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

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Aim: To outline the role of the information specialist in supporting the production and review of technology appraisals at the National Institute for Health & Clinical Excellence (NICE)

Introduction

The NICE (National Institute for Health and Clinical Excellence) Information Services (IS) team provide information support for staff, including support for the production of NICE guidance. This paper highlights the contribution of information specialists within the IS team to the development of health technology appraisals, in particular the role played in scoping new topics and assessing whether a technology appraisal should be reviewed.

NICE

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation based in England responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. The National Institute for Clinical Excellence (NICE) was set up in April 1999 as a National Health Service (NHS) special health authority for England and Wales. The Department of Health commissions NICE to develop different types of guidance for the NHS, comprising clinical guidelines, public health guidance, technology appraisals and interventional procedures.

Health Technology Appraisals

Health Technology appraisals are recommendations on the use of new and existing medicines and treatments within the NHS, such as:

- drugs
- medical devices (for example, hearing aids or inhalers)
- diagnostic techniques (tests used to identify diseases)
- surgical procedures (such as repairing hernias)
- health promotion activities (for example, ways of helping people with diabetes manage their condition).

The Centre for Health Technology Evaluation (CHTE) at NICE develops health technology appraisals. The appraisal of a health technology is divided into the following phases:

- scoping the question;

- data collection and evidence review;
- appraisal recommendations

The scoping phase assesses the suitability of a topic. The assessment phase is a systematic evaluation of the evidence available on a technology. The NHS National Institute for Health Research (NIHR) Health Technology Assessment Programme commissions the health technology assessment reports which lead to the production of NICE technology appraisals to independent academic centres in the UK. The independent academic centres carry out the assessment process (i.e. the searching for evidence and the systematic evaluation of the relevant evidence).During the appraisal recommendations phase an Appraisal Committee (an independent advisory body) will appraise the evidence and formulate recommendations to NICE from the health technology assessment report.

Recommendations are based on a review of clinical evidence which measures how well the medicine or treatment works as well as economic evidence which measures how well the medicine or treatment works in relation to how much it costs the NHS and whether it represents value for money. There are two types of appraisals – single technology appraisal (STA) and multiple technology appraisal (MTA). An STA is specifically designed for the appraisal of a single product, device or other technology with a single indication where most of the relevant evidence lies with one manufacturer or sponsor. An MTA includes more than one product, device or technology or more than one indication or more than one manufacturer or sponsor.

The end product of the health technology process is either a single or multiple technology appraisal guidance. The Secretary of State for Health has directed that the NHS provides funding for technologies that have been recommended by NICE within three months from the date the guidance is published.

Supporting the development of a draft scope

The beginning of the appraisals process involves a scoping phase. The topic being scoped can be either a new topic or a review topic (i.e. an existing health technology appraisal that is being reviewed). The scope contains details of what an appraisal will and will not cover and outlines the boundaries of the topic (for example, the population, the intervention, any comparators). The finalised scope will be sent to the Department of Health to help ministers decide whether a technology should be formally referred to NICE for appraisal and whether it should be referred as an STA or an MTA.

The first step in the scoping process is to identify information relating to the technology. This task is carried out by the information specialists at NICE, in collaboration with a CHTE technical analyst who will write the draft scope. The parameters that the information specialist would gather information on include:

- the clinical problem
- the technology being appraised
- the population involved
- current treatments

- the comparator technologies
- the evidence base
- other considerations, including related NICE guidance; related policy developments;

Once this information has been collected it is made available via a page on the NICE intranet, where it can be accessed by the CHTE project team at NICE.

The clinical disease/condition

Information is collected describing the disease and will include disease stages where relevant.

The population involved

Information on the population eligible for the technology will be sought. The information specialist may be searching for a particular age group (e.g. older people or children) or there may be particular subgroups of people with the disease/condition (e.g. metastatic cancer). The CHTE will try to define the population as precisely as possible. In addition statistical information on the disease will also be collected, in particular information on incidence and prevalence, with statistics for England and Wales being the preferred choice. If these are not available then statistics for the UK are acceptable. Finally the information specialist will check to see if particular patient sub groups (e.g. race, gender, sexual orientation etc.) are affected by the disease/condition.

The technology being appraised

Information describing the technology is required. If the technology is a licensed drug, information on what the drug is licensed for is necessary. If the drug is unlicensed information will be sought from the manufacturer on the proposed indication and any timelines. This information will be confidential to anyone working on the scoping document The circumstances in which the technology can be used will also be considered by the CHTE project team and specified in the scope (for example, a drug can be licensed for more than one disease/condition).

Current treatments

The information specialist will be required to provide information on what treatments are currently available in the National Health Service (NHS). Is it possible that current treatments will not include drugs (e.g. surgery or watchful waiting). In addition the IS may be required to judge where the new technology would fit into the current care pathway (the stages of care for a specific disease/condition).

The comparator technologies

It is expected that comparator technologies will be identified, including the natural history of the disease/condition without treatment. There will often be more than one relevant comparator because routine practice may vary across the NHS. Relevant comparator technologies may also include drugs or devices that do not have a marketing authorisation (or CE mark for devices) for the indication stated in the scope but that are used in the NHS.

The evidence base

During the scoping phase the information specialist will identify key clinical trials. Usually only phase III or phase IV randomised controlled trials (RCTs) are included but if there are no phase III trials available the information specialist will look at phase II trials. Online databases, (Medline, Embase, Medline In-process and Cochrane Central Register of Controlled Trials (CENTRAL)) will be searched to identify relevant published studies. Searches are usually limited to systematic reviews and RCTs. At this stage of the process the literature search is not expected to identify every study on a given topic as this will done later if a full appraisal is carried out. The Information Specialist is looking for key studies to give the CHTE technical lead an overview of the evidence base.

Other considerations

In addition to searching for the above types of information the information specialist will look for related NICE guidance, such as a clinical guideline or technology appraisal. The IS will also identify related policy documents, such as National Service Frameworks (policies that define a standard of care for a particular medical condition).

Monitoring the topic

While the scope is being written the information specialist will monitor the appraisal topic through to publication. It is particularly important to monitor the progress of unlicensed drugs to gather information on when the drug gained a licence or if the licence failed or was delayed. In addition the information specialist will monitor the successful completion of key trials (or their failure) and highlight any new trials that are relevant.

Once the draft scope has been written by the CHTE technical analyst, outlining what the appraisal will cover and the questions that need to be addressed, the next step is a consultation stage. The aim of the consultation is to gather views from consultees and commentators on whether NICE should appraise the technology. This process lasts for 20 days. After the comments have been submitted a scoping workshop is held to discuss the issues raised during the consultation process. NICE then finalises the scope and submits it to the Department of Health.

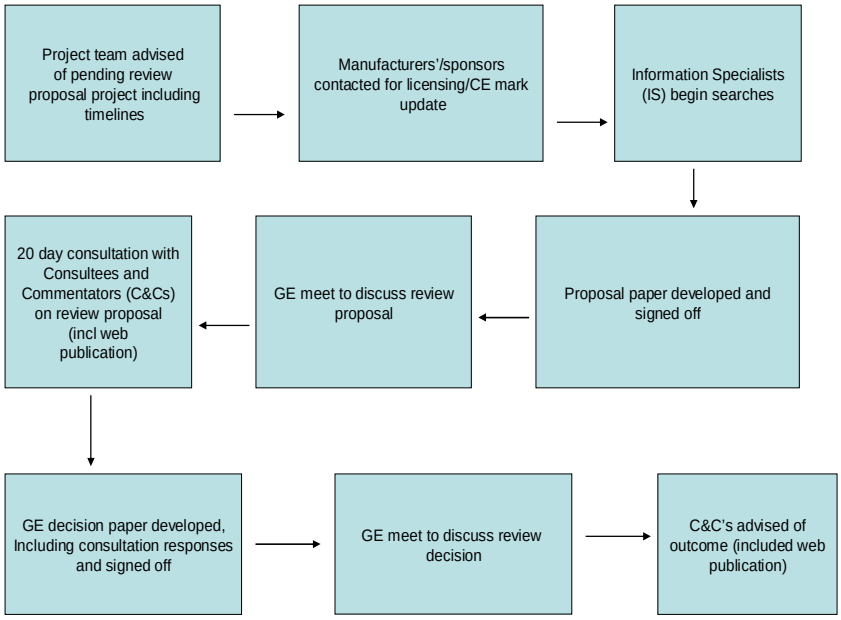
Searching for the information gives the information specialist an opportunity to identify some of the issues that will become relevant when the scope is written. The information specialist plays a key part in contributing to the scoping work by searching for information and tracking licensing information and key trials on each scoping topic.

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 review date is the month and year when NICE will consult on proposals for reviewing the guidance with relevant organisations. The aim of the review is to decide whether or not the guidance needs to be updated. The review date is set in reference to the anticipated rate of development in the evidence

base for the technology. The length of time between guidance publication and the review date will vary between 1 and 5 years. The review proposal programme sits within the Centre for Health Technology Evaluation, with input from Information Services.

Flowchart of review process



Gathering the information

An information specialist and CHTE technical analyst will be allocated at the beginning of a review and they will be given a detailed timetable outlining the steps to be followed for the project, including all deadlines. The task of the information specialist is to collect and evaluate information on the topic in order to decide if there is sufficient evidence to warrant a review. Before doing anything the information specialist will familiarise themselves with the guidance about to be reviewed. The information specialist will then carry out a literature search, which aims to identify information in the following areas:

- Related NICE guidance (this could be published guidance, guidance in development and/or proposed guidance). It may be that the guidance being reviewed could be updated in a clinical guideline or combined with another technology appraisal (for example there may be another technology appraisal guidance on the same disease or condition and the two technologies could be combined in one set of guidance).

- New indications for drugs included in the original guidance. This could be the trigger to review the guidance.

- Information on the progress of ongoing clinical trials, in particular phase III and IV Randomised Controlled Trials (RCTs). Publication of key trial results can mean that a review is necessary or a review may be deferred until the results of a key trial have been published.

- New research that has been published since the original health technology assessment search was run. This involves searching four key database: Medline, Embase, Medline in Process and the Cochrane Library. This search should highlight whether there is sufficient new evidence to make a review necessary.

- Related new drugs could possibly trigger a review. Each health technology appraisal is carried out in response to a remit from the UK's Department of Health (DoH), which outlines what the appraisal will cover. If the remit from the Department of Health specifies a named drug a review cannot include additional drugs without a new referral from the DoH. However, if the remit does not specify a named drug (i.e. mentions "licensed treatments" this could mean that newer drugs could be considered.

The results of the literature search are saved in a Reference Manager database and sifted by the information specialist to identify any new evidence. For example, the information specialist will look for a key clinical trial that could lead to the deferral of the review or the published results of an RCT which may contradict one of the review recommendations.

Collating the evidence

Once the relevant information has been gathered it is summarised and collated in a document called a "proposal paper" by the information specialist. This will summarise any new evidence and make a proposal (or recommendation) for how to proceed with the review. This decision is made in conjuction with the CHTE team. The options available include:

- Reviewing the guidance.

- Deferring a review of the guidance (for example, to await the results of a key clinical trial).

- Deciding that a review of the guidance should be combined with a review of a related technology appraisal.

- Deciding that a review of the guidance should be combined with a new technology appraisal that has recently been referred to NICE.

- Incorporating a review of the technology appraisal into an on-going clinical guideline (in practice the clinical guideline will signpost the technology appraisal and both will stay as separate documents).

- Updating a review of the technology appraisal into an on-going clinical guideline (the content of the technology appraisal will be updated and

included in a clinical guideline and the technology appraisal will no longer exist).

- Transferring the technology appraisal to the "static guidance" list. This would happen if no significant changes to the evidence are expected for the foreseeable future and there are no relevant ongoing trials. If this is the case, guidance on the static list will be looked at once every five years to make sure there have been no significant changes to the evidence base.

In some cases the appropriate recommendation will be straightforward based on the evidence found during the information gathering stage. However, sometimes there may be one or more recommendations that are appropriate. In addition to stating which recommendation has been chosen reasons need to be given for each of the other options stating why they were not relevant.

The proposal paper is then sent to a technical analyst in the Centre for Health Technology Evaluation, who also reviews the evidence, highlights any relevant technical information and decides whether they agree with the recommendations made by the information specialist. Once this process is complete the paper is signed off (agreed) by an associate director in the Centre for Health Technology Evaluation.

What happens next?

Once the proposal paper has been signed off it will be discussed by the senior management team at NICE (called Guidance Executive). They will decide if they agree with the proposed recommendation in the paper. Their decision is followed by a period of public consultation with consultees and commentators for 20 working days. Five days after the proposal has been sent to consultees and commentators it is published on the NICE website.

Once the comments have been received they are summarised by the information specialist in a second paper, called a "decision paper". The information specialist notes whether each consultee or commentator agrees or disagrees with the recommendation made in the proposal paper. Responses that require a reply are usually dealt with by the technical analyst. The decision paper states the proposal that was agreed by Guidance Executive prior to the consultation stage. It then confirms if that decision still stands or recommends a new proposal based on the consultation responses. Once the information specialist and the technical analyst are in agreement, the decision paper is signed off (agreed) by an Associate Director in the Centre for Health Technology Evaluation.

The decision paper is then considered by Guidance Executive who make a final decision on the most appropriate option for the technology appraisal guidance. Once that decision has been made consultees and commentators are notified and the decision is published on the NICE website. The Centre for Health Technology Evaluation team then put the proposal into practice, for example, they may schedule a review into the technology appraisal work programme (in which case the process for a review scope will be carried out) or the guidance may be moved to the static list. One of the key roles within the CHTE team is that of the project manager who manages the reviews (there may be up to 20 reviews occurring at the same time). The project

manager sets the timelines for each review and keeps track of each one to make sure that deadlines for each stage of the process are met.

The information specialists in the NICE Information Services team play a key part in contributing to the technology appraisal review process. Not only are they responsible for gathering the evidence, they are also expected to understand and evaluate it, and make recommendations based on the evidence. Selecting and summarising the key information to present to CHTE technical analyst is a key part of the information specialists role. This is a unique opportunity within the Information Service teams and carries with it a level of responsibility since the recommendations made at the review stage influence the future work programme of NICE.

Conclusion

This paper has aimed to outline the contribution of the information specialist at NICE to the development of technology appraisals. Information specialists are given an opportunity not only to gather information, but also to critically evaluate the evidence they collect, summarise key findings and make recommendations to NICE. In addition, supporting the review of health technology appraisals requires excellent project management skills and the ability to work on several projects at different stages in the process at the same time. The role allows information specialists to use a wide range of skills in order to contribute to the development of NICE guidance.

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