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## **Public health policy decisions on medical innovations: What role can early economic evaluation play?**

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**Public health policy decisions on medical  
innovations:  
What role can early economic evaluation play?**

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## ABSTRACT

**Objectives:** Our contribution aims to explore the different ways in which early economic data can inform public health policy decisions on new medical technologies. **Methods:** A broad explorative literature research was conducted to detect methodological contributions covering the health policy perspective. **Results:** Early economic data on new technologies can support public health policy decisions in several ways. Embedded in horizon scanning and HTA activities, it adds to monitoring and assessment of innovations. It can play a role in the control of technology diffusion by informing coverage and reimbursement decisions as well as the direct public promotion of health care technologies, leading to increased efficiency. Major problems include the uncertainty related to economic data at early stages as well as the timing of the evaluation of an innovation. **Conclusions:** Decision-makers can benefit from the information supplied by early economic data, but the actual use in practice is difficult to determine. Further empirical evidence should be gathered, while the use could be promoted by further standardization.

**Keywords:** economic evaluation, early data, innovation, public health policy decision-making

## INTRODUCTION

Against the background of rising health care costs, public health policy focuses on the best use of scarce resources as well as on availability and diffusion when it comes to the introduction of innovative products. Market access is mainly controlled by regulation of approval, whereas coverage and reimbursement by health insurance impact directly on diffusion, access and use [1]. In numerous countries today new technologies have to prove cost-effectiveness, affordability and benefits to the health care system before national health services or insurance systems provide coverage [2, 3]. To document cost-effectiveness, economic evaluation, defined as “the comparative analysis of alternative courses of action in terms of both their costs and consequences” [4], is the most widely recognized methodology. When conducted early in the life cycle of a new or emerging technology, it can inform public health policy in a number of ways which were to be explored in the course of this study.

This work is part of the EU-funded Inno-HTA research project aimed at broadening the scope of classical HTA to assess innovative technologies in their early phases. With economic evaluation being a core element of HTA, our paper provides an overview over possible contributions of economic evaluation conducted in early phases of product development and its role in decision-making. After a short introduction on the methodology of our study, we briefly present policy objectives that are central in decisions on medical innovations before we present different areas in which early economic evaluation can support public health decision-making and serve various health policy activities. Benefits and challenges are discussed, before the conclusion rounds up our findings.

## MATERIALS AND METHODS

As the research question of the use of early data – defined as either phase I/II data or data of technologies described as emerging or investigational - in economic evaluations and their potential uses was too unspecific and broad to employ a specific search algorithm, we conducted an explorative literature research in January and February 2007 to detect methodological papers addressing the contributions of early economic assessments as well as economic evaluations that actually used data from early phases of product development<sup>1</sup>. Databases researched were PUBMED, The Cochrane Library, CRD (including DARE, HTA and NHS EED), MEDLINE, DAHTA, EconLit, Embase, BIOSYS Previews, the UK

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<sup>1</sup> The encountered methodological works could be distinguished into contributions covering the public health policy perspective and the industry perspective (e.g. the use of early economic data for early market assessments, R&D portfolio management or first estimations of pricing and reimbursement scenarios). The latter, together with the results of the empirical review of economic evaluations actually based on early data, are reported elsewhere [5].

Department of Health Database publications library and the Cost Effectiveness Analysis Registry, by various text words and MESH terms (phase II, randomized controlled trial, controlled clinical trial, clinical trials, clinical trial phase I, clinical trial phase II, economic evaluation, early pharmacoeconomics, early technology assessment, healthcare evaluation mechanisms, economics, cost, cost analysis). Online available issues of potentially relevant journals (International Journal of Technology Assessment in Health Care, Expert Opinion on Investigational Drugs, Pharmacoeconomics) were investigated. References of relevant publications were tracked, an additional internet research was conducted via Google Scholar, and websites of institutions related to innovations in health care (acatech association, EUROSCAN, NHS National Innovation Centre) were screened. Complementarily, reports of international horizon scanning agencies published in 2004 were investigated in April 2007 for emerging technologies which were researched for available economic evaluations. The year 2004 was chosen to account for the lag in scientific publishing, to enhance chances to find economic evaluations for the identified technologies. More than 1000 titles and abstracts were reviewed, publications in English, German, French and Spanish were included. 83 economic evaluations actually using early data, 41 papers discussing the role of early economic evaluation from an industry perspective, as well as 47 studies dealing with the potential or actual contribution of early economic assessment to decision-making in public health policy were identified.

## RESULTS

### **Policy objectives: access to innovation and efficient resource allocation**

In dealing with medical innovations, health policy decision-makers pursue goals like the promotion of high-quality innovative healthcare or an equitable access to new treatments for all citizens, while, at the same time, they are restrained by limited budgets and the need to put these resources to the best use. To do so, the question when it comes to the introduction of new technologies usually is whether the additional patient benefit provided by the technology at issue justifies the increased costs, as economic value mostly is a crucial criterion. The answer is provided by economic analysis, and identifying early the economic value and likely impact of new therapies enables decision-makers to be knowledgeable in time, take choices accordingly and so maximize health benefits obtainable from a given budget or, alternatively, minimize costs of achieving a given health benefit goal. At the same time, these criteria set incentives for industry to focus on innovations that can meet them, which will ultimately benefit healthcare efficiency [6-8].

For the decision-maker, the management of innovative healthcare technology is challenging. As the economic impact of a new technology is difficult to assess before it is applied in real

practice, many countries either allow the market introduction of technologies that are not yet fully assessed, or they oppose their release until meaningful clinical and economic evidence is available. Alternatively, a technology can be allowed on condition of collecting further evidence; this approach which is known as 'coverage with evidence development', attracts growing attention in the debate on appropriate strategies of adopting a new healthcare technology [9]. As most societies face rising health care expenditure but have to react to a host of evolving new health technologies, early economic evaluation would serve as a welcome strategic tool to support decision-making and could be put to a number of beneficial uses.

## **Monitoring and assessment of medical innovations**

### ***Horizon Scanning – monitoring of emerging technologies***

To support the management of technology diffusion, health care systems are increasingly making use of "horizon-scanning", the early identification of new drugs and medical technologies which may have a significant impact on the health care system. Various countries have set up corresponding institutions, and on the European level, the EUROSCAN network has been established to foster collaboration and informational exchange on medical innovations [10-12]. Policy makers are alerted of upcoming innovations, their properties and well as their consequences as far as they can be assessed. Decision-making on new technologies can thus also be sped up [13, 14]. The leverage role horizon scanning can have greatly depends on whether the activities reach the target group and the relevant decision-makers. Empirical studies find that early warning has a direct impact on policy making and is likely to entail a more detailed scrutiny of innovations deemed important [14]. In international comparisons, extent and organisation of horizon scanning varies considerably, as do target audiences and technologies selected [12, 13].

To what extent economic criteria play a role in horizon scanning cannot be determined in a generally valid way. While one of the objectives of horizon scanning can be to narrow down the economic consequences of an upcoming technology, the use of economic criteria largely depends on the objectives of the healthcare policy that employs it. In a system focused on cost containment, economic features will have more weight than in an environment promoting rapid access to medical innovations. As a consequence of the increasing political importance of financial sustainability, costs are considered in most horizon scanning systems, whereas cost-effectiveness hardly plays a role – presumably due to the considerable uncertainty that comes along with cost-effectiveness estimates at these very early stages [13].

***Health Technology Assessment – a framework for the evidence-based evaluation of new technologies***

Rising healthcare costs and the continuous emergence of new medical technologies led to the idea of a systematic assessment of healthcare technologies. Health Technology Assessment (HTA) is basically concerned with a systematic analysis and synthesis of the available evidence of clinical and cost effectiveness of medical technologies to support healthcare policy decision-making. In a number of countries, economic evaluation is a central focus of HTA [15-19]. Economic evaluation with early data is relevant as HTA is often applied to new technologies about to diffuse, playing an important role for decisions on medical innovations as it links the evaluation of evidence to policy making and application in practice. Its results can greatly improve resource allocation, in particular as it has a broad focus including medical, economic, ethic and societal consequences [20]. In an empirical investigation, a Euroscan research group that examined the diffusion of six different medical innovations, found that the use of HTA or similar guidance in a healthcare system was associated with a higher rate of diffusion in five of the six cases [14].

However, a state-of-the-art evidence-based assessment is not feasible for all technologies. Surgical innovations for example often evolve in practice and might be unsuitable for a comparison in RCTs, and the success of a new operation technique also depends on the surgeon, as well as on the training and learning that takes place as the technology spreads [21].

**Control of diffusion and use of technologies**

***Impact factors on diffusion and use of medical innovations***

The diffusion of an innovation depends on a number of factors regarding market access, e.g. approval or coverage and reimbursement mechanisms, as well as market characteristics ranging from aggregate income levels, the role of competition, centralized versus local decision-making, to behavioural aspects such as healthcare providers' attitudes towards innovations [22]. While approval is a prerequisite for market entry, economic evaluation sets in with decisions on resource use, financing and reimbursement and can play a major role in decisions taken on economic grounds. The organization of coverage and reimbursement is a major public policy tool to control the diffusion and use of new medical technologies, which also takes into account early economic data. The pharmaceutical industry uses early economic evaluations to inform decision-makers in view of later reimbursement, payers include pharmacoeconomic information in their formulary decisions [23]. In differently organized healthcare systems, the mechanisms applied to manage the diffusion of technologies are diverse, among which the financial framework is of paramount importance.



National health services mostly operate under budgets, while third-party-payers use coverage and reimbursement decisions to control the use of new technologies. Guidelines are issued from diverse players (governmental agencies, medical societies, insurers) to ensure the appropriate utilization [22]. These findings are empirically supplemented. Oh (2005) presents factors that influence technology diffusion, including economic as well as organizational and structural characteristics. The results show that economic power – in terms of purchasing power and economic incentives present through payment methodologies – promotes technology diffusion [24]. Similar results are encountered in a Euroscan study [14].

### ***Timing of early evaluation***

It is a central dilemma when it comes to the assessment of innovative medical technologies in early stages that at the time when political decisions have to be taken, the available evidence of clinical and cost effectiveness is usually still lacking or only available to a very limited extent. “Buxton’s law of technological evaluation” is referring to this situation: “It’s always too early until, unfortunately, it’s suddenly too late” [25, p.1664].

A full assessment can only be undertaken when enough relevant data is available, but at that point of time, the technology is mostly already in a stage that can no longer be considered experimental or emerging. Obviously, an evaluation for a mature technology already in use can no longer influence its diffusion [22, 25-27]. This holds particularly within the jurisdiction of one decision-maker; on an inter-jurisdictional level, the interaction can be different.

In general, a delayed diffusion based on more mature evidence has to be weighted against the diffusion of a technology with yet not fully known characteristics [25]: The rapid diffusion of a new technology might result in avoidable health damages due to risks which are not detectable in the time frame of the phaseII/III trials. However, delaying the use of the new technology likewise might result in avoidable health damages if in the end the technology proves to be effective and safe. Collecting the necessary evidence in a controlled way avoids uncontrolled diffusion at early stages, which is important as effective policy measures are hard to implement afterwards [25, p.1664]. This trade-off between the rapid availability and a sufficient level of evidence is particularly difficult but also significant in emergency situations, e.g. with clinical tests for infectious diseases like SARS [26].

One possible solution is to allow and reimburse a technology on condition of further data collection, as practiced for example by Medicare in the United States with the “Coverage with Evidence Development” initiative. In case the available evidence of clinical effectiveness is deemed insufficient to determine whether a new therapy meets the criteria “reasonable and

necessary”, a technology can be covered within the framework of a research study [28]. Similar approaches are the “PRUFE” framework in Ontario, Canada, where real-world evidence is gained in “field evaluations” to reduce uncertainty regarding safety, effectiveness and cost-effectiveness before unlimited public funding is provided [29], and the “only in research (OIR)” option which occasionally is applied by NICE [30]. Value of information analysis can assist the design of the research process accompanying coverage with evidence development by identifying those determinants of cost-effectiveness with the highest costs of uncertainty, i.e. that additional evidence which would deliver the most valuable information gains. A major advantage of such approaches is that patients can benefit earlier than usual from a new treatment. However, once a technology is covered, even if only on a preliminary basis, it can be politically difficult to withdraw it when it proves ineffective [9]. To avoid a shift in the burden of proof, it should not be up to the health system to demonstrate that the product doesn’t meet the requested value. The responsibility to prove the product’s benefits and value should stay with the manufacturer [7].

An important issue when it comes to the timing of the evaluation of a new technology is the availability and spread of the necessary clinical expertise, knowledge or training to apply it. It is crucial to consider the clinical learning curve, as an assessment of outcomes and costs before enough experience is gained may yield biased results. This holds particularly for surgical innovations. Again, by the time enough experience has accrued, a procedure might no longer be in an experimental stage [22].

## **Direct public promotion**

### ***Public promotion of research in the field of neglected diseases and orphan drugs***

Public promotion as a direct way of steering diffusion is particularly relevant regarding the development of vaccines and treatments for neglected diseases mainly concentrated in low-income countries. Even though social need is high, commercial prospects are poor due to the poverty prevalent in many of these countries as well as often severe health care market imperfections. As companies rather dedicate their limited resources to projects which are likely to generate adequate returns, more remunerable markets are generally favoured. As a result, there is insufficient research targeted at diseases like tuberculosis, malaria or HIV/AIDS. [31, 32]

To overcome the mismatch between medical need and research incentives, special mechanisms have been designed that can be divided into push mechanisms aimed at reducing R&D costs, like financial support of research activities, and pull mechanisms that address market failures. The most prominent concept is the so called advance purchasing or

market commitment, where a sponsor - a government or a private foundation - commits himself to finance purchases at a determined price and quantity of the product that meets specified criteria, rewarding successful production. These products can then be made available to patients at no or low costs, improving access. For the producer, the market uncertainty is greatly reduced as quantity and price are predetermined, so that neglected diseases are more advantaged in R&D resource allocation decisions [31-33]. In this context, early economic evaluation can yield valuable additional information to support decision-making, and for example help estimate the cost-effectiveness of commitments for different vaccines for a given set of prices and number of persons immunized [31].

Similar problems arise with orphan drugs for rare diseases. Incentives for manufacturers are limited, and measuring against commonly used cost-effectiveness thresholds is difficult. Small patient target groups often make recouping development costs difficult, resulting in high incremental costs per QALY, and hamper the generation of high-quality efficacy data. Appraisal criteria should account for societal preferences, including the seriousness of the condition, the availability of treatment alternatives or the costs to the patient if the treatment is not covered. To ensure patient access and equity, public funding of research and use of orphan drugs is recommended [33].

### ***Technology diffusion supported by governmental programs***

Technology assessment programs implemented by governmental bodies, such as e.g. the American National Institutes of Health, have a direct impact on the diffusion and implementation of new technologies, especially when they also account for the cost-effectiveness not only of the technology but also its implementation in clinical use. It is hoped that an improved co-operation between governmental organizations, science and industry can generate synergies in bringing new technologies on the market, improving quality and cost-effectiveness of health care on a nationwide scale [34].

Early economic evaluation can inform decisions on public support for new medical technologies, shed light on the potential cost-effectiveness of the promoted technology and thus enhance allocative effectiveness of public sponsorship. An example would be the comprehensive report on tissue engineering that the German Federal Ministry of Education and Research commissioned to optimize the promotion of these technologies [35].

However, there are not only advantages, but also problems and difficulties related to the use of early economic evaluations in public health policy decision-making, which will be briefly discussed on the following section.

### **Public policy benefits and challenges with early economic evaluations**

From the public policy point of view, early economic evaluations enhance transparency regarding upcoming products, reducing the informational asymmetry usually prevailing on the market. Decision makers have a chance to early capture the value and the economic properties of an innovation. Population-based assessments sum up epidemiological factors as the prevalence and burden of a health problem, thus helping to define medical needs, so that the policy decisions can be put in perspective [6-8].

Problems with early economic evaluation encompass the insufficiently available data and related methodological weaknesses, so that the results have to be treated with caution. The findings of an assessment of a technology in its early stages cannot be considered as conclusive. Efficacy data stem from clinical trials, whereas the effect of a new treatment in real practice is what is relevant to policy makers. As a remedy, “real world trials” have been advocated [6, 7, 36]. The technology has not yet exploited its full potential in practical use, benefits and costs in different scenarios have not yet been fully recognized, and long-term outcomes are still unknown. In addition, learning effects, expanding target patient groups and indications are hard to account for [22, 37].

### **Budget impact of new technologies– beyond the concept of economic evaluation**

Before we discuss our results, we think it fit to give a brief outlook on budget impact analysis which is beyond the concept of cost-effectiveness evaluation that is the focus of our study. The economic effects of the introduction of a new medical technology are of paramount importance for a healthcare system, yet the assessment of the budget impact has to be distinguished from economic evaluation. While the latter depicts the relative economic value of two alternative medical treatments, a budget impact analysis addresses the affordability in predicting the impact of the introduction of a new technology on a particular budget holder’s budget. It serves additional informational needs as decision-makers in healthcare often have to operate within given budgets. Even if the cost-effectiveness of a technology is favourable, it can still be not affordable without overspending, and a reallocation of resources, however socially beneficial, is often politically difficult. Furthermore, budget impact analysis enables health policy makers to identify potential conflicts between a comprehensive societal assessment and an assessment from the perspective of a particular third party payer or health care provider and to recognize the need for additional intervention in order to ensure the successful diffusion of a new technology, e.g. by changing healthcare financing arrangements.

Budget impact analysis also varies in methodology as it has to meet the needs of the

targeted decision-maker which can differ from what is customarily provided in efficiency analysis. Instead of the societal perspective for example, decision-makers are rather interested in the relevant costs that will incur to their particular budget, as mostly they cannot profit from savings occurring in any other area. Similarly, the time horizon might be unapt as compensating overspending in the short term with savings occurring some time in the future may be no feasible option. Besides the estimated market diffusion of a new technology and the impact its implementation has on service delivery, a budget impact analysis should address whether it has a substitution potential or would require additional funding, and imply what this means for the decision-maker, accounting not only for the acquisition cost but also for the financial consequences over time [38].

Just as economic evaluations, budget impact analyses conducted at an early stage are subject to considerable uncertainty and equally have to rely on assumptions and modelling to some extent. Particularly the degree and speed of the adoption of an innovation is hard to predict, depending on the possible substitution of existing treatments, the demand that can be stimulated with providers and patients as well as on the required training or equipment.

Economic evaluation and budget analysis address different but equally important questions, so that they are two complementing components to inform decision-making. This is mirrored in the fact that in several countries, budget impact analyses are required for coverage decisions in addition to economic evaluations, e.g. in Australia, the UK or in the Netherlands [39, 40].

## **DISCUSSION**

In a number of situations, early economic evaluation can serve as a useful tool supporting health policy and management of emerging innovative technologies. For a number of reasons it is difficult though to determine the role early economic data actually plays in decisions. One is the nature of the decision - while coverage decision processes are mostly rather transparent with accessible reasoning, this is not necessarily the case with other policy decisions such as priority setting or the promotion of health care programs. Furthermore, public decision-making not only has to be seen in the context of the political and institutional environment, but is also subject to individual attitude, so that the motivation for a decision can hardly be fully transparent. Another reason is the uncertainty inherent in early economic evaluation which may lead to a rather reluctant use of its results.

Another economic aspect is relevant in decisions on medical innovations. From an economic point of view, the control of technology diffusion should be judged in the light of efficient resource utilization. Technology diffusion that uses resources inefficiently should be

restrained, while the mere limiting of technology diffusion as such is not likely to enhance efficiency [24].

Medical innovations can entail particular challenges on the health policy level. Individualized medicine for example can greatly benefit a particular patient, but at the same time raises general questions regarding privacy and discrimination, approval, service delivery and funding, e.g. how a promising innovation such as genetic testing affects an individual's insurability, or how society should value expensive interventions that are highly beneficial but targeted only at a very limited patient group. Even if an univocal answer is not at hand, society should ponder such issues potentially arising with the introduction of new technologies [22].

A shortcoming of our study is the rather explorative nature of our research due to the broad and unspecific research question, so that our review cannot claim to be comprehensive and can only spotlight the current use of early economic evaluation. In addition, an empirical verification is hampered by scarce evidence, suggesting that early economic data are generally no standard tool in decision-making.

## **CONCLUSIONS**

To health policy decision-makers, early economic data on new and emerging technologies can be supportive in different ways. Along with horizon scanning, they can deliver first information on the potential value of a technology, followed by a more detailed economic assessment within the framework of health technology assessment. They can impact on the steering of diffusion, adoption and use of new technologies, mainly through the regulation of coverage and reimbursement. One crux is the ideal timing of the evaluation of an innovation, what has led to forms of preliminary reimbursement in different countries. At the same time, early economic evaluation can improve the allocative efficiency of direct public promotion programs of health care, as for example in the field of neglected diseases and orphan drugs.

Problems with early economic data stem from their preliminary character, the fact that they cover only a relatively short period of time and are likely to be different in real-world practice, so that the conclusions drawn cannot be taken as "hard facts". This uncertainty has to be accounted for in the decision.

In actual decision-making, the use of early economic data is difficult to capture, and empirical evidence is not abundant. A harmonization or standardization of the methodology of economic evaluation, particularly with early-stage data, would be likely to promote its use in political decision-making.

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