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Clinical Guidelines: A NICE Way to Introduce Cost-Effectiveness Considerations?

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ABSTRACT

The National Institute for Health and Care Excellence (NICE) in the United Kingdom initiated its clinical guidelines program in 2001 and more than 200 guidelines have been produced to date. As with most of NICE's other programs, the clinical guidelines program also must take into account the relative costs and benefits of interventions when deciding whether to recommend them. The three main advantages of the program are that 1) it represents an important collaboration with the medical profession, thereby increasing the likelihood of recommendations being adopted; 2) the guidelines provide an opportunity to review all aspects of the clinical pathway, rather than focusing on only the adoption of a new technology; and 3) the guidelines offer the potential to discuss disinvestment as well as new investment. All the guidelines contain a systematic review of the relevant economic evaluation literature, and the 12 guidelines published from January 1 to August 31, 2015, contain 28 de novo economic analyses. The main challenges encountered in the guidelines program are that 1) there is an inevitable tension in advising on the quality of care that individual patients could expect while recognizing the broader public health objectives of equity, fairness, and efficiency; 2) the impact of economics is sometimes lessened because of the lack of time to conduct de novo analyses; and 3) unlike NICE's technology appraisal program, the adoption of recommendations is not mandatory for the UK National Health Service.

Keywords: clinical practice guidelines, cost, cost-effectiveness analysis, oncology, value frameworks.

Background to the Clinical Guidelines Program of the National Institute for Health and Care Excellence

The clinical guidelines program is one of several programs operated by the National Institute for Health and Care Excellence (NICE) in the United Kingdom. Others include programs on technology appraisal, public health, social care, diagnostics, medical technology (devices), and interventional procedures. One of the distinctive features of the clinical guidelines program is that it focuses on improving the present standard of care, whereas most of the other programs focus on assessing new technologies entering the National Health Service (NHS) in the United Kingdom.

NICE has a strong commitment to cost-effectiveness. Its procedures state that "[t]hose developing *clinical guidelines*, *technology appraisals or public health guidance must* take into account the relative costs and benefits of interventions (their 'cost effectiveness') when deciding whether or not to recommend them" [1]. But "[d]ecisions about whether to recommend interventions should *not be based on evidence of their relative costs and benefits alone*. NICE must consider other factors when developing its guidance, including the need to distribute health resources in the fairest way within society as a whole" (principle 3).

The clinical guidelines program was initiated in 2001 and since then more than 200 guidelines have been published. Typically, they give broad guidance covering all, or specific, aspects of the diagnosis and management of a particular condition. They also incorporate any relevant technology appraisals or interventional procedure guidance that NICE has already produced for the condition concerned. Unlike NICE's technology appraisals, the clinical guidelines are not mandatory for the NHS, but often they form the basis of the development of standards to evaluate clinical practice.

A key feature of the clinical guidelines program is that NICE shares the "ownership" of the program with the various "royal colleges" of medicine, which are the central clinical associations in the United Kingdom. Historically, the national collaborating centers producing the guidelines have been located in the various royal colleges, although the guidelines are produced according to a template devised by NICE. The topics for guidelines are selected on the basis of the need to develop quality standards and assigned to the various collaborating centers. A scoping exercise is then undertaken, in consultation with interested parties, including professional societies, the NHS, the Department (ministry) of Health, and, if relevant, technology manufacturers. Then a guideline development group (GDG) is appointed, comprising

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relevant clinical experts and patient/carer representatives. The GDG is provided with technical support, including expertise in systematic reviews and health economics. A critical feature of the process is to identify a number of "key clinical questions," which form the basis for the systematic reviews of existing evidence on effectiveness and cost-effectiveness, plus any de novo economic analysis in situations in which relevant cost-effectiveness evidence is absent or inadequate. Typically, the GDG meets 12 times over a period of up to 2 years. At each meeting, the GDG reviews and discusses the clinical and economic evidence pertaining to one to three key clinical questions.

Once completed, the guideline is circulated for extensive consultation and is then revised before the sign-off by NICE. Several documents are produced, the main one being a summary of the recommendations, the "NICE guidelines." In addition, interested individuals can also obtain the "Full guidelines," or, in the newer guidelines, a range of documents that give details of the evidence and analyses used to support the recommendations. There is also a nontechnical version, called "Information for the public," which can be helpful for patients and their families. NICE also supports the implementation of the guideline with a number of tools and resources for the NHS, the most important ones being a "baseline assessment tool" and a "costing statement," which helps health authorities estimate the likely financial impact of adopting the recommendations in the guideline. The present list of published guidelines, plus those in development, can be accessed via the NICE Web site (http://www.nice.org.uk). The earlier guidelines are called "clinical guidelines," and the more recent ones are called "NICE guidelines" [2].

Advantages of the Clinical Guidelines Program

The NICE clinical guidelines are probably not as widely known as its technology appraisals, which sometimes attract attention because they imply rationing or restrictions on the availability of new treatments and procedures. The guidelines, however, do have a number of important advantages. First, because the operation of the program is shared with the medical profession, it represents an important collaboration aimed at improving the standard of care in the NHS. Thereby, it is more likely that clinical opinion leaders will be willing and able to help in encouraging the adoption of recommendations. Second, the guidelines provide an opportunity to review all aspects of the care pathway, rather than focusing on only the adoption of a new technology. Third, the guidelines offer the potential to discuss disinvestment (in practices and procedures) as well as new investment.

A common criticism made of technology assessment by health care decision makers is that it often only offers advice on how to spend resources on new technologies and rarely discusses how those resources can be found, especially in situations (like the one faced by the NHS in the United Kingdom) of having a fixed budget. During the production of a guideline, the GDG often discusses practices or procedures that may be discontinued because they are of limited use, or can be streamlined because they are at present being applied in an inefficient manner. Some of these suggestions are included in the "Do not dos" list published on the NICE Web site [3].

Contributions of Economic Analyses

As mentioned previously, the role of the health economist supporting the GDG is to undertake systematic reviews of the economic evaluation literature relevant to each of the key clinical questions and, if necessary, conduct a de novo economic analysis. Table 1 details the economic analyses conducted for the guidelines published from January 1 to August 31, 2015. The expectation is that normally one to two new economic analyses will be required per guideline. It can be seen that de novo analyses were conducted to help answer at least one of the key clinical questions for all but one of the guidelines over the period considered here. Some of the analyses were merely costing studies, or adaptations of existing economic analyses, but most of them used a decision-analytic model and are comparable with the analyses carried out in the context of NICE's technology appraisals.

The economic analyses can support the guidelines in a number of ways. In the case of lipid modification (CG181), an economic analysis was conducted to support the recommendation that a high-intensity statin (e.g., atorvastatin 20 mg daily) should be offered for the primary prevention of cardiovascular disease in people who have a 10% or higher 10-year risk of developing the disease. It was thought that this recommendation might be controversial, given the high number of individuals who would be brought into therapy and the likely budget impact. Extensive cost-effectiveness modeling provided a robust defense of the recommendation on economic grounds.

In the case of bladder cancer (NG2), NICE was aware that this is one of the most expensive cancers to manage, and so economic considerations were potentially important. In this case, two economic analyses were carried out. The first analysis compared a single instillation of chemotherapy immediately after transurethral resection of bladder cancer tumors versus no chemotherapy. The study found that chemotherapy was highly cost-effective in all risk groups. The second analysis assessed the cost-effectiveness of reduced follow-up and/or using newer tests and procedures compared with present practice. It was found that reducing cystoscopic follow-up was cost-effective in low- and intermediate-risk patients.

Therefore, taken together, these economic analyses addressed both the potential for investment in therapy as well as the potential disinvestment. From time to time NICE has produced lists of items of its guidance that have the potential for cost reductions [4]. Table 2 provides some examples of the possibilities for cost reductions relating to clinical guidelines. This list is based on costing work undertaken at the time the guidance is published and covers all clinical guidelines from January 2005. (Some of the earlier guidelines on the list have since been updated and are no longer applicable.) All guidance that was considered to deliver a net saving has been identified. There may be elements of other guidelines that will deliver savings, but in some circumstances fully implementing the guidance requires investment. These figures are only estimates and are not to be taken as NICE's view of desirable, maximum, or minimum figures, but they are useful in providing a sense of the scale of savings achievable. Also, these "savings" are *potential* savings only. In many cases actions will be required to realize them. NICE encourages users of the costing templates to modify the assumptions used in the templates to more accurately reflect local circumstances.

Challenges and Issues for Further Discussion

Despite the attractions of introducing cost-effectiveness considerations into NICE clinical guidelines, many challenges remain. First, some economists have argued that, compared with NICE's technology appraisal program, the influence of economics has been lower because of the joint ownership of the program with royal colleges. For example, Wailoo et al. [5] argued that NICE clinical guidelines should be subjected to independent appraisal like the technologies considered in NICE's technology assessment program because the cost-effectiveness of some clinical procedures might not be sufficiently scrutinized. Littlejohns et al. [6] acknowledged this concern and pointed to the inevitable tension