NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Briefing paper for methods review workshop on patient evidence 2: patient evidence, qualitative research and synthesis

The briefing paper is written by Dr Ruth Garside in collaboration with members of the Institute's Technology Appraisals team. It is intended to provide a brief summary of the issues that are proposed for discussion at a workshop to inform an update to the Institute's Guide to Methods of Technology Appraisal. It is not intended to reflect a comprehensive or systematic review of the literature. The views presented in this paper are those of the authors and do not reflect the views of the Institute.

The briefing paper is circulated to people attending that workshop. It will also be circulated to the members of the Method's Review Working Party, the group responsible for updating the guide.

For further details regarding the update of the Guide to the Methods of Technology Appraisal please visit the NICE website at http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisallprocessguides/GuideToMethodsTA201112.jsp

1 Review of the 'Guide to Methods of Technology Appraisal'

The Institute is reviewing the 'Guide to the methods of technology appraisal', which underpins the technology appraisal programme.

The original Methods Guide was published in February 2001, and a revised version was published in 2007. The Methods Guide provides an overview of the principles and methods used by the Institute in assessing health technologies. It is a guide for all organisations considering submitting

evidence to the technology appraisal programme and describes appraisal methodology.

The current 'Guide to methods of technology appraisal' is available from the NICE website at http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/guidetothemethodsoftechnologyappraisal.jsp

The review of the Methods Guide will take place between October 2011 and April 2012. As part of the process, a number of workshops will be held to help identify those parts of the Guide that require updating. These workshops will involve a range of stakeholders, including methods experts, patient representatives, industry representatives, NHS staff and NICE technology appraisal committee members.

A summary of the discussion at the workshop will be provided to the Methods Review Working Party, the group responsible for preparing the draft update of the Methods Guide. Further details of the process and timelines of the review process are available from the NICE website.

The revised draft of the Methods Guide will be available for a 3-month public consultation, expected to begin in May 2011. We encourage all interested parties to take part in this consultation.

2 Background

The Technology Appraisals uses a variety of types of evidence to arrive at its recommendations. Section 3.4 of the guide includes the following text:

> *In addition to evidence on treatment effect and cost effectiveness, the appraisal of health technologies requires consideration of a range of other issues. A variety of types of evidence generated from a range of sources, of both quantitative and qualitative origin, is relevant to these areas. […]*

Information on whether a health technology is considered to be an acceptable or appropriate technology (compared with alternative technologies) by patients, carers or healthcare professionals is useful. Individuals or groups may prefer particular health technologies, for example, because of the frequency or nature of adverse events or the route or frequency of administration. The health impact of most of these factors (for example, adverse events) is expected to be reflected in the estimation of HRQL. In addition, individuals or groups may be concerned about the ethics of using a particular technology. These are relevant considerations for an appraisal because they influence judgements on the usefulness of technologies, inform the nature of choice between alternative technologies and provide important evidence on the extent to which these considerations have been adequately captured in measurements of HRQL. Evidence relevant to these considerations can come in various forms, be based on quantitative or qualitative measurements, and originate from a range of sources that have different methodological strengths and weaknesses. Such evidence includes literature reviews, adverse effect/adherence/continuation data collected in research studies, patient surveys (for example, of adverse effects or preferences) and summarised testimonies from clinical specialists and patients.

Thus, in addition to seeking the views and experiences of patients through their direct involvement in Committee meetings and in consultations on documents, other types of evidence on the experience of patients can also contribute to the evidence base for a Technology appraisal.

Whilst there is a laudable aim to ensure that the patient voice is heard in the appraisal process, the current methods guide conflates a number of issues that make the *purpose* of doing this and the *methods* for it unclear. For example, within a technology appraisal, it seems to conflate *de novo* patient/public involvement strategies and understandings about the kind of pertinent research evidence that might already exist. Potentially, this leads to

neither goal (meaningful patient involvement with the process and use of existing patient centred research) to being effectively reached.

There is a need to distinguish clearly between the following types of evidence:

1. Quotes and written submissions from people who have a disease or condition (or their family or carers) about their experience of this, and/or its treatment. This could be called **Qualitative Evidence** – that is, evidence in the form of text/words (such as that provided through the contributions of patient experts at committee meetings) which has not be subject to formal research methodology in order to collect or analyse it.

2. Research which analyses group or individual interviews or written texts with patients (or their family or carers) about a particular topic in order to produce an analytic account of the nature of living with a condition (and/or its treatment) based the experience of a number of such people. This is **Qualitative Research Evidence** – that is, evidence that has been collected and analysed using one of a number of recognised approaches to this type of research.

3. As for other forms of evidence used in technology appraisals, systematic review and synthesis procedures can be applied to existing qualitative research evidence in order to produce a coherent understanding of the body of work about living with a particular condition, and/or its treatment. This is a **Synthesis of Qualitative Research Evidence**. A range of approaches have been described for this and systematic reviews and syntheses of qualitative research are already in use by the CPHE at NICE to inform the production of public health guidance.

Patient involvement is being considered in more detail by Dr Staniszewska, so this paper focuses on patient evidence which is sourced from research. It will focus on qualitative research, which has the potential to reveal the patient experience, although quantitative surveys and questionnaires may also be a source of relevant information.

3 Proposed issues for discussion

After consideration of the developments in this methodological area, the current Methods Guide and the requirements of the Institute's Technology Appraisal Programme, it is proposed that the following key areas are discussed at the workshop.

3.1 Using patient evidence to inform technology appraisals

3.1.1 Qualitative evidence from submissions

Section 4.3.4 of the methods guide states the following:

> *For the purpose of informing its technology appraisals, the Institute is looking for a concise and balanced overview that reflects the range of patient and carer perspectives, including majority views and potentially important views that may be held by only a few patients. The Institute is interested in capturing a range of patient and carer views on, and experiences of, living with the condition, and the impact of a technology on a patient's symptoms and physical, social, psychological and emotional state. It is also interested in what it might be like living without the technology being appraised.* ***Patient evidence is most useful when presented as a synthesis of information, balancing positive and negative views, rather than as a series of individual testimonials.***

The highlighted in bold preference above for "synthesis of information….rather than as a series of individual testimonials" seems to imply that the most useful form of patient evidence is that derived from qualitative research, whether individual reports or an evidence synthesis (2 or 3 above), although currently it collects qualitative evidence (1 above) from groups and individuals. Patient groups collate the concerns and testimonies of their members, although there are no current guidelines for how, and from whom this is done. It would, in theory, be possible for NICE, or another group, to formally analyse this

submitted, textual information in order to identify the key concerns raised by those who have provided submissions or taken part in the consultations.

3.1.2 Qualitative research evidence

Alternatively, qualitative research could be used to obtain patient evidence. Such research could include that undertaken with patients, their families and/or carers which explores areas such as:

- the impact of having a condition of disease,
- the experience of being within the healthcare system for treatment of that condition,
- the experience of undergoing specific treatments for that condition.

If new research were to be undertaken, the guidance should expand on who should undertake this research, and the methods for identifying, sampling and recruiting participants. It would also need to guide the researchers as to how and by whom, areas for investigation should be identified; for example, through reflection on the quality of life tools currently used, recognition of particular issues in comparing treatments such as balance of adverse events etc. or by allowing patients themselves to prioritise what they discuss by using more unstructured interview methods. Preferred methods of data collection and analysis might also be mentioned.

3.1.3 Syntheses of qualitative research evidence

Where existing research is to be considered as providing patient evidence, it is likely that systematic review and synthesis will provide the most useful framework to understand what is known in the literature as a whole about the experience of a condition and its treatment. Aspects of intervention design, acceptability, implementation and context, are unlikely to be illuminated by the results of quantitative research, and may also be found in qualitative research.

Section 5.3 of the methods guide gives guidance on the review and synthesis of evidence on clinical effectiveness, principally focusing on evidence from randomised controlled trials. There is no corresponding guidance on using

existing qualitative research, including methods of identification, quality appraisal or synthesis.

There are a number of approaches to such review and synthesis, which synthesise qualitative research alone, or with quantitative research including narrative synthesis, meta-ethnography and meta-synthesis (Britten, et al., 2002; EPPI-Centre, 2007; Jensen, et al., 1996; Mays, et al., 2005; Petticrew, et al., 2006; Popay, et al., 2006). The nature of the evidence identified may dictate the most appropriate synthesis methods. In addition, some aspects of the systematic review, such as the most appropriate way to identify qualitative research (Shaw, et al., 2004), and methods of appraising qualitative research, remain contentious (Dixon-Woods, et al., 2004; Wallace, et al., 2004). Despite this, there is increasing acceptance of the methods of synthesis and appreciation of its utility, including in a policy making context (Centre for Public Health Excellence, 2009). For example, recent syntheses have explored the experience of heavy menstrual bleeding (Garside, et al., 2008); strategies employed by patients to manage their psychotropic medicine taking (Britten, et al., 2010); and beliefs about skin cancer and tanning, in the context of providing information to prevent skin cancer (Garside, et al., 2009).

3.1.4 Questions for discussion

3.1.4.1 Qualitative evidence from submissions

Should existing submissions be treated as qualitative evidence which needs to be formally analysed? If so, by whom? Using what methods?

What guidance should be given about the nature and quality of submissions?

3.1.4.2 Qualitative research evidence

Should the Technology Appraisals methods guide give guidance on the use of new qualitative research?

To what extent should the submission of new qualitative research evidence be encouraged in the Technology Appraisals methods guide? From whom and with whom should such research be undertaken? How would the scope and methods of enquiry be determined?

What guidance should be given to optimise the methodological quality of qualitative research evidence used in the Technology Appraisals programme?

3.1.4.3 Syntheses of qualitative research evidence

Should the Technology Appraisals methods guide give guidance on the use of syntheses of qualitative research? By whom should these be undertaken?

How could these syntheses be incorporated into the overall clinical and cost effectiveness evidence base?

4 References

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