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Briefing Document

Comparative Effectiveness Programs:

A Global Perspective: Discussing Germany and the UK

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Some Preliminary Observations on the Use of Health Economic Evaluation in the Context of Health Technology Assessments

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Background

Expectations (and fears) regarding the impact of Comparative Effectiveness Programs (CEPs) vary widely. Quality improvement and efficiency gains are among the most commonly cited objectives. Interestingly, an important CBO paper of December 2007 set the scene by first discussing Medicare and Medicaid spending trends and projections, implying that the need to cope with rising health care costs constitutes a major impetus behind the interest in CEP.

Beyond cost containment, and irrespective of the current debate in the United States about the appropriate primary focus of CEPs, either the (comparative) clinical effectiveness or the cost effectiveness of medical treatments, the overarching goal to get better health value for the dollars spent (i.e., increased "*efficiency*") ranks prominent on the agenda of health care policy makers.

Following the early examples of Australia (since 1992) and Canada (since 1994), many European jurisdictions now use cost effectiveness analysis as a tool to support policy makers in developing guidance on the use of health care technologies, to assist specialists issuing clinical guidelines, and to aid payers making decision on coverage and maximum reimbursement prices. Typically, pharmaceutical products represent the type of technology most intensely scrutinized.

1. Market Failures in Health Care

Under collectively financed health schemes, neither patients nor doctors pay (directly) for drug prescriptions and medical care, creating artificially enhanced levels of demand for health care (i.e., "*moral hazard*"). Patients often are less well informed than their physicians, and may sometimes even be in a psychological state of dependency. This not only creates opportunities for providers to determine, and possibly induce, demand for their services – but also the vision of autonomous decision-making by patients has been attacked for ignoring "*the ontological assault of illness*" (cf. Mark A. Hall, 1997).

As a consequence, many scholars agree that there are no effective market mechanisms generating optimum prices for medical care in general, and for prescription pharmaceuticals in particular. Hence, there is reason to expect a loss of social welfare from market failures. Unregulated

reimbursement may contribute to excessive pricing policies by health care providers, including pharmaceutical companies.

For these (*and other*) reasons, many jurisdictions have turned to health economics as a discipline that promises guidance on how to make best use of scarce resources, by identifying the "value for money" offered by specific health care programs. In a view shared by many scholars, health economic analyses serve as a substitute for the failing health care market.

2. Perspectives for Evaluation

In principle, comparative economic evaluations assess the full range of consequences (costs and effects) of adopting a program. Then a program is a good one if its benefits (the net *value* of its full range of effects) exceed its *opportunity costs*. Most if not all health economists will agree that the appropriate perspective for an economic analysis is the societal one. By definition, this perspective includes all direct costs (medical and non-medical) as well as indirect cost (loss of productivity). In practice, many Health Technology Assessment (HTA) agencies use a more restrictive concept of cost, stipulating that analyses be done from a *payer's perspective*[1]. This is a much narrower approach, which is prone to miss a whole category of societal consequences. Analysts conducting cost effectiveness evaluations sometimes defend it by the view that, *given a health care budget constraint*, the relevant opportunity cost would be defined by the benefits conferred by an alternative use of limited resources available for health care.

Even with this restriction, however, cost effective analysis (CEA; like other variants of economic evaluation) offers the potential to overcome the "budget silo mentality" prevailing in health care, which has been characterized by looking at health care expenditures from a component management perspective, i.e., by sector (hospitals, physician services, drugs, devices, etc.) and by budget cycle.

CEA holds the promise to increase the rationality of decision-making by incorporating consequences beyond single component silos and budget cycles.

3. Effectiveness as a Prerequisite for Cost Effectiveness

It is obvious that cost effectiveness cannot exist in the absence of effectiveness. Therefore, international HTA agencies rely heavily on systematic assessments of clinical effectiveness, following the concepts of evidence-based medicine (EBM) and Cochrane-style reviews. Usually evaluations of cost effectiveness build upon the results of a prior assessment of clinical effectiveness. In many respects, this approach may offer a pragmatic starting point, laying the foundation for subsequent analyses of costs and effects.

Yet there remain important *differences between clinical effectiveness reviews and economic evaluation*. While both (should) attempt to make use of the best available evidence, the latter will notably differ from EBM by including (a) the notion of opportunity cost and "efficiency" (with implied *value judgments* concerning the appropriate "effectiveness" criteria), (b) the need to include all relevant effects (costs and consequences), very often over a time span exceeding that documented by clinical data (randomized clinical trials or else), (c) the real-life performance of health care programs ("effectiveness") as opposed to their efficacy under the ideal conditions of well-controlled clinical studies, and (d) the need to apply a universal and comprehensive measure of (clinical?) benefit.

As to (d), the major contenders to date have been the (maximum) individual willingness-to-pay (WTP) as a measure of utility in cost benefit analysis, and quality-adjusted life years (QALYs) as a preference-based aggregate measure of the health-related consequences of health care programs, capturing effects on longevity and quality of life.

It is well established that the WTP measure is more closely grounded in economic welfare theory. In the health care field, however, the use of QALYs has been widely preferred over individual WTP. As exemplified by the reasoning of the influential *Washington Panel on Cost Effectiveness in Health and Medicine*, a major reason for the preferential use of the QALY metric has been the concern that individual WTP, because of its link to individual ability to pay, may "inherently favor the wealthy over the poor" (Marthe R. Gold et al., 1996).

[1] The two exceptions are Sweden and The Netherlands.

4. The Logic of Cost Effectiveness

Accordingly, the logic of cost effectiveness currently represents the prevailing paradigm adopted by international HTA agencies using 'economic' evaluation. It rests on the unproven premise that the *objective* of collectively financed health schemes ought to be *to maximize the aggregate health gain* produced with a given level of resources (e.g., Anthony J. Culyer, 1997). From there, it is straightforward to derive a context-independent (constant) shadow price (or 'social' willingness to pay) for a unit of health gain, typically measured in terms of QALYs. Of note, any call for "*consistency*" of decision-making on grounds of this logic rests on the implicit (normative) assumptions underlying this logic, and on an imposed constant (context-independent) social value of a QALY.

The distribution-indifference of the QALY aggregation rule, which entails an interpersonal allocation algorithm, has given rise to normative concerns. Actual *benchmarks* for maximum allowable cost per QALY vary across jurisdictions and have remained artificial in the sense that they lack a sufficient theoretical and / or empirical justification. More fundamentally, some *rankings* of interventions in terms of their cost per QALY gained ("cost effectiveness league tables") have proven counterintuitive and failed to pass tests of reflective equilibrium. Thus the validity of the underlying quasi-utilitarian calculus has been challenged, and in the light of a rapidly growing number of studies on social preferences, the assumption that policy-makers, patients, or the general population (*should?*) wish to maximize the total number of QALYs produced must be considered as counterfactual[2] – in other words, *the QALY maximization hypothesis is empirically falsified* in the sense that it does not reflect the goals of major stakeholder groups.

Empirically[3], *context matters* for instance with respect to the initial severity of a health state (as distinct from the capacity to benefit from an intervention), non-discrimination against the permanently disabled and chronically ill, the dispersion of health benefits across individuals (i.e.,

[2] Apart from normative concerns, the QALY maximization hypothesis contradicts the historic roots of health care; the stated (official) objectives of policy makers, payers, and providers of care; (revealed and) documented public preferences; legal and constitutional provisions (Source: Michael Schlander, Health economic evaluation of medical interventions: answering questions people are unwilling to ask? 5th World Congress of the International Health Economics Association (iHEA), Barcelona, Spain: Book of Abstracts, pp. 354-355. Available online at www.michaelschlander.com/presentations.htm.)

the number of patients sharing a benefit), and the maintenance of hope (chances for access to care). The real-life relevance of these observations may be illustrated by a range of *examples*, such as sildenafil treatment of erectile dysfunction and the surgical removal of tattoos (both are associated with very favorable cost effectiveness ratios) and expensive drugs for rare disorders ("orphan treatments" and some cancer drugs, which fail to meet current cost effectiveness benchmarks). Importantly, in our view the number of contextual factors precludes an easy fix by the application of severity or equity weights.

From a *conceptual perspective*, Richard Smith and Jeff Richardson (2005) have proposed at least four core issues that, if unresolved, may offer an explanation for the problems encountered, namely, (1) can social WTP be reconstructed simply by the sum of individual WTP, (2) how does individual utility map into social value, (3) what is the appropriate budget constraint, and (4) (how) should WTP be adjusted for ability to pay? This list might be extended, for example by considering process utility (e.g., "caring externalities" – generally, people are not indifferent with regard to the way how an expected consequence will be achieved). In light of all this, it appears uncertain if not unlikely that a (context independent) social value of a QALY does exist outside the narrow theoretical framework of the logic of cost effectiveness. The potential implications for the conventional logic of cost effectiveness are fatal.

5. Opportunity Cost (Budgetary Impact)

Applying the logic of cost effectiveness – with or without QALYs as the preferred metric of clinical benefits conferred – produces information in the form of incremental cost effectiveness ratios (ICERs), or (less frequently) closely related variants hereof.

As a ration an ICER remains silent on the size of its numerator and denominator; it does not provide any hint on the *dimension* of the health care program under consideration. For this reason, and for some related problems, the opportunity cost or budgetary impact of adopting a program remains either entirely unknown or, if estimated separately, outside the decision-making

[3] For references, see for example Jeff Richardson and John McKie (2007).

algorithm (i.e., using a cost per effect benchmark) proposed under this logic.[4] This void has been identified as a major deviation from economic theory:

As early as 1993, health economists Amiram Gafni and Stephen Birch of McMaster University in Hamilton, Ontario, warned that this deficiency might provide for "a prescription for uncontrolled growth in expenditures," and pointed to the unresolved issue of where the resources for additional spending would come from in case of a positive ICER – i.e., the absence of any information about the opportunity foregone in association with redeployed resources. In the meantime, the Canadian economists' prediction has materialized in the United Kingdom, where positive recommendations by the National Institute for Health and Clinical Excellence (NICE) have led to local funding problems at the level of the budget holders within the National Health Service (NHS), the Regional Health Authorities. In some cases this has led to slow uptake of new technologies despite NICE guidance recommending their use.

Not surprisingly, the failure of the ICER[5]-orientated logic of cost effectiveness to adequately address, from a decision-maker's perspective, the *opportunity cost of adopting new programs* may have contributed to above-average increases in pharmaceutical expenditures in Australia and Canada during the 1990s. In England, prescription drug spending increased from £ 5.6 billion in 2000 to £ 7.9 billion in 2005, or by a compound annul growth rate of 7.4%. According to internal estimates from NICE, full implementation of NICE guidance from 1999 to 2004 would have had a cumulated budgetary impact on the NHS of £ 800 million, equivalent to 1% of total NHS spending.

While it is difficult to isolate the net effects on spending attributable to NICE guidance, when also taking negative NICE recommendations into account, it appears obvious that *the logic of*

[4] This further implies that our societal WTP for an intervention under a collectively financed health scheme should be strictly proportional to the number of patients receiving it. This assumption not only ignores distributive concerns (issues of "vertical equity") – it is at odds with the cost structure of the research-based pharmaceutical industry and with the very nature of pharmaceutical research and development efforts, which typically do not increase with the number of eligible patients in a strictly proportional manner. While it is certainly a matter for debate whether or not this should be reflected in coverage and reimbursement decisions, the issues briefly mentioned early, surrounding expensive drugs for rare disorders and their (/lack of) cost effectiveness, highlight its practical relevance.

[5] S. Birch and A. Gafni, in subsequent papers (the two quoted here appearing in 2006), went further, paraphrasing the ICER as "information created to evade reality" and lamenting "the silence of the lambda," with the "lambda" referring to the cost effectiveness benchmark needed to interpret cost per QALY ICERs.

cost effectiveness does not provide for an effective cost containment device. Policy makers would seem well advised to temper any such expectations.

6. Process Matters

There is little if any controversy surrounding the quest for *technical efficiency* (i.e., in the present context to achieve a defined objective for a given patient group with a minimum level of resources spent). In striking contrast, contentious issues arise once it is – more ambitiously – attempted to address the challenge of an optimal interpersonal allocation of resources (i.e., "*allocative efficiency*"). This is an inescapable but genuinely normative challenge, the difficulty of which cannot be simply done away by making reference to a quasi-utilitarian framework (such as the conceptually narrow QALY maximization hypothesis).

Since democratic societies find it difficult to reach consensus concerning the just allocation of health care in the face of limited resources, Norman Daniels and James Sabin have argued in favor of *procedural justice* for policy makers to gain legitimacy of coverage decisions. Under their concept of "accountability for reasonableness," four requirements are to be met, (1) publicity (transparency, i.e. public accessibility of decisions and their rationales), (2) relevance (rationales must rest on evidence and principles that all "fair-minded" stakeholders can agree are relevant to deciding ho to meet the diverse needs of a population), (3) an appeals mechanism should be in place, and (4) the enforcement condition is meant to ensure that the first three conditions are met.

Thus a call may be made for an intense and open public deliberation on principles and objectives of collectively financed health care provision. It should be noted here that (a) some philosophers have warned against a "black box of process," and that (2) HTA agencies face a range of practical issues when attempting to implement the concept. In Europe, the National Institute for Health and Clinical Excellence (NICE) says it has officially espoused the principles of accountability for reasonableness.

7. The Paradox of Fourth Hurdle Regulation

Health Technology Assessments (HTAs) – with or without economic evaluation – may be used to produce guidance, guidelines, and recommendations. In some jurisdictions, HTAs are (also) used to inform *decisions on pricing and reimbursement*, usually of pharmaceuticals. In common parlance, the latter case is referred to as "fourth hurdle "regulation, and it cannot come as a surprise that an additional hurdle results in *delays in access* to novel treatments. In certain European health care systems, such as Belgium, these delays have exceeded one year on average.

If the logic of cost effectiveness is adopted, another unintended effect may be *industry moral hazard*, i.e., the maximization of asking prices (and expected profits) so as to just hit the official threshold for cost effectiveness. There is anecdotal evidence from England; reportedly, some pharmaceutical companies have set product prices as to exactly meet the upper cost effectiveness threshold (£30,000 per QALY gained) defined by NICE.

At the time of market introduction of a new technology, limited data is available on its performance under the conditions of routine care (clinical *effectiveness* ["*does it work*?"]), as opposed to data generated by randomized clinical trials (*efficacy* ["*can it work*?"]; cf. D. Schwartz and J. Lellouch, 1967). Nevertheless, in order to have policy impact and not to remain a merely academic exercise, evaluations need to be done early in the technology life cycle.

The resulting challenges are aggravated by the well-known fact that the cost effectiveness of technologies may change over time. There is no ideal solution to this dilemma, for which the term *Buxton's law* has been coined: "It is always too early [to evaluate] until, unfortunately, it's suddenly too late" (Martin J. Buxton, 1987). If anything, the challenge is further aggravated by the fact that sound economic evaluations of complex clinical problems require substantial resources – including time – especially when they embedded in truly participatory processes.

There are at least two implications worth mentioning here:

First, there is a need to use decision analytic *modeling* to extrapolate beyond the data observed in clinical trials. Second, in order to use the *best available evidence* at the time of an assessment, it appears necessary to include conference abstracts and presentations of new data that have not yet been published in peer-reviewed journals. This creates challenges regarding complete search

strategies, access to relevant data, and evaluation of the quality of findings presented. Moreover, these implications mark critical departures from well-established principles of evidence-based medicine.

A final aspect relates to a general limitation of applied health economics. Economic analyses at best represent a snapshot, capturing the situation at the time of assessment. In line with the preoccupation of much of academic economics with issues of equilibrium and hence *static efficiency*, trade-offs with *dynamic efficiency* are typically ignored. However, today's innovative products will be tomorrow's generics, and there are striking examples for learning curve effects that have improved the cost effectiveness of technologies before patent expiry.

Summing up, it can be concluded that currently used methods are not perfect. There is a strong need for research into economic evaluation methods better reflecting prevailing social value judgments, and better capturing the dynamic nature of medical care. At the same time, however, there is a widely acknowledged need to increase (a) the rationality of health care provision in general and (b) the efficiency, fairness, and transparency of health care resource allocation mechanisms *now*.

Two European jurisdictions, England and Germany, have developed quite differently in this respect.

8. European Experience at a Glance: England (NICE) and Germany (IQWiG)

Fundamentally, both NICE and IQWiG operate in a free-pricing environment for innovative medicines.

The **National Institute for Health and Clinical Excellence (NICE)** was established in 1999 as a Special Health Authority within the United Kingdom National Health Service (NHS). Its mandate includes (but is not limited to) technology appraisals, which result in recommendations on the use of new and existing medicines and treatments. The appraisal process consists of three (to four) phases, scoping, assessment, appraisal, and (if applicable) appeal. Throughout the four phases, well-defined opportunities to participate are offered to stakeholders.

More than other international HTA agencies, NICE relies on cost effectiveness analysis using QALYs as a comprehensive and universal measure of health outcomes, applying a *benchmark* of £ 20,000 to £ 30,000 per QALY gained. Once an ICER exceed £ 30,000 per QALY gained, NICE will most likely reject the technology for that use within the NHS. Frequently, NICE has issued guidance restricting the use of a technology, for example by severity of a disorder or by patient subgroups.

Since 2004, its approach to economic evaluation ("cost utility analysis") is highly standardized, adheres to a reference case stipulating the perspective of the NHS (and Personal Social Services, PSS) for costing, and adopts the view that each QALY gained should be of equal value ("*QALY egalitarianism*") as its fundamental equity position. In response to critique that NICE guidance was issued (sometimes too) late, which led to slow uptake rates of novel technologies that had not yet been appraised (a phenomenon referred to in England as "*NICE Blight*"), the Institute introduced a new appraisal process (single technology appraisals, STA) in 2005. Many observers consider NICE as an international role model for the implementation of cost effectiveness analyses. In particular the *transparency* and inclusive nature of its processes – although shown to be less than perfect – have been praised by many observers.

On various occasions, usually when the Institute issued negative recommendations or restrictions of use in the NHS, NICE has drawn fire from patient organizations and pharmaceutical manufacturers.

In particular, a number of *new cancer treatments*, which had been shown to extend patients' life expectancy by several months but did so at a cost per QALY exceeding NICE's benchmark, were rejected by NICE under the new STA process. A recent study by researchers from the University of York suggests that these decisions were (internally) consistent, i.e., did not reflect a change of NICE's evaluation criteria, especially concerning its cost effectiveness benchmark. NICE has been trying to salvage its almost exclusive reliance on QALYs and cost per QALY benchmarks by introducing an artificial new category of ultra-orphan drugs, which should be evaluated by different standards, and by proposing to put a higher value on end-of-life QALYs – in response to critique regarding its refusal to recommend four new treatments for kidney cancer in 2008.

NICE also encountered experienced difficulties integrating its (largely separate) streams of work related to either clinical or economic evaluation.

Furthermore, the robustness of the NICE approach has been challenged, and it has been asserted that it lacks the flexibility necessary to adapt the solution strategy to the specific clinical problem at hand. An astonishing number of technical flaws observed in an in-depth study of one technology assessment gave rise to calls for more effective quality assurance processes at the Institute.

The German **Institute for Quality and Efficiency in Health Care** (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, **IQWiG**) was founded in 2004 as a state-independent scientific institute. To date, the Institute has reported comparative analyses of clinical benefit only, with a strong emphasis on concepts of *evidence-based medicine*, and heavily relying on data from randomized clinical trials. Some observers claimed that IQWiG was too restrictive in its selection of clinical evidence, which has been seen as a prime cause for controversial conclusions by IQWiG about the absence of sufficient clinical evidence of superiority. The consequences of such assessments by IQWiG can be drastic for pharmaceutical manufacturers; if IQWiG finds no superior "clinical benefit" compared to a standard, the respective products will be subjected to reference price regulation, irrespective of their patent status.

Since April 2007, the German Institute has been entrusted with the development of methods for the economic ("cost benefit") evaluation of drugs. Draft methods for economic evaluation were published by IQWiG in January 2008 and are now undergoing feasibility testing. In striking contrast to NICE, *IQWiG does not encourage the use of QALYs* as a presumably comprehensive and universal measure of clinical benefit.

Instead of using cost utility analysis, IQWiG seems to emphasize cost consequence analysis. The Institute has suggested that health care policy makers at the German Federal Joint Committee (in this respect, roughly corresponding to the appraisal committees at NICE) and at the Federal Association of Statutory Sick Funds should decide on reimbursement and (maximum) "ceiling prices" for pharmaceutical products using this data. IQWiG says its approach is deliberately restricted to the assessment of technical efficiency, and that it is intending to avoid interpersonal

comparisons. The objective then is to increase the level of transparency within a given indication.

To this end, IQWiG relies on a concept called "*efficiency frontier*" analysis, which in essence appears to represent the standard textbook decision rule of cost effectiveness analysis, albeit by another name. IQWiG further intends to use *budgetary impact analysis* in an attempt to predict the affordability of new therapies, and possibly to address the legal requirement in Germany to respect the need of pharmaceutical companies to recoup research and development expenditures. Immediately upon presentation of its draft methods, IQWiG was harshly criticized by a group of German health economists for not adopting the QALY-based logic of cost effectiveness.

Given the discussion of the logic of cost effectiveness above, it is argued here that the cautious stance of IQWiG towards the use of CEA for interpersonal allocation may be well justified. It is, however, important to recognize that this relatively conservative approach to the adoption of economic evaluation methods will be a temporary solution only; IQWiG's current position will need to be supplemented by an intense research effort into improved evaluation methods that offer the potential to better incorporate social values, prominently including concerns for fairness.

At this point in time, many questions remain open as to the actual application of economic analysis by IQWiG and its regulatory impact, especially since IQWiG intends to commission "cost benefit" evaluations only after a prior assessment of clinical benefit has been positive.

9. Some Implications

Some suggested implications[6] for United States policy makers include consideration of:

- NICE demonstrates the *feasibility* and the potential of cost effectiveness analysis as a tool to increase transparency of decision-making in health care, and to differentiate

[6] For a more complete account of NICE technology appraisals, see: M. Schlander: Health Technology Assessments by the National Institute for Health and Clinical Excellence: A Qualitative Study. New York, NY: Springer, 2007.

between more and less cost effective uses of medical technologies. But NICE also demonstrates the limitations of the approach.[6]

- The *logic of cost effectiveness*, as applied by NICE and based upon the QALY maximization hypothesis, fails to adequately capture well-documented prevailing social value judgments. The hypothesis must be considered as *empirically falsified*. It also deviates from economic welfare theory in crucial aspects.
- International experience suggests, in line with theoretical considerations, that health care *spending may increase* under comparative cost effectiveness programs. Cost effectiveness analyses, like health economic evaluations in general, should not be misrepresented as cost containment devices.
- As to the application of 'economic' evaluation methods in health care, there is a trend towards *increasing international heterogeneity*. Some international HTA agencies, for example IQWiG in Germany and HAS in France, appear to be adopting approaches very different from the NICE model.
- The extent that NICE relies on the QALY metric remains a controversial issue not only on normative grounds; there are also examples illustrating that an *overreliance on QALYs* (at the expense of other clinical effect measures) may contribute to a *neglect of important clinical evidence*.
- Meaningful economic evaluations usually require a broader evidence base than comparative clinical effectiveness programs, including but not limited to data from open-label "pragmatic trials" and observational studies. The distinction between efficacy and effectiveness should be taken seriously. Decision analytic modeling can be used effectively, and models should be made fully transparent
- The well-justified quest for *efficiency* requires prior definition of the objectives to be pursued by collectively financed health care; in the absence of well-defined effectiveness criteria, "efficiency" would at best be meaningless. There are compelling arguments in favor of *public deliberation* about the primary objectives of a

health scheme, which represent genuine value judgments.

- *Standardization* of processes and methods is needed for comparability of analyses, but it may also hinder the flexibility to adjust the problem solution strategy to
- *Standardization* is no substitute for effective *quality assurance* of economic analyses; neither are conventional peer reviews.
- There are further issues that deserve careful consideration, including the appropriate timing of technology appraisals, the design of the appraisal process, the use of truly multidisciplinary assessment teams, and issues related to the implementation of recommendations – to mention a few.

References will be furnished on request.

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