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Health technology assessment: history and demand

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Summary

Health technology assessment (HTA) – the provision to decision makers of information on the value of treatments and tests – has come of age in the last two decades. But it has deep roots in health care, with notable landmarks in (1) the mid eighteenth-century development of empiricism, (2) the twentieth century interest in outcomes and variation in health care, and (3) the pioneering work of Archie Cochrane and others in the 1970s.

Three main forces have driven the recent developments of HTA: a combination of concerns about the adoption of unproven technologies, rising costs, and an inexorable rise in consumer expectations. The HTA response, essentially initiatives supporting the provision of reliable synthesised research information on the effects and costs of health technologies, have been well supported in the United Kingdom and internationally. We can be sure that HTA is here to stay.

Keywords: decision making, history, evidence-based health care, demand management, consumer demand

Introduction

Health systems across the world have seen an explosion of interest over the last 20 years in health technology assessment (HTA), evidence-based health care (EBHC) and the analysis of cost effectiveness (CEA). This growth has been manifest in new journals, new courses, international collaborations, specific research and development programmes (notably the National Health Services's (NHS's) R&D HTA programme), new HTA research teams, and last but not least the emergence of national policy customers for HTA reports, including the National Institute for Clinical Excellence (NICE) in England and Wales.

This paper deals with three central concepts: EBHC (the extension of evidence-based medicine to all health-care decision-makers), CEA (a group of analytic tools bringing together costs and effectiveness) and HTA. HTA is the provision for health care decision-makers of high-quality research information on the cost, effectiveness and broader impact of health technologies; where health technologies are not just high-tech 'kit', but all interventions offered to patients. These three are not synonymous, but they are converging and they have common characteristics. These include a systematic approach to the evidence, a focus on patient-relevant outcomes, and the notion that policy decisions for one set of patients will affect others. There is thus a concern not just with effectiveness but also with transparency, opportunity costs and practical relevance.

In this paper, we offer an overview of key developments in EBHC, CEA and HTA. We acknowledge that our perspective is public health- and UK-based and that our methods are not systematic.[1] But we believe that many of our observations will be relevant in other countries and hope that readers will find our framework of 'origins, forces and response' helpful.

Origins of HTA

The origins of effectiveness research in western medicine have usually been traced back to the 'méthode numérique' of Pierre Louis in Paris in the 1830s and the demonstration that phlebotomy did not after all improve survival for patients with pneumonia.[2] The starting point can, however, plausibly be traced back another 80 years to mid-eighteenth-century Britain and the 'arithmetical medicine' associated particularly with graduates of the Edinburgh medical school.[3] One of these, James Lind, memorably conducted a controlled trial of six different treatments for scurvy. Others have looked back to the book of Daniel in the Old Testament.[4]

At the start of the 20th century, Ernest Codman in Boston called for detailed follow-up of patient outcomes.[5] What is now called health services research dates back in England to the 1930s, when it emerged partly from epidemiological research, a classic case being Glover's findings of a 10-fold variation in tonsillectomy in England and Wales.[6] Glover's work appears not to have been taken further in the United Kingdom until a flurry of studies in the 1970s and 1980s demonstrating wide geographical variations in general medical admissions and in a

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range of operations (including tonsillectomy, appendicectomy, hysterectomy, cholecystectomy, prostatectomy and caesarean section).[7]

Such variations exposed uncertainty about the 'appropriate' rates of a treatment in a population, which in turn raised questions about the treatment's effectiveness and cost-effectiveness. Such questions are best answered by randomized controlled trials (RCTs) and one of the most famous early RCTs, published in 1948, demonstrated the life-saving effects of streptomycin in tuberculosis;[8] but it was by no means the first.[9]

A more recent milestone in the effectiveness revolution was the publication in 1972 of Archie Cochrane's *Effectiveness and efficiency: random reflections on health services*.[10] Cochrane identified both the paucity of evidence of effectiveness for much health care at the time, and also strongly advocated the RCT as its solution. The 1970s also saw *Limits to medicine*, in which the Austrian Ivan Illich described the medical establishment as a major threat to health;[11] and Thomas McKeown's *The role of medicine*, which challenged the idea that major improvements in the population's health were due to advances in medical care.[12] Health economics as a distinct academic specialty grew steadily from the mid-1970s; and in the 1980s, research on variations in health care, successors to Glover's work, became widespread.[7] A notable example was the work by Wennberg *et al*. in the USA, demonstrating large variations in the rates of prostatectomy for benign prostatic hyperplasia.[13] Those workers suggested that the existence of such variations meant either under-provision in some places and/or over-provision (and possibly ineffective treatment) in others.[14]

These pioneering perspectives provided the tools for the assessment of both new and existing health care technologies: scepticism, the investigation of variations, RCTs and cost-utility analysis. The most recent addition to the toolkit – systematic reviews – has dramatically accelerated the development of robust HTA. The need for reviews to be systematic was clearly demonstrated by Mulrow in her scathing assessment of the narrative reviews that used to dominate the review article in the medical literature.[15] The Cochrane Collaboration, responding to this and other challenges, has provided a world-wide lead in helping 'people make well-informed decisions about healthcare by preparing, maintaining and promoting the accessibility of systematic reviews of the effects of healthcare interventions'.[16] At the time of writing, the Cochrane Database of Systematic Reviews in the Cochrane Library (2003, issue 1) had 2796 entries. As a result of all this hard work, the systematic review, complemented with analysis of cost-effectiveness, has become the centre-piece of health services' increasingly voracious appetite for accurate information on the value of health technologies.

Forces for HTA

That appetite has been driven by a number of forces. The first is the widespread realization that many medical interventions may be under-researched and may not do more good than harm. Many interventions are seen to be based on conventional wisdom rather than robust science, with perhaps only 50 per cent of health care procedures based on good RCTs.[17] (Some have reported a figure as low as 15 per cent,[18] although the meaning of such figures has also been disputed.[19]) The long-term follow-up of outcomes has also demonstrated that unproven technologies may not have their intended benefits (radical mastectomy for breast cancer,[20] for instance) – or even worse, do more harm than good (as with, dramatically, the thalidomide disaster[21]).

In 1992, the Department of Health published a landmark report on *Assessing the effects of health technologies*.[22] This proposed a fourfold classification of the use of technologies that is still helpful today. First were widely used technologies ultimately shown to be ineffective or harmful, such as the freezing of peptic ulcers, and the use of prophylactic anti-arrhythmics in myocardial infarction. Second, the report highlighted the sometimes damaging delay in the introduction of valuable technologies, such as tamoxifen in early breast cancer and aspirin following myocardial infarction. Third were new technologies falsely promoted over existing ones, such as routine use of tissue plasminogen activator over streptokinase in acute myocardial infarction and chorion villous sampling over amniocentesis. Finally, the report pointed to uncertainty about the value of technologies as demonstrated by variations in their use, such as prostatectomy and caesarean section.

Not only was there clearly a shortage of evidence in many situations, but also sometimes where the evidence had amassed there was a costly (in terms of lives) delay in its being translated into accepted 'knowledge'. A retrospective cumulative meta-analysis of therapies for myocardial infarction demonstrated in 1992, for instance, that there had been a 10–15 year delay between the sufficient accumulated evidence of the value of streptokinase and its acknowledgement in standard medical texts (review articles and book chapters).[23]

The second principal driver for HTA has been, of course, cost. Cost-containment has been a concern of the NHS virtually since its inception and in practice almost no technologies (except perhaps immunization) have ever been cost reducing. Cost pressures on health services come from a number of elements: general inflation in the economy, growing demand as a result of population ageing and changing expectations, altered methods of working and, notably, the impact of new technologies.[24]

New technologies drive up costs in three main ways. First, there is the impact of the apparently exponential increase in numbers of new technologies. Over the last three decades, this has been particularly visible with expensive diagnostic technologies (CT scanning, MRI, digital imaging systems, tele-imaging), but for the last 10 years (and for the foreseeable future) disease-modifying technologies have also come to the fore. Some have been treatments for previously untreatable conditions (although their value has at times been questioned), such as donepezil in Alzheimer's disease and beta-interferon in multiple sclerosis.

Second, the unit cost of the new technologies has often been startlingly higher than the treatments they replace. Selective seratonin reuptake inhibitors, for example, cost six times as much as tricyclic antidepressants;[25] taxanes are several thousand pounds per patient treated more expensive than previous anticancer treatments;[26,27] and two new drugs for severe rheumatoid arthritis – etanercept and infliximab – can cost nearly £10 000 per patient for every year that they are treated.[28] Third, many new technologies are less unpleasant for patients than those they replace, so lowering clinicians' treatment thresholds and encouraging patients to seek treatment, and thus increasing the total number of patients treated. The rapid replacement of open by laparoscopic cholecystectomy in the early 1990s is an example.[29]

The third driver for HTA has been the rise in consumer expectations and demand. This has been important both indirectly (by increasing the use of health care and so fuelling the pressures described above) and directly (as consumers have become more demanding, one of the things they have demanded is better information, to help them make informed choices[30,31]). This consumer demand for HTA is fairly new but will surely be of great importance in the future.

The HTA response

The NHS has seen many policy responses to these pressures: the more managerial culture dating back to the Griffiths report in 1983,[32,33] the purchaser–provider split brought in by the Conservative government in 1991[34] and the Labour government's quality initiatives from 1997.[35] The critical response has been the provision of information in general and health technology assessment information in particular. More recently, the setting up of systems for appraising such information (i.e. receiving, considering and acting on it) has been a key development. This was seen with the former regional Development and Evaluation Committees[36,37] and, nationally and with more sophistication, with the establishment of NICE's appraisal function.

The central element of HTA is 'high quality research information for health service decision makers on the costs, effectiveness [i.e. benefits] and broader impact of health technologies'.[38] The provision of such information was given a major boost by the 1988 House of Lords report, which stressed that 'the NHS should articulate its research needs, assist in meeting those needs and ensure that the fruits of research are systematically transferred into the service'.[39] This report led to the establishment of the NHS R&D programme of which HTA has been the centre-piece. Since it started in 1993, the NHS HTA programme has commissioned 398 pieces of research to answer questions of importance to decision-makers in the NHS; 162 reports have already been published.[38]

The NHS HTA programme has been part of an array of HTA-related developments. A large number of other bodies in the United Kingdom are funding HTA research: the Medical Research Council, charities, industry and NHS bodies. In response, many more research centres are undertaking HTA, including private organizations, pharmaceutical companies, and a growing network of universities (seven of the latter are now commissioned by the NHS HTA programme to provide NICE with technology assessment reports to assist in its making of appraisal decisions). The research they undertake is of a wide range. For instance, the research commissioned by the NHS HTA programme includes both systematic reviews (of varying length and complexity, depending on the needs of the customer) and new primary research (usually trials). The HTA banner also includes the plethora of guidelines being developed to assist clinical care as well as wider reviews such as the health care needs assessment series.[40,41] A number of new co-ordinating institutions have been created to handle the new work, notably, the UK Cochrane Centre, the NHS Centre for Reviews and Dissemination at York, the National Co-ordinating Centre for HTA in Southampton, and the InterTASC group of university teams producing HTA reports for NICE. A number of training initiatives have been developed to enhance skills in and dissemination of health technology assessment. Finally, a number of major 'vectors' have been developed for disseminating HTA and other medical research information: key electronic databases include not just Medline but also the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effects, the Health Technology Assessment database and the Department of Health's National Research and Research Findings Registers.

The NHS has unique features internationally, but no health system is an island and HTA is an international movement. The term 'health care technology assessment' has its origins in the 1970s in the USA, where health technologies were among a number of technologies that Congress saw the need to evaluate. Its history has been chequered there, but in many European and Commonwealth countries HTA centres have had steady government sponsorship. International collaboration can be seen in ISTAHC,[42] the collaboration of individuals working on health technology assessments; INAHTA,[43] a collaboration of HTA organizations; and Euroscan, a European group to monitor emerging technologies.[44] There is some sharing of work programmes between the USA, English and Swedish HTA programmes. And NICE is being watched internationally wherever 'fourth hurdles' (systems that decide whether drugs that have been licensed should be reimbursed) are being considered.

The future

We believe that HTA is here to stay. The need to contain costs and to reduce unjustified variations in clinical practice and health service provision will mean that decision-makers need more, not less, high-quality information on treatments' impacts. Developments specific to the NHS may mean an even greater need for HTA. The UK government's commitment to NHS modernization and sustained increases in health service spending leads to the need to increase investment in treatments and

services likely to be of benefit to patients. HTA should be a central mechanism for ensuring that this modernization has its desired impact.

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