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Does the National Institute for Health and Clinical Excellence only appraise new pharmaceuticals?

Luan Linden
The University of Birmingham

Hindrik Vondeling
University of Southern Denmark

Claire Packer, Alison Cook
The University of Birmingham

Objectives: To determine the relative extent to which the National Institute for Health and Clinical Excellence (NICE) appraises new versus existing technologies, and pharmaceutical versus nonpharmaceutical health technologies.
Methods: We categorized technologies within NICE appraisals published between March 2000 and June 2006 by type and classified them as new or existing using the timeline between launch in the United Kingdom and referral to NICE. We used a 3-year postlaunch cutoff to determine whether a technology was new, with a sensitivity analysis of 1 and 5 years.
Results: We reviewed 159 technologies from 88 appraisals. Of these, 84 (53 percent) were new (sensitivity analysis 36 to 67 percent) and 75 (47 percent) were existing technologies. A total of 119 (75 percent) were pharmaceuticals, 22 (14 percent) were devices, 14 (9 percent) were procedures, and 4 (3 percent) were categorized as miscellaneous. Classification according to newness and technology type showed that 62 percent (42 to 75 percent) of the pharmaceuticals appraised were new.
Conclusions: By developing and applying a definition of new, we have found that the criticism of the bias toward new technologies is unfounded when applied to the appraisal program overall. At the same time, new pharmaceuticals are over-represented in the program compared with devices and procedures. This domination may cause inflationary pressures on the health service, but any wholesale move away from the technological frontier may be more costly.

Keywords: National Institute for Health and Clinical Excellence, Health technology, Health technology assessment, Topic selection, NICE

The National Institute for Health and Clinical Excellence (NICE) was established in April 1999 to provide the National Health Service (NHS) with guidance on the clinical and cost-effectiveness of health technologies. In the consultation papers that heralded its introduction, it was envisaged that both new and existing technologies would be covered (9), but that initially the program would focus on new technologies, with a catch-up program planned for existing technologies once the program became more established. It was also envisaged that all types of clinical intervention would be included on an equal basis (10).

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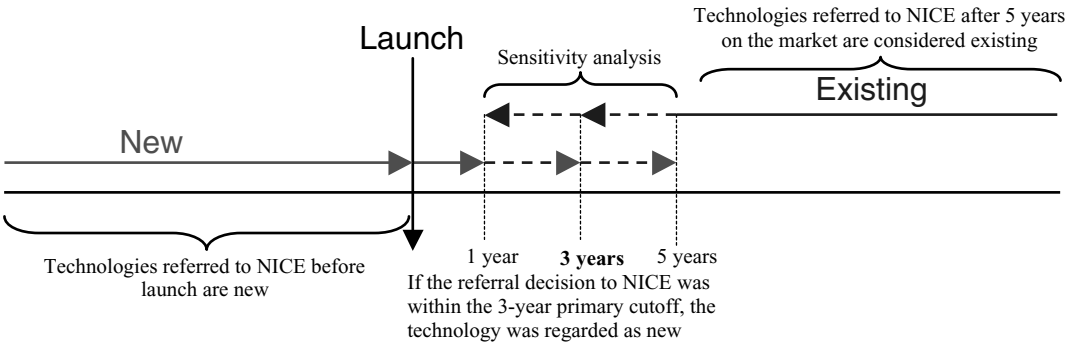

Figure 1. Cutoff points for referral to National Institute for Health and Clinical Excellence (NICE) used to categorize technologies.

Until summer 2006, appraisal topics were selected by the English Department of Health (DH). In 2006, NICE was given responsibility for the initial topic selection with the final topic selection announced by Ministers (5). Although NICE had not been responsible for the selection of appraisal topics, it has faced criticism of an apparent bias toward appraising new technologies, particularly pharmaceuticals, at the expense of neglecting old ineffective or inefficient technologies whose removal from practice may offer the opportunity to provide savings for the NHS (3;8;13;14). The concern is that such a bias toward new technologies is likely to result in expenditure increases, which could ultimately threaten the financial sustainability of the NHS (8).

None of the critics of NICE topic selection has so far enumerated the case or defined a distinction between an existing or new technology. We, therefore, test two hypotheses, that there is a bias toward new technologies and a bias toward pharmaceuticals, by analyzing technologies that were appraised in the first 100 published NICE appraisals.

METHODS

For a technology to be included in our analysis, it had to have an appraisal published between March 2000 and June 2006 and be explicitly cited in the title or summary of the guidance. These guidances correspond to a referral period from Health Ministers to NICE between November 1999 to June 2004. Appraisals may have included more than one technology. For instance, in the guidance on the selection of prostheses for primary total hip replacement (appraisal number 2), over sixty devices were assessed, but the comparison was essentially between cemented, cementless, and hybrid prostheses. The appraisal was, therefore, considered to contain three technologies. Reviews of existing appraisals were only included if the scope had altered and only technologies additional to those originally appraised were counted.

We distinguished three major categories of technologies: pharmaceuticals, devices, and procedures (diagnostic or therapeutic), and one miscellaneous category for technologies such as settings of care.

Existing and new technologies were defined according to the time elapsed between launch and referral to NICE. Technologies were defined as "new" if they were referred to NICE before their launch, or if less than 3 years had elapsed between their launch and their referral to NICE (Figure 1). The rationale is that a new technology is one in the phase of adoption that has only been available for clinical use for a short time and will generally be in the launch or early postmarketing stages. Typical diffusion rates would put this timing at around 3 years (2;11). Technologies were defined as "existing" if they were referred to NICE 3 or more years after launch. We conducted a sensitivity analysis using 1- and 5-year postlaunch cutoff points (Figure 1).

Launch dates for pharmaceuticals were obtained from the pharmaceutical database Adis R&D Insight (http://www.adisinsight.com/) with a 20 percent random sample checked with manufacturers to validate accuracy. For devices, the date of availability outside a research setting in the United Kingdom was used as a proxy for the launch date. Information was obtained directly from manufacturers or UK distributors, except for devices that were launched pre-1994 (i.e., 5 years before the first referral from the DH), when exact dates were not required as they would be classed as existing technologies. For procedures, the date of first journal publication by UK authors, obtained through Medline and Embase searches, was used as a proxy for launch. The date of referral to NICE was defined as the date at which a technology was formally referred by Ministers to NICE. This information was sought directly from the DH.

RESULTS

Pharmaceuticals account for 75 percent of the total number of technologies considered in the 88 appraisals included in our analysis (12 reviews were not included; Table 1). New technologies make up 53 percent of appraised technologies (Figure 2). This proportion is sensitive to the cutoff point used: changing to 36 percent with the 1-year cutoff, and 67 percent with the 5-year cutoff. The proportion of new technologies appraised is much greater for pharmaceuticals

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Table 1. Frequency and Proportion of Individual Technologies by Technology Type

Appraisal type	No. of technologies appraised ($n = 159$)
Pharmaceuticals	119 (74.8%)
Devices	22 (13.8%)
Procedures (diagnostic/therapeutic)	14 (8.8%)
Miscellaneous	4 (2.5%)

(which dominate the program) than for other technologies (62 percent; sensitivity analysis 42 to 75 percent).

DISCUSSION

Our data suggest that the referral system to NICE favors the appraisal of pharmaceuticals in preference to any other technology type and that approximately half of all technologies and 62 percent of pharmaceuticals appraised can be considered as new. Although enumeration of the problem has shown the criticism of a bias toward new technologies to be unfounded when applied to the appraisal program overall, it is true of pharmaceuticals. The domination of the program by pharmaceuticals has been a feature from the outset, as shown by an earlier analysis of the first thirty-two technology appraisals where around two thirds of technology appraisals were of pharmaceuticals (14).

One caveat is that the cutoff between new and existing is subjective. With pharmaceuticals, the sensitivity analysis found that a relatively large proportion of those initially categorized as existing, using a 3-year cutoff, were reclassified as new using the 5-year cutoff. This result lends weight to the finding of a bias toward new pharmaceuticals, because even 5 years after launch, many pharmaceuticals may not be fully diffused (4;11). At the other extreme, it is unlikely that a technology would have completed its diffusion by 1-year postlaunch, and in the majority of cases classifying a technology as old at 1-year postlaunch is unlikely to be realistic (1). Nonpharmaceuticals typically diffuse more slowly (2).

A second caveat of our analysis of the proportion of new technologies appraised is that, for every new technology appraised, arguably there is one or more existing comparators considered in the appraisal. However, although this argument may be valid in some cases, many new technologies are additions to current therapy rather than substitutes. In addition, a strategy of appraising only new technologies risks never considering the existing technologies in areas where no new technology appears.

Although the appraisal program was never intended to represent the "real world" in terms of the technological

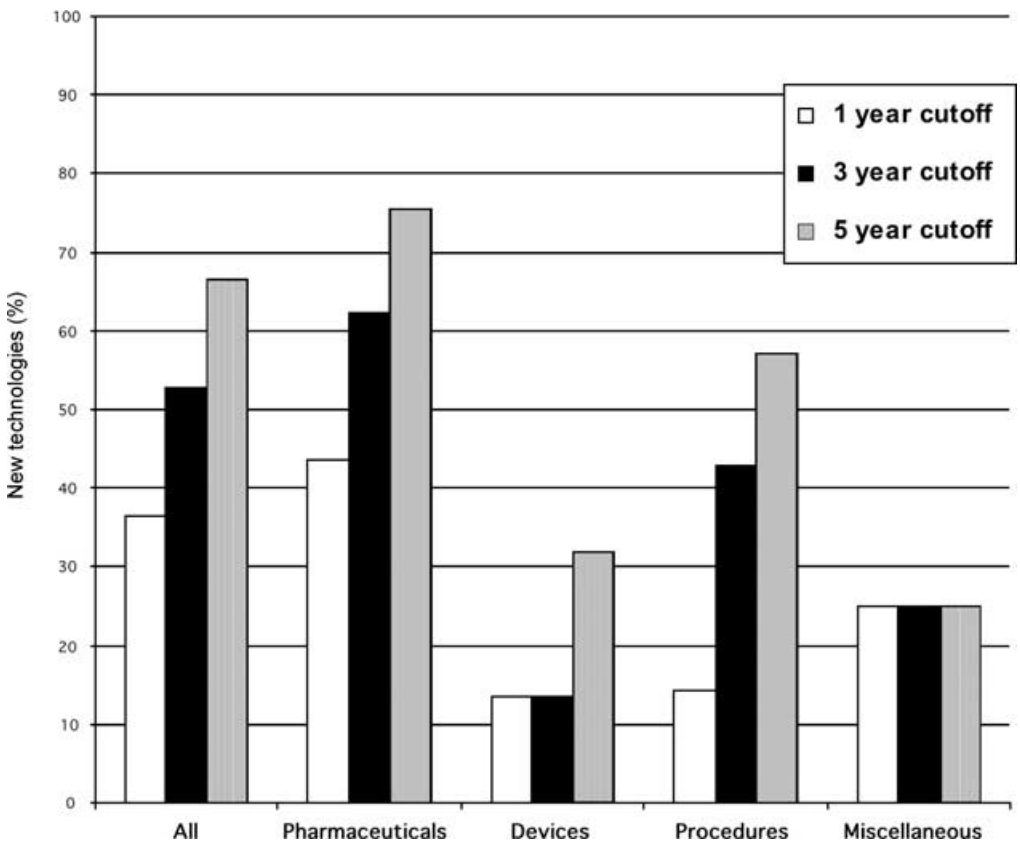

Figure 2. Percentage of new technologies appraised by technology type.

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landscape, it is of interest to consider whether our findings reflect this. In the case of pharmaceuticals, given that less than 50 new chemical entities are approved each year (7), the denominator for the number of new pharmaceuticals launched into the market during our period of analysis (November 1996 to June 2004, inclusive of an additional 3-year diffusion period before the first referral to NICE) could only amount to a maximum of 400. There are more than 1,250 drug monographs listed in the British National Formulary. On this basis, NICE has appraised 9.5 percent of all pharmaceuticals, 19 percent of the maximum number of new drugs, and 5 percent of the estimated number of existing drugs ($\chi^2 = 53.844$; $p < .001$; $df = 1$). In comparison, there are approximately 6,000 Office for Population Censuses and Surveys (OPCS)-coded procedures, and around 1,100 product categories that cover an estimated 50,000 medical devices (12). From this perspective, proportionally, the appraisal program has addressed less than 0.1 percent of nonpharmaceuticals.

However, is the greater proportion of appraisals allocated to pharmaceuticals, and especially to new pharmaceuticals unreasonable? Arguably the policy objective was to keep some balance between appraising new and existing technologies, and between pharmaceuticals and other technologies, but not at the expense of failing to appraise important new pharmaceuticals close to launch. NICE has been under increasing pressure to appraise new technologies at or as close to launch as possible to prevent inappropriate diffusion. New pharmaceuticals in particular, have the potential to impact on healthcare budgets quickly, because in general, they can be prescribed by any doctor and usually require no special systems or equipment for administration.

Different behavior from the industrial sponsors of technologies may also impact on the favoring of new pharmaceuticals. Inclusion of a technology in NICE's appraisal program has important implications for its adoption and subsequent diffusion, particularly since January 2002, when healthcare providers were obliged to comply with NICE's appraisal recommendations (6). New nonpharmaceuticals tend to have less commercial pressure behind them and make their initial impact over a longer time frame than pharmaceuticals, often because they require consideration of capital expenditure, or need specialist training or equipment for utilization. Procedures are also less likely to have industry supporting their introduction, as they are often pioneered by clinicians.

Under-representation of new nonpharmaceuticals could also be a product of the often incremental developments associated with medical devices and procedures. As well as reducing overall impact, the rate at which modifications occur often means that each version of the technology has a short life-span, making it more difficult to appraise and giving the final appraisal a short shelf-life. Each modification could make that technology new, but essentially the concept is old.

Arguments against the current dominance of new pharmaceuticals in NICE's appraisal program are that a continuing bias toward new and expensive pharmaceuticals could set up further financial problems for the health service and that tightly controlling the introduction of innovations to prevent inappropriate diffusion could stifle future development for new patient indications (depending on whether NICE tends to approve or limit the technologies it appraises).

CONCLUSIONS

Certainly, if the appraisal program of NICE is to meet its original objective of representing technology types equally, then the selection process will need to change. In addition, if the health service is serious about targeting the removal of ineffective technologies, the selection process may need to pilot new identification methods, as previous initiatives to identify obsolete or ineffective technologies have not led to many published appraisals. NICE is constrained in terms of the number of technologies it can appraise and to change the emphasis from the new technology frontier to rationalize the old could prove far more costly to the NHS than any savings that could potentially be accrued. The introduction of the single technology appraisal process may free up some resources to concentrate on existing practices, and time will tell if transferring responsibility for initial topic selection from the disbanded Department of Health Advisory Committee for Topic Selection to NICE's Consideration Panels will have an impact on the configuration of the technologies appraised in the future.

CONTACT INFORMATION

Luan Linden, BSc (Hons), MSc (l.p.linden@bham.ac.uk), Research Associate, Department of Public Health & Epidemiology, The University of Birmingham, Edgbaston, Birmingham, B15 2TT, UK

Hindrik Vondeling, PhD (hvo@sam.sdu.dk), Associate Professor, Department of Health Economics of the Institute of Public Health, The Faculty of Social Sciences, University of Southern Denmark, J.B. Winsløws Vej 9B, Odense, DK-5000, Denmark

Claire Packer, BM, BS, (c.packer@bham.ac.uk), Senior Clinical Lecturer in Public Health, **Alison Cook**, BSc (Hons), PhD (a.m.cook@bham.ac.uk), Research Fellow, National Horizon Scanning Centre, Department of Public Health & Epidemiology, The University of Birmingham, Edgbaston, Birmingham, B15 2TT, UK

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