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Health Economics as Rhetoric: The Limited Impact of Health Economics on Funding Decisions in Four European Countries

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ABSTRACT

Background: A response to the challenge of high-cost treatments in health care has been economic evaluation. Cost-effectiveness analysis presented as cost per quality-adjusted life-years gained has been controversial, raising heated support and opposition. **Objectives:** To assess the impact of economic evaluation in decisions on what to fund in four European countries and discuss the implications of our findings. **Methods:** We used a protocol to review the key features of the application of economic evaluation in reimbursement decision making in England, Germany, the Netherlands, and Sweden, reporting country-specific highlights. **Results:** Although the institutions and processes vary by country, health economic evaluation has had limited impact on restricting access of controversial high-cost drugs. Even in those countries that have gone the furthest, ways have been found to avoid refusing to fund high-cost drugs for particular diseases including cancer, multiple sclerosis, and orphan diseases. Economic evaluation may, however, have helped some countries to negotiate

price reductions for some drugs. It has also extended to the discussion of clinical effectiveness to include cost. **Conclusions:** The differences in approaches but similarities in outcomes suggest that health economic evaluation be viewed largely as rhetoric (in D.N. McCloskey's terms in *The Rhetoric of Economics*, 1985). This is not to imply that economics had no impact: rather that it usually contributed to the discourse in ways that differed by country. The reasons for this no doubt vary by perspective, from political science to ethics. Economic evaluation may have less to do with rationing or denial of medical treatments than to do with expanding the discourse used to discuss such issues.

Keywords: cost-effectiveness, health economics, health policy, reimbursement.

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Introduction

A feature of the economic growth, first of the West and more recently of most of the rest of the world, has been increased spending on health care. Although the balance varies by country, most systems rely heavily on public funding. Some systems rely on taxation (Beveridge) and other systems on social insurance (Bismarckian). All share problems to do with priorities in health care, such as how much to spend and on what. These problems have become matters of public debate and concern. Issues to do with the funding (or no funding) of particular cases have featured prominent decisions in various countries [1–10].

While the language of medicine and the clinic has to do with individuals, that of the state-funded health care has to do with populations. Individuals feature only as abstractions, such as the value of a statistical life [11]. When patients pay health care professionals directly, the link is personal and immediate. When

health care professionals and services are paid by a health system, that link is less direct.

Economics, describing itself as the science of choice under scarcity, may provide tools to solve the problem of prioritizing in health care. Cost-effectiveness analysis was developed to deal with such problems when the market was unable to function. Health economics emerged as a branch of applied economics over the last four decades. One of its main contributions has been a generic measure of health, the quality-adjusted life-years (QALYs). This takes the value of a statistical life further by expressing it in life-years, adjusted for health-related quality of life. With a cost per QALY for every treatment, the number of QALYs can be maximized from a given budget for health care by adjusting the mix of services until each had the same marginal gain.

Although this approach has had criticism, it has been adopted in some form by many countries [12]. The International Society for Pharmacoeconomics and Outcomes Research, an international

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organization with strong links to the pharmaceutical industry, publishes details of the 50 or so countries that have adopted formal methods for the application of cost-effectiveness analysis to health services, mainly but not entirely addressing pharmaceuticals.

Although pharmaceuticals account for only 10% to 20% of health care spending, they share several features, which facilitate regulation of reimbursement and pricing. They are heavily regulated mainly because of a history of harms. Randomized trials demonstrating efficacy are required for market access. Safety is monitored and serious adverse events may lead to loss of market authorization. Pharmaceuticals are usually provided by private companies, which have become multinationals. Prices for new pharmaceuticals have risen sharply in recent years to multiples of the average spent per person. The question arises as to why new pharmaceuticals need to be so expensive [13,14]. Consequently, affordability, particularly but not exclusively, of drugs has become a major concern in health care.

Many studies identify the adoption of economic evaluation by health care systems [15–22]; much fewer, however, have explored its impact on priority setting [23–27]. One measure of impact would be the influence on decisions on what to fund. Another might be its impact on the language used to discuss health care priorities.

Our aim was to assess the impact of economic evaluation in four European countries, ranging from those who have embraced it (England, the Netherlands, and Sweden) to one that has largely rejected it (Germany). By impact we mean funding decisions, particularly refusals to fund high-price drugs deemed not cost-effective.

Full details of each country have been published elsewhere [23,25–27]. In this article, we report country-specific key points and discuss the impact of health economics on decision making on what to fund.

Methods

We used a protocol (see Appendix 1) to structurally review the key features of the application of economic evaluation in reimbursement decision making in four European countries: England, Germany, the Netherlands, and Sweden. These four European countries were selected because the relevant agencies started to use health economics as an official criterion at different points in time (England as the first in 1999 and Germany as the last in 2007) and they differed in the implementation of health economics. These countries were those with social health insurance systems as well as tax-funded systems. The study protocol was completed on a personal basis by informants holding senior positions in each country.

Results

All four countries have national agencies responsible for assessing health economic evidence for reimbursement decision making. Health economics is a formal priority setting criterion in all four countries. It is mandatory in all four countries except Germany. England and Germany request economic evaluations from a health care (insurer) perspective, whereas the Netherlands and Sweden request economic evaluations from a societal perspective. Nevertheless, the scope of health economics is, in practice, mainly focused on drugs in all four countries. Germany is the only country that has not adopted, whether formally or informally, the QALY. Only England uses a formal cost-effectiveness threshold. Table 1 provides a summary of the characteristics of the four countries.

Country-Specific Key Points

England

In England, health economic evaluation is embedded in four key agencies: the National Institute for Health and Care Excellence (NICE), the National Screening Committee, the Joint Consultants on Vaccination and Immunisation, and the Health Protection Agency. The methods have been highly specified, mainly by NICE, and developed with leading academic health economists.

The methods of economic evaluation have been termed “extra-welfarist” [28] to distinguish them for neoclassical welfare economics. Key differences include measurement and valuation of both benefits (QALYs) and costs (from a National Health Service [NHS] perspective). Discounting of benefits has also changed over time and by agency. The debate over aligning NICE’s methods more closely with the Treasury guidance on economic evaluation has been most prominent in the failed attempt to develop value-based pricing [29].

NICE has become more explicit about its use of a cost per QALY threshold:

NICE has never identified an ICER [incremental cost-effectiveness ratio] above which interventions should not be recommended and below which they should. However, in general, interventions with an ICER of less than £20,000 per QALY gained are considered to be cost effective. Where advisory bodies consider that particular interventions with an ICER of less than £20,000 per QALY gained should not be provided by the NHS they should provide explicit reasons (for example that there are significant limitations to the generalisability of the evidence for effectiveness). Above a most plausible ICER of £20,000 per QALY gained, judgements about the acceptability of the intervention as an effective use of NHS resources will specifically take account of uncertainty, how well health gain is captured, and innovation. [30]

Economic evaluation has, however, not prevented some decisions proving to be politically unacceptable. First, drugs for multiple sclerosis and then those for cancer were funded through special funds after being rejected by NICE on grounds of cost-effectiveness. Adjustments were also made to allow for drugs for patients near the end of life (NICE advised end-of-life criteria in 2009). Seventy-five patient access schemes have been introduced that involve companies reducing prices to meet NICE’s cost-effectiveness thresholds. Since introduced, such schemes apply in around one-third of all NICE technology appraisals. Economic evaluation has facilitated price negotiation for drugs otherwise likely to be refused by NICE.

NICE has successfully resisted challenges to its procedures in the form of judicial reviews [31]. The biggest challenge for NICE was the testing of its powers in a high court case in 2007, in which those powers were largely affirmed. The high court found in favor of NICE on five of the six grounds brought against it. NICE’s procedures were deemed fair and its decision making flexible and not irrational. It was judged to have failed on one duty: not offering advice regarding people with learning difficulty or those for whom English was not the first language [32].

Germany

The German statutory health insurance (SHI) system is based on the German Social Code Book V. Health economic evaluation was explicitly introduced as a pricing tool under the pressure of rapid rising prices of drugs in 2007. Evaluation of relative benefits and costs is required to set an appropriate and affordable price for expensive new drugs. Hereto, Germany adopted the “efficiency

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