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Title: Are NICE processes fit for the evaluation of new interventional procedures?

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Abstract

The recent changes in the guidance issued by the National Institute for Health and Care Excellence (NICE) regarding the use of endovascular aneurysm repair highlight many of the difficulties faced in the evaluation and introduction of new interventional procedures. This paper questions whether the current processes for evaluation, largely based upon cost-utility analysis, are adequate to address the issues raised by such technologies. In particular, it considers the implications of rapidly evolving technologies, time preferences and process utilities for the evaluation and introduction of new procedures and devices.

Introduction

Guidance issued by the National Institute for Health and Care Excellence (NICE) regarding the use of endovascular aneurysm repair (EVAR) for abdominal aortic aneurysm (AAA) illustrates many of the difficulties inherent in providing evidence-based advice to the NHS.

The procedures and devices used for EVAR have developed rapidly over the past 20 years and many now consider it the first line elective treatment for AAA in most circumstances. The procedure has been considered by NICE on several occasions through different processes (see Table 1). Following publication of the early results of the EVAR trials [1], it was considered sufficiently safe and efficacious for use in the NHS (IPG163). The 2009 appraisal (TA167) recommended it as a treatment option for patients with unruptured infra-renal abdominal aortic aneurysms with some anatomical, clinical and demographic factors to be taken into account in making the decision. The guidance appeared to partly contradict the findings of the assessment report, which demonstrated that EVAR was unlikely to be cost effective in fit patients, when compared to open surgical repair. [2]

EVAR has been widely adopted in the NHS, now accounting for about 70% of elective cases [3] and is used increasingly in emergency cases, following promising trial results. [4] The concurrent introduction of aneurysm screening has increased the proportion of younger and fitter patients undergoing elective aneurysm repair, the group least likely to be cost effective, according to the economic modelling. [2]

The draft NICE guidance issued in May 2018, suggesting EVAR should not be offered to people with an unruptured infrarenal AAA, has proved controversial, and a joint statement from several professional societies has condemned the guidance [5].

NICE decision-making

IPAC considers only safety and efficacy, whilst technology appraisal and guidelines include detailed assessment of cost effectiveness. However, NICE states that it does not prescribe to a specifically utilitarian approach, but focusses on 'procedural justice' that has amongst its principles; scientific rigour, inclusiveness, transparency and independence. [6]

NICE methods guidance describes, in considerable detail, the methods of technology appraisal, including the cost effectiveness analysis to be undertaken, [7] specifying the perspective of the health and social care system, and a version of cost effectiveness based upon the cost per quality adjusted life year (QALY). QALYs are based upon their preferred health outcome measure, the EQ-5D, a generic measure with five dimensions, each valued on a three-point scale and converted to a utility using a standard tariff. A 'discounted cost-per-QALY' is compared to a nominal 'willingness-to-pay' threshold of £20,000 per QALY, which, in certain circumstances, can be extended to £30,000.

The threshold was set nearly 20 years ago and some empirical evidence suggests that this may already be set too high, [8] whilst many technologies are approved well above this threshold, [9] and subsequent changes have stretched this further for end-of-life drugs [10] and highly specialised technologies. [11]

Apart from concerns about aspects of health outcomes that are not adequately captured by EQ-5D [12], other aspects of healthcare provision that are valued by society, are excluded from the calculations. These include issues such as equity, burden of disease, wider societal impacts, autonomy, dignity, continuity of care, location of services and aspects of the process of care, such as the invasiveness of treatment. NICE considered including some of these issues in relation to 'value-based pricing' in 2014, but dropped the proposals following consultation. [13] [14]

Issues for interventional procedures

Although there is no 'gold-standard' for methods of evaluation, the choice may have significant impact on the technologies that appear advantaged or disadvantaged. Specific considerations are of particular relevance to interventional procedures.

Process utilities

The 'process utility' is the additional value that might be attached to particular modes of treatment, such as different routes of administration, outpatient vs. inpatient treatment or more or less invasive methods. Evidence suggests that these may be valued over and above any short-lived differences in health captured by instruments such as the EQ-5D. [15]

NICE may consider such preferences through its deliberative processes, for example, using a raised threshold to allow for the convenience of the oral rather that parenteral administration. However, major surgical procedures, compared

to minimally invasive or medical options, are of a different order of magnitude and adjusting the threshold to allow for this may be unsatisfactory (see below).

Time preferences

Major surgical procedures may result in very different risk profiles compared to less invasive or conservative treatments. To someone needing treatment in their 80's for AAA, the risk of procedure-related mortality for open repair may be 5-10% with EVAR carrying about one-third of this risk. [16] This early advantage may be given far more weight than risks of complications and retreatments years in the future. The strength of this preference is unlikely to be adequately represented by the discount rate of 3.5%, used for NICE economic evaluations. [17]

Evolving technologies

Drugs are stable technologies with pivotal clinical studies prior to licensing, defining the formulation and dosage regimes. In contrast, interventional technologies are usually evolving, creating difficulties in assessing and applying evidence of effectiveness to procedures that are in a state of flux, or devices that may no longer be current.

A changing selection of EVAR devices and techniques may suit patients with specific clinical and anatomical characteristics. Thus, unlike drugs for which indications and are clearly defined, clinicians are not simply learning a new procedure, but developing experience in how particular methods or devices will suit individual circumstances.

Pricing and costs

Drug prices are fixed through various national mechanisms and there is an opportunity for (indirect) negotiation through patient access schemes. [18] There are no such fixed prices or opportunity for national negotiation for devices and a significant aspect of the cost of procedures may relate to hospital and staffing resources, which vary between centres, may be affected by individual patient characteristics and are subject to differences in practice.

Wider impacts

Choices between different modalities of treatment will often have implications for wider aspects of service configuration, such as the location of services, training requirements, the need for capital equipment, shifts in workload or joint working between specialities. Such changes may result in significant sunk cost or organisational changes associated with the new technology.

The evaluation of EVAR

Modelling of cost effectiveness using the methodology and limits usually set by NICE has been consistent in finding that, for relatively young and fit patients, EVAR is unlikely to be cost effective, and may be dominated by open repair. Most models have considered alternative scenarios and subgroup analyses, and suggest that there are older, less fit people, for whom EVAR is a cost-effective option. [2 19] Modelling for the guideline did not consider such alternative scenarios in detail and identifying an appropriate subgroup is not easy, due to the absence of accepted methods for risk scoring, lack of relevant anatomical

and clinical data, and reluctance to use factors such as age and gender to determine treatment policies.

The appraisal in 2009, despite evidence that the procedure was unlikely to be cost effective on average, [2] allowed clinical discretion, but drew attention to factors that may be relevant to the decision. This appeared, in effect, to place responsibility for cost effective decision-making on the individual clinician. This proved unsatisfactory for several reasons.

Whilst those with clinical expertise are clearly important stakeholders in determining guidelines under which new technologies are made available, it is important to separate their policy role from their dealings with individual patients. Patients expect that individual clinical advice is based upon the most effective treatment available and to base such advice on budgetary considerations is likely to undermine the relationship of trust between clinician and patient. Experience also tells us that such discretion is likely to favour more informed and empowered groups within society. [20] In the case of EVAR it is clear that asking clinicians to make decisions based upon cost effectiveness was ineffective. Given clinical freedom, decisions reflect the personal preferences of the clinician and/or patient.

Improving decision-making

There is no 'right' or 'wrong' method for making decisions about the distribution of scarce healthcare resources. With many competing demands on resources, trade-offs are required between utilitarian approaches that might maximise differing measures of benefit, and other libertarian or egalitarian considerations. However, in a publicly funded healthcare system in a democratic society it is,

perhaps, reasonable to expect that the process results in decisions that broadly reflect societal preferences. There are a number of measures relating to NICE methods, or areas where further research is required, that might help achieve this aim.

Better measures of health utility

The primary outcome measure recommended by NICE for generating the utilities used in calculating QALYs is the tariff derived from the EQ-5D. This lacks sensitivity to small changes in health status and does not address significant aspects of health that may be considered important. [12] This has resulted in the development of a five-level version of the measure and the suggestion of various 'bolt-ons' to address areas such as hearing and visual impairment. [21] NICE has not currently adopted these modifications.

Valuing process utility

In addition to the health outcomes measured by EQ-5D, processes of care may be very important to patients, particularly in relation to interventional procedures where options may include major invasive surgery. It is possible to measure the value that is put on aspects of process, and formally consider trade-offs against other aspects of outcome. [22]

Wider aspects

Healthcare decisions are not made in isolation, and healthcare and health outcomes have wider societal and personal impacts. Whilst NICE considered some of these issues as part of the consultation on value-based-pricing, they decided against formally including them in calculations of cost effectiveness. [13]

Considering net benefit

The use of a cost effectiveness threshold, which is varied in certain circumstances, has resulted in a system which tends to favour certain technologies, particularly end-of-life drugs and highly specialised technologies.

The deliberative process used for NICE decision-making, accounts for 'other factors' by raising (never lowering) the threshold in certain circumstances. Additional factors are only considered in relation to the new technology under consideration and not in relation to any existing technology that is likely to be displaced. Disinvestment decisions do not undergo the same level of scrutiny as new technologies and are often invisible to decision-makers and service users who may be affected by such decisions. To include consideration of more sensitive or inclusive outcome measures, process utilities or wider impact, requires that such criteria are extended to potentially displaced activities.

Accounting for such factors by adjusting the threshold particularly benefits high-cost interventions. An alternative approach would be to calculate net monetary or health benefit (or cost). A committee might consider it worth a few additional pounds per patient for a less invasive procedure, but not several thousand pounds, a difference that may not be apparent when considering this in terms of ICERs and thresholds (see Table 2).

Admitting to uncertainty

NICE guidance is based upon evidence that is subject to considerable uncertainty, but clear guidance may inhibit further research. Evidence regarding EVAR has changed little since the original randomised trials and it is unlikely that further randomised studies would be feasible. Data collected through the

National Vascular Registry lacks long-term follow up, [3] whilst routine data can reveal readmissions, re-treatment and mortality, but does not include detailed clinical or anatomical information.

If the modelled costs are accurate then it is likely that EVAR has cost the NHS in excess of an additional £100 million since the appraisal in 2009. A decision at that time for 'coverage with evidence' could, at a small fraction of this cost, have provided the evidence for detailed predictive models, which could be used to identify appropriate populations for the cost-effective use of EVAR. Unfortunately, the financial arrangements that separate clinical and research budgets may mitigate against decisions that are subject to further research and evidence collection.

Conclusions

Whilst the problems encountered in providing guidance about EVAR are not unique, there are various issues that are specific to, or more significant, when considering interventional procedures. Since all NICE decisions are ultimately based upon societal preferences, it seems inconsistent to consider only the preferences for the narrow range of dimensions incorporated in the EQ-5D, and not for care processes or wider impacts that may be valued by society.

Whilst further research is needed to evaluate the strength of such preferences, a move towards the use of net benefits, rather than a variable ICER threshold, may provide more transparency regarding the weight that is given to such considerations. However, the inclusion of other criteria is complicated by the need to ensure that any such modifications in process are applied equally to

technologies that may be displaced, rather than simply inflating the price that the NHS is willing to pay for new technologies.

With technologies that are new and evolving, or where evidence is immature, a more flexible approach to approval for use with evidence collection, or ‘only in research’ may help to avoid the threatened reversals that have occurred in the evaluation of EVAR.

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