

Executive summary

When and how to assess fast-changing technologies: a comparative study of medical applications of four generic technologies

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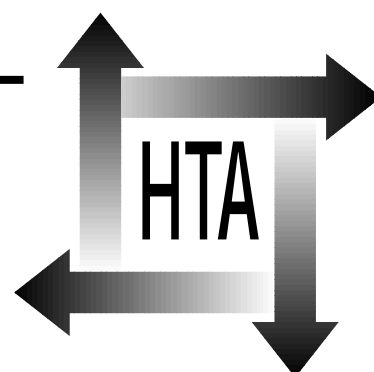
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Health Technology Assessment
NHS R&D HTA Programme





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Objectives

- To try to identify the optimal time at which to start assessing new and fast-evolving health technologies.
- To provide insight into factors influencing the timing of assessments and the choice of methods for assessing new and fast-changing technologies.

How the research was conducted

A series of literature reviews were undertaken covering the general principles involved in the timing of health technology assessments (HTAs). Additionally, the reported assessments of laparoscopic cholecystectomy, chorionic villus sampling (CVS), teleradiology, teledermatology, genetic screening for predisposition to breast cancer, and gene therapy for cystic fibrosis were reviewed to try to identify the factors that influenced the timing of these assessments. Key individuals in each field were also interviewed. The selected technologies allowed comparison between those that were new and evolving and those that were relatively well-established.

A bibliometric study of publication trends was also undertaken to see whether these trends would suggest points in the development of a technology that could be used as indicators that assessment should be started.

Research findings

Timing

The precise point at which assessment should start was not identified but the bibliometric study suggested that extending this approach might give useful results.

For all health technologies, more regular reporting of outcomes and side-effects should be encouraged during the period after initial assessment and, where the technology is fast-changing, reassessment should take place from time to time. The precise intervals were not identified and the problem remains of deciding when a technology has changed enough to warrant reassessment.

Factors influencing timing

Published reports of assessments did not generally specify the reasons for their timing, but a number of factors appear to have influenced the timing of those assessments, directly or indirectly.

Product champions and opinion leaders pioneer the introduction of new technologies into clinical practice, and their reports may lead to the rapid diffusion of such technologies before they have been adequately evaluated, as was the case with laparoscopic cholecystectomy; this diffusion may limit the methods of evaluation that can then be used. It is therefore important to assess new health technologies before diffusion takes place.

The extent to which **regulatory control** is imposed on the introduction of new health technologies can also influence the timing of assessments. Such controls might have helped to restrict the diffusion of laparoscopic cholecystectomy, making a large and widely generalisable randomised controlled trial (RCT) feasible.

The **source and availability of funding** for studies may influence the nature and timing of trials. Many telemedicine evaluations were funded by commercial telecommunications organisations and were thus restricted in their timing (and biased towards the technological aspects of the applications) by the availability of funds.

Media coverage undoubtedly has an influence although this influence is not always predictable; it may generate 'favourable' publicity about new health technologies, which can lead to immediate demands for the new technique, as was the case with laparoscopic cholecystectomy with its apparent benefits. Thus assessments should be made before media coverage exerts popular pressure on purchasers to adopt the technology and dissuades patients from participating in RCTs (because of fear they may be randomised to the standard treatment as occurred in a US trial of CVS). Innovators should also be cautious in the claims that they make to the media.

Clinical uncertainty or equilibrium also affects the timing of assessments. During the period when clinicians have no preference between the

treatment options to be compared, they may be prepared to ask patients to participate in trials; however, once clinicians come to prefer either the standard or the alternative treatment, they may feel ethically obliged to provide only the treatment that they believe to be the best. This argument was given as a reason for abandoning a proposed RCT of laparoscopic versus open cholecystectomy. The counter-argument is that randomisation is a hedging, risk-minimisation strategy when the true risks and benefits are not known.

The existence of the **clinical learning curve** also influences the timing. Assessments made before clinicians have acquired enough skill in the new procedure may produce misleading findings on benefits and costs. Assessments may need to be postponed until clinicians have reached an appropriate point on the learning curve but this can usually only be recognised retrospectively, by which time clinicians may no longer be prepared to randomise patients.

The fact that the development of some health technologies is **technology-driven** or **commercially-driven**, rather than needs-based, affects the timing of assessments to the extent that advances in the technology, in conjunction with a **reduction in costs**, have largely determined the timing of assessments (e.g. teleradiology).

Assessment methods

HTA has traditionally focused on clinical outcomes but there are now demands for a wider range of criteria including social and ethical impact, effect on patterns of healthcare demand, cost-effectiveness and other issues.

The reviews of the various applications indicate that HTA can never be perfect but that best practice uses a number of methods of assessment, rigorously applied and reported, to achieve the most satisfactory outcomes for patients. Rare side-effects are often only detected after extensive use, and new problems can arise because of the different ethical and cultural concerns of different patient groups. New patterns of demand, created by the availability of new techniques, can invalidate economic studies.

The problems of assessing fast-changing technologies are similar to those of assessing stable technologies but are likely to arise more often during the development phase of a technology. Regulation is restricting the genetic technologies to research use or controlling their diffusion until assessment gives satisfactory outcomes. Telemedi-

cine, however, is only beginning to be assessed on a limited basis and there are no controls on adoption. Thus, approaches to assessment are more a function of perceived risk than of rate of change.

Both stable and fast-evolving technologies lack a framework of standard guidelines and incentives to ensure that users assess unregulated or lightly regulated health technologies in an approved and consistent way and report the results. In addition, guidelines are needed to ensure that the decision about when a procedure has changed enough to be regarded as new is clearer and less subjective.

Conclusions

- Assessment should be initiated early, using a variety of complementary assessment approaches.
- Methods of assessment and reporting should be more standardised from the earliest stages, to improve the usefulness and comparability of data.
- Resource issues should be incorporated into assessments from an early stage.
- All technologies should not be dealt with in the same way – they should be assigned to categories for which appropriate common triggers can be identified.
- Trials should be randomised from the outset.
- Assessment should be an iterative process.
- Citations and publication trends may be useful for identifying triggers.

Research recommendations

- Bibliometric studies involving a larger number of established technologies should be undertaken to detect whether there is a sufficiently consistent pattern to the publication trends of new and fast-changing health technologies to allow identification of a 'critical point' at which assessment should be recommended.
- Guidelines for the study and interpretation of different types of health technologies should be developed to facilitate assessment decisions.

Publication

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NHS R&D HTA Programme

The overall aim of the NHS R&D Health Technology Assessment (HTA) programme is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and work in the NHS. Research is undertaken in those areas where the evidence will lead to the greatest benefits to patients, either through improved patient outcomes or the most efficient use of NHS resources.

The Standing Group on Health Technology advises on national priorities for health technology assessment. Six advisory panels assist the Standing Group in identifying and prioritising projects. These priorities are then considered by the HTA Commissioning Board supported by the National Coordinating Centre for HTA (NCCHTA).

This report is one of a series covering acute care, diagnostics and imaging, methodology, pharmaceuticals, population screening, and primary and community care.

The views expressed in this publication are those of the authors and not necessarily those of the Standing Group, the Commissioning Board, the Panel members or the Department of Health.

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