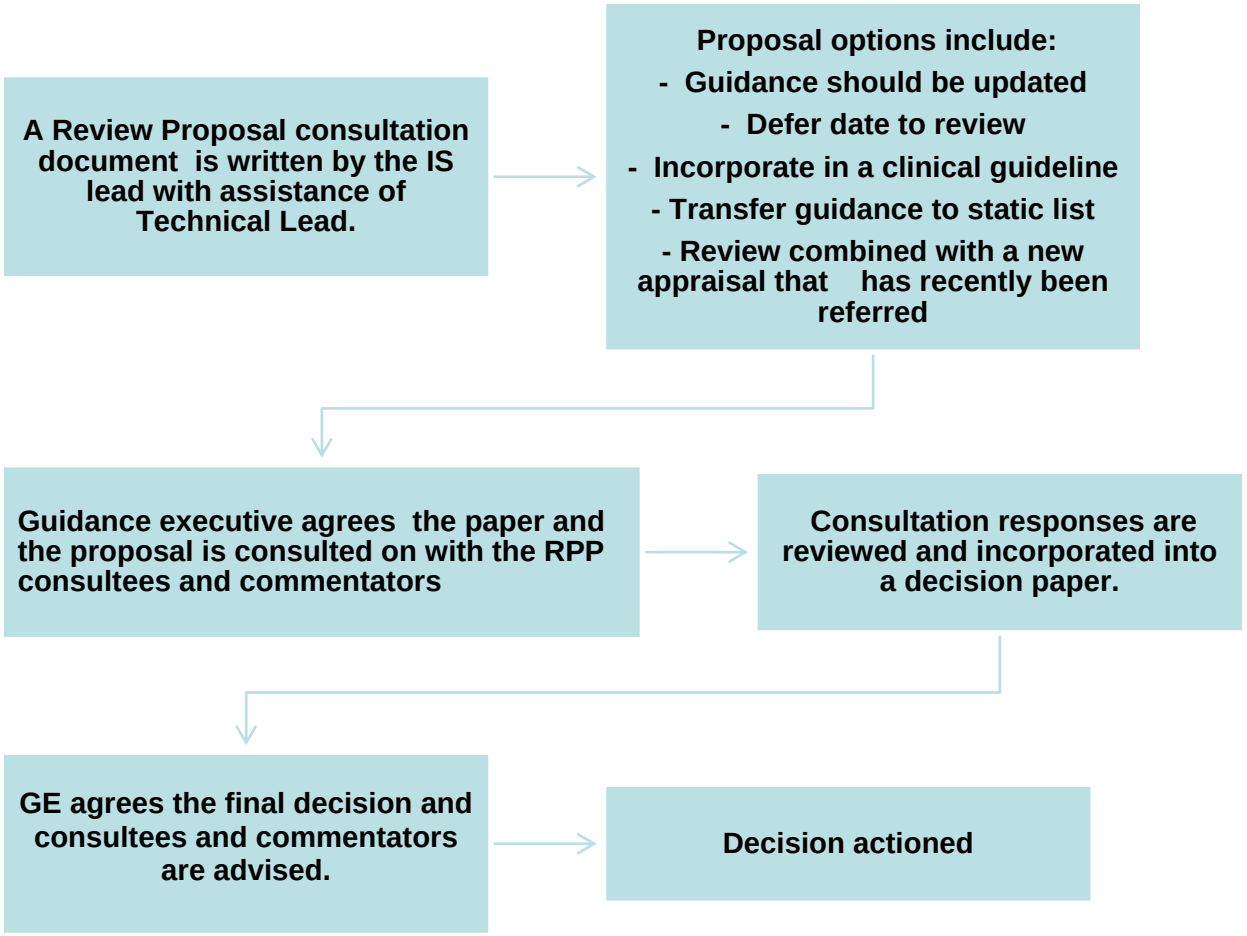
Reviews of technology appraisal guidance

- When NICE publishes a technology appraisal it will indicate the review date on the front cover of the guidance
- The aim of the review process is to decide whether or not the guidance needs to be updated
- The length of time between guidance publication and the review date will vary between 1-5 years

Review proposal process



Gathering the evidence

- The task of the information specialist is to collect information and decide if there is enough evidence to warrant a review of the guidance.
- Information is gathered from the following areas:
    - related NICE guidance
    - new indications for drugs
    - progress of ongoing clinical trials
    - new research published since original health technology assessment search was run
    - related new drugs or devices
    - information from manufacturers

Collating the evidence

- Evidence is summarised by the information specialist in a “proposal paper”
- The review options are:
    - to review the guidance
    - to defer the review
    - to combine with a review of a related drug or device
    - to include the guidance in a clinical guideline
    - to update the guidance in a clinical guideline
    - to transfer the guidance to the “static guidance” list. This means the guidance does not need to be updated for five years.

Example “Proposal” paper

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GUIDANCE EXECUTIVE (GE)

Review of TA99 immunosuppressive therapy for renal transplantation in children and adolescents

This guidance was issued in April 2006 review date of March 2009.

Recommendation

- A review of the guidance is planned into the appraisal work programme. That we consult on the proposal.

Consideration of options for recommendation:

Options	Comment
A review of the guidance should be planned into the appraisal work programme.	**a) A manufacturer has withdrawn marketing authorisation for one of the drugs recommended in the guidance (daclizumab).** **b) There is a newly licensed drug (thymoglobuline) for the prophylaxis and treatment of graft rejection after renal transplantation; however there is no paediatric data on thymoglobuline for the treatment** **c) Tacrolimus has received a positive opinion (19 March 09) ‘for the prophylaxis and treatment of transplant rejection in adult and paediatric kidney… recipients’ (oral suspension, potentially relevant to children).** **d) There have been safety issues concerning prograf and advograf (both tacrolimus, but advograf is not licensed for use with children) so a review would give an opportunity to reinforce safe and appropriate use. See MHRA statement Jan 09.**
The decision to review	New information requires that the guidance be

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What happens next? (1)

- Technical analyst decides if they agree with recommendation of the information specialist
- Proposal paper agreed by an associate director
- Proposal paper discussed by senior management team at NICE (called Guidance Executive)
- This is followed by a period of public consultation with consultees and commentators (20 working days)
- Consultation comments summarised by information specialist in a second paper, called a “decision paper”

Example “Decision” paper

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

Review of TA99 immunosuppressive therapy for renal transplantation in children and adolescents

This guidance was issued in April 2006, with a review date of March 2009.

Background

At the GE meeting on 12 May 2009 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

Proposal put to consultees:	A review of the guidance is planned into the appraisal work programme. That we consult on the proposal.

GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with any responses from the appraisal team. It is asked to agree on the final course of action for the review.

Recommendation post consultation:	A review of the guidance is planned into the appraisal work programme to include the license extension to tacrolimus (for the prophylaxis and treatment of transplant rejection in adult and paediatric kidney) and the recently licensed thymoglobuline (subject to DH agreement).

Respondent	Response to proposal	Details	Comment from Technology Appraisal
Royal College of Pathologists	Disagree	Consultee believes there is no new evidence to warrant a review.	The license extension to tacrolimus and thymoglobulie (not covered by existing guidance) make it worthwhile updating the guidance.
Department of Health	No comment		
Kidney Alliance	No objection	[redacted]	Comment noted. The details of this trial and abstract were considered during the review proposal. [redacted]
Novartis Pharmaceuticals (basiliximab, ciclosporin & mycophenolate sodium)	Disagree	Consultee believes there is no new evidence to warrant a review.	The license extension to tacrolimus and thymoglobulie (not covered by existing guidance) make it worthwhile updating the guidance.

What happens next ? (2)

- Decision paper confirms if the original review decision still stands taking into account comments received
- Decision paper agreed by technical analyst and associate director
- Final decision made by Guidance Executive
- Consultees and commentators will be informed and the decision will be published on the NICE website.

Information specialist role in scoping and review process

- Gathers the evidence
- Evaluates the evidence
- Summarises key evidence
- Makes recommendations based on the evidence
- Works to tight timelines (overseen by Project Manager from heath technology appraisals team)

Summary

- Information specialists use a wide range of skills when supporting the scoping process and the reviews of health technology appraisals
- Information service team do 3 RPPs and 7 scopes per month in addition to work for other Directorates at NICE
- Any questions
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