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PRE-ASSESSMENT TO ASSESS THE MATCH BETWEEN COST-EFFECTIVENESS RESULTS AND DECISION MAKERS' INFORMATION NEEDS

An Illustration Using Two Cases in Rehabilitation Medicine in The Netherlands

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Abstract

Objective: To determine if a pre-assessment can be used to establish whether cost-effectiveness results would meet the actual information needs of Dutch healthcare decision makers.
Methods: Two recent studies in rehabilitation medicine served as study material. Based on Wholey, a limited pre-assessment was performed in which the potential impact of cost-effectiveness analysis (CEA) results on intended users' decision making was assessed. Desk research and semi-structured interviews with several intended users of CEA results were performed. These included general practitioners, representatives of health insurance companies, the Health Care Insurance Board (CvZ), and medical guidelines committees.
Results: In day-to-day decision making of the interviewed decision makers, a cost-effectiveness criterion seemed to be of limited importance. Instead, results from clinical effectiveness studies and budget impact studies appeared to be sufficient. CvZ, however, preferred relative cost-effectiveness to be a criterion for inclusion in future reimbursement guidelines. In both cases the limited pre-assessments changed the expectations of the investigators regarding decision-making impact of an economic evaluation.
Conclusion: This study revealed that the use of CEA results for Dutch micro- and meso-level healthcare decision making is not self-evident. The main purpose of CEA results is to support health policy making and planning at a macroeconomic level. Pre-assessment can be a valuable tool in designing a CEA to support the actual information needs of the decision makers.

Keywords: Economic evaluation, Cost-benefit, Decision making, Health insurance, Rehabilitation

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The use of health economic evaluation, e.g., cost-effectiveness analysis and cost-benefit analysis, in healthcare decision making is an important topic since the development of the field. Use of evaluation results at several decision-making levels, by different decision makers, and concerning different decisions were identified as well as advocated (6;14;18). Despite the fact that many methodologic problems have been solved and the political and economic environment has changed favorably, several studies indicate that the possible impact on healthcare policy and decision making has not yet been fully established (1;3;12).

Several authors identified and argued causes why results of health economic evaluation are not integrated in healthcare decision making. Besides deficiencies in study methodology (5;8;12;14;21) and presentation and communication of the results (3;4), it also appears that the formal organization of health care does not facilitate appropriate use of health economic research in healthcare decision making. The healthcare structure does not always permit efficiency, and incentives can be insufficient for physicians and health insurers to act toward the relative efficiency of new healthcare technologies (5;14;23). On the contrary, health economic researchers should be more concerned with the information needs of the intended users of evaluation results (4;8;17), the time and regulatory affairs required for decision making (4;17;23), and the phase of the technology life cycle (2). In addition, decision making is not focused on relative efficiency alone (3;17), and the actual use of cost-effectiveness analysis (CEA) results is more evident if the authorized body that requests an evaluation is also the responsible decision maker (3).

It is considered crucial to use these experiences to improve the actual use of results of health economic evaluation in decision making. To avoid unprofitable evaluation, Drummond et al. (7) emphasize the need to assess the potential impact on decision making before conducting the evaluation. Such an evaluation should support whether an evaluation has to be conducted at all and with what specific requirements. So far, little has been published on theoretical background and the actual procedure of such assessments in health economic evaluation. In social program evaluation, however, evaluability assessment, or pre-assessment, has been documented by Wholey and other authors (18;22;24;26). Their approach is instrumental, i.e., the results of an evaluation are to be used by managers and policy makers (these can be referred to as the intended users) in decision making. This result-oriented management is seen as the main purpose of medical technology evaluation. Pre-assessment is a method that is used to explore whether result-oriented management can indeed be expected as well as to determine which aspects of the medical technology assessment are relevant to the decision makers. Close cooperation with each of the decision makers is obvious in a pre-assessment.

In the context of health economic evaluation and the attempts that have been undertaken to assess the potential impact of evaluation results on decision making, some observations can be made from the experiences in social program evaluation. First, different kinds of use of CEA results by different kinds of decision makers can be identified. In order to focus a pre-assessment, choices have to be made regarding the context of the decision, the decision maker, and the intended use of evaluation results. Second, in order to succeed in actual use of the evaluation results, the decision makers, should both be willing and able to act on the evaluation results. Third, it is obvious that the aspects of the performance of a medical technology that are relevant to the decision maker should be given attention in an evaluation. It should be clear what performance, i.e., clinical effect, must be shown in order to influence the decision makers' actions. Also, the desired detail of such information and the relevant outcome measures should be clear. Fourth, the medical technology that is evaluated should have plausible causal assumptions in a way that the desired performance can indeed be expected and measured.

Based on these observations, we aim to present and discuss recent experiences with pre-assessment of the potential use of CEA results in decision making. Two cases in the field

Table 1. Summary of the Consecutive Parts of the Pre-assessment

	Expected impact of CEA results on decision making
Evaluation purpose and intended users	
Evaluation purpose	Define the desired decision to which the evaluation results should contribute
Intended users	Assess relevant decision makers (stakeholders able to act toward the evaluation purpose)
Decision-making process	
Decision context	Assess the role of evaluation results in decision making, and determine other decisive factors
Performance indicators	Assess minimum program effect sizes that will be judged relevant
Information needs	Assess preferred evaluation design and relevant time availability
Expected evaluation result	
Assess the expected program performance (literature, systematic review, pilots)	

Based on Wholey's evaluability assessment. The expected impact of the results of a CEA is a combined judgment of the first three parts (evaluation purpose, decision context, performance indicators, information needs, and expected performance).

of rehabilitation medicine and rehabilitation technology serve as material. In both cases it was discussed whether a CEA analysis could potentially influence actual decision making. This could be either including a device in the benefit package (case 2) or the justification of budget allocation for inpatient rehabilitation (case 1). Both pre-assessments were based on our experiences in social program evaluation as introduced previously.

METHODS

Analytical Framework

The pre-assessments comprised four consecutive steps, of which the last phase was the integral analysis of previously collected information (Table 1). In general, four different stakeholders are involved in a pre-assessment. A *stakeholder* is defined as "people" or "organizations" that have an interest in the technology under consideration. Usually there may be a commissioner of an economic evaluation, e.g., an industry. The other stakeholders are the investigator who designs and conducts the analysis, the decision maker whose decision making is relevant to the commissioner, and experts that are expected to provide information about the effectiveness and cost implications of the technology under consideration.

Evaluation Purpose and Stakeholders Involved. The pre-assessment started with a semi-structured interview with the commissioners of the economic evaluation. It was asked what the evaluation results ultimately should be used for and which legal bodies are expected to be responsible for the actual decision making (decision maker). Additionally, an analysis of the literature on healthcare financing in the Netherlands was carried out and expert opinions were obtained regarding possible intended users. Selection of relevant stakeholders was performed based on three criteria (power, legitimacy and urgency) as opposed by Mitchell et al. (15). These criteria can be used to determine stakeholders who have a dominant influence. Dominant stakeholders are those who actually decide on prescription and reimbursement of a healthcare technology in practice (primary decision maker). Usually, dominant stakeholders are healthcare professionals and technical advisors of insurance companies. Other stakeholders that can be identified are involved in decision

making but from a healthcare policy perspective (e.g., these stakeholders are involved in guideline development). Each stakeholder can be an intended user of the evaluation results, i.e., they all have a professional interest in the evaluation.

Decision Makers to Reach. Subsequently, semi-structured interviews with the representatives of legal bodies that were in charge of decision making were carried out. If the responsible persons were not available for interviewing, another representative or content expert was interviewed. All relevant regulatory and legislative information was studied prior to conducting the semi-structured interviews. Key information to be obtained by the interviews was whether results of either a CEA or other kinds of evaluation were expected to influence decision making. It was also asked what other aspects could influence a decision (decision context), and what level of performance on relevant outcome measures should be shown to dominantly influence the decision. Based on the previously obtained information, the decision makers were asked for CEA design features considered essential for the decision making process (e.g., outcome measures, comparator, time horizon) and the time period in which the results should become available in order to influence decision making.

Expected Performance of the Medical Technology. Expected performance was assessed by analysis of medical and economic literature collected from the MEDLINE and EconLit databases. Also, interviews with professionals involved in the actual treatment were carried out regarding hypothetical treatment effects, medical consumption, and treatment effects that were seen in practice. If required, cost prices were based on the guidelines stated in the Dutch guidelines for health economic research (16).

Analysis. The potential decision making impact of CEA results was assumed to depend on two criteria: a) the specific contribution of CEA results in a decision (to what extent are CEA results decisive); and b) the actual performance of the new treatment in a healthcare technology evaluation. In addition, besides a full CEA, other types of evaluation (i.e., effectiveness or cost studies) could be considered as well.

Case Descriptions

Case 1 concerns a chronic low back pain rehabilitation program (25). This multidisciplinary rehabilitation program is designed for intensive therapy of short duration, aiming at resocialization and return to work. A randomized controlled trial was presently carried out by researchers of the rehabilitation center comparing the back pain treatment with a control group that was allowed to follow a usual care approach. A CEA was planned alongside the trial. The principal investigators were interested in the use of CEA results from the perspective of the rehabilitation center. They were first interviewed for the evaluation purpose of the CEA.

Case 2 concerns the economic evaluation of a neuroprosthesis (i.e., an orthosis that provokes muscle stimulation via electrical current), which was being introduced to the Dutch market at the time this assessment was performed. The orthosis was to be used by chronic stroke patients to reduce arm spasticity and to improve upper extremity motor function (11). The marketing director of the company producing the assistive device assumed CEA results positively influenced reimbursement decisions of healthcare insurers, and it was decided to investigate the usefulness of conducting a CEA.

RESULTS

Case Chronic Low Back Pain Treatment

The evaluation purpose in this case appeared to be a justification for the healthcare budgets allocated to inpatient rehabilitation of patients with chronic low back pain. This purpose

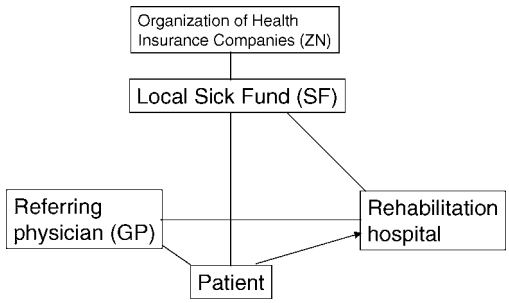

Figure 1. Decision context in the low back pain rehabilitation case. Patients are submitted to a rehabilitation hospital by a GP. It is assumed that patients receive their insurance from a local sick fund, and private insurance is not considered in this case. The rehabilitation hospital is expected to negotiate with the sick fund about the number of treatments they can offer on an annual basis.

was defined from a hospital perspective and would possibly also result in an increase in referrals and budgets. Decision makers that were identified were the referring physicians and two representatives involved in treatment budget negotiations, i.e., the account manager of the local sick fund and the representative of the Dutch Federation of Health Insurance Companies (Figure 1). Program documents showed general practitioners (GPs) to be the main referrers. Two GPs were randomly selected for interviewing.

A clinical evaluation of the performance of the program was considered relevant for all decision makers. However, none of the intended users seemed primarily interested in the outcome of a CEA, in which relative costs are compared to relative effectiveness. The sick fund account manager and the representative of the Dutch Federation of Health Insurance Companies were merely interested in micro- and macro-budgetary impact, whereas the referring physicians were only interested in clinical effectiveness on health-related quality of life, disabilities, and impairments (Table 2). The interviewed sick fund account manager did not provide much information about other decisive aspects that determined the decision context. Time of the evaluation did not appear critical since budget negotiations between hospital and healthcare insurer take place every year and patients are referred to the hospital during the entire year.

Analysis. The impact of CEA results on decision making of the intended users can be expected to be low. However, the randomized controlled trial study that was conducted appeared relevant to decision making anyhow. Results on clinical effectiveness might very well increase patient referral by GPs. However, the expected costs of the treatment were too high to be considered as "budget neutral," which was the performance indicator of the sick fund account manager and the representative of the Federation of Dutch Health Insurance Companies. Increase of treatment budget to a hospital therefore cannot be expected to result from budget impact analysis. Budget neutrality can, however, be obtained if costs of treatment of chronic low back pain in primary care are considered in the analyses. However, this is a typical constraint in healthcare financing because insurance companies are not able to transfer budgets between extra- and intramural treatment (9).

Case Neuroprosthesis

Support of inclusion of the neuroprosthesis in the benefit package appeared to be the evaluation purpose. In social health insurance, which was the main source of healthcare financing at the time, four relevant stakeholders were identified (Figure 2). The technical advisor of the sick fund is responsible for decisions on reimbursement in individual patients

Table 2. Results of the Pre-assessment in the Back Pain Case

	Selected Intended users		
	General practitioners	Account manager SF[a]	ZN[b] representative
Evaluation purpose	Increase patient referral to rehabilitation center	Increase back school budget	Increase back school budget
Decision context			
Evaluation role	Confirm clinical experience	Confirm cost assumptions	Confirm cost assumptions and major health effects
Other decisive factors	Patient's preference Distance to clinic	?	
Performance indicators			
	Any effect on QoL/ disability/impairment	SF microbudget neutrality	Macrobudget neutrality
Information needs			
Outcome	QoL/disability/ impairment	SF microbudget costs	Social health insurance Macrobudget costs
Comparator	Regional available alternative	Regional available alternative	National available alternative
Follow-up	Short & long term	Short & long term	Short & long term
Time availability	Not important	Not important	Not important
Expected performance	QoL/disability/ impairment	US $ 1,200/patient treated microbudgets: US$ 0	Macrobudget: US $ 1,200/patient treated

[a]SF = Local sick fund.
[b]ZN = Federation of Dutch Health Insurance Companies.

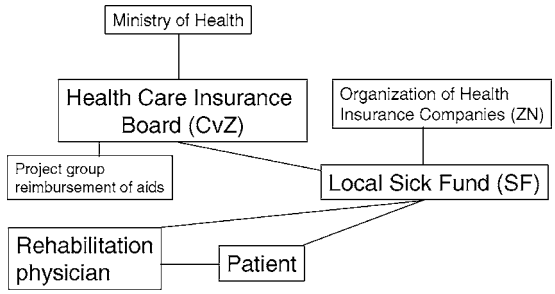

Figure 2. Decision context in the neuroprosthesis case. Patients are considered for prescription of the neuroprosthesis by a physician for PM&R, and an application for reimbursement is submitted to the patients' insurance company. The technical advisor of the insurance company judges the application using reimbursement guidelines that are developed by the healthcare insurance board. The healthcare insurance board only recently installed a project group that should advise on reimbursement guidelines for (rehabilitation) aids.

(decision maker), but his reimbursement decisions are imposed by guidelines of the medical advisor of the Health Care Insurance Board (CvZ). However, the guidelines for reimbursement of assistive devices were revised at the moment because of an increasing pressure on budgets for assistive devices. Therefore, it was decided to interview the head of the orthopedic shoes project group as well as the guideline project coordinator. The head of the orthopedic shoes project group is responsible for the guideline developments regarding orthopedic shoes. It is assumed that he may also represent the orthoses project group where a project coordinator has not yet been appointed. The project co-ordinator actually supports the development of reimbursement guidelines.

Some other intended users were only partially available for interviewing. A physician experienced with reimbursement of new medical technologies was interviewed in addition to the technical advisor of the sick fund. Legislative regulations, jurisdiction, and existing correspondence were studied instead of interviewing the medical advisor of the CvZ.

Only one of the intended users (project coordinator of the CvZ) seemed interested in the relative cost-effectiveness of the neuroprosthesis. However, other kinds of evaluation such as budget impact analysis and evaluation of clinical effectiveness were relevant to decision making of the other intended users (Table 3).

Analysis. The neuroprosthesis was technically described in the reimbursement regulations of CvZ, which is the most important decisive factor. However, individual reimbursement depends on clinical results. Budget neutrality, which was the major performance indicator for the local sick fund technical advisor, is not expected. On the contrary, evaluation of therapeutic value, effect duration, and macro-budget impact might very well contribute to a positive general reimbursement statement by the medical advisor of the CvZ.

Scientific evidence of a treatment effect is important to decision makers. In earlier correspondence the medical advisor noticed that not enough conclusive evidence on clinical effectiveness was shown so far, and inclusion of the neuroprosthesis in the reimbursement guidelines eventually requires more scientific evidence. Although cost-effectiveness is not relevant at the moment, it is expected that a cost-effectiveness criterion will be implemented in reimbursement guidelines within 2 years.

DISCUSSION

The present study was aimed at investigating the use of a pre-assessment to determine whether a CEA would meet the decision makers' actual information needs. Like previous studies, it was found that the expected use of CEA results in supporting decisions is low. In general, stakeholders at different levels (macro, meso, and micro) did not intend to use CEA results as a ratio of incremental costs and incremental effects.

In the chronic low back pain case, there obviously was a difference of interest between representatives of insurance companies and healthcare professionals (GPs). The representatives from insurance companies seem notoriously interested in budget neutrality, rather than clinical effectiveness or cost-effectiveness. In this particular case, it is sufficient to analyze the clinical benefit to justify the inpatient rehabilitation program. In addition, budget negotiations between hospital and insurance company reveal the number of patients that can be treated on an annual basis.

The neuroprosthesis case, has a slightly different scope because it assesses the possibility and requirements of adding the device to the benefit package. Like the first case, the local sick fund was mostly interested in budget neutrality. However, in this case it appeared that regulatory bodies such as the Health Care Insurance Board are interested in relative cost-effectiveness of the treatment. At least they put an effectiveness criterion in their judgments. Since the device is technically described in the reimbursement guidelines (category of devices that have a similar function), a local sick fund may at present decide to reimburse the neuroprosthesis in individual patients. Cost-effectiveness of the device has, however, not yet been established, and it is expected that this criterion will become relevant once the reimbursement guidelines for prescription of orthoses are developed.

In both cases the pre-assessment did change the prior expectations of the principal investigators on potential impact of CEA results on decision making and showed that other types of evaluation are more relevant to decision making. The evaluation approach in case 1 required the most attention. It was concluded that budgetary impact and clinical effectiveness should be studied separately. A CEA was found to be useful in case 2 for inclusion of the

Table 3. Results of the Pre-assessment in the Neuroprosthesis Case

	Selected intended users			
	Technical advisor SF[a]	CvZ[b] medical advisor	Head project group reimbursement	Guideline project coordinator CvZ
Evaluation purpose	Reimburse neuroprosthesis	Positive general reimbursement advice	Inclusion of neuroprosthesis in reimbursement guidelines	Inclusion of neuroprosthesis in reimbursement guidelines
Decision context				
Evaluation role	Confirm cost assumptions	Scientific evidence is decisive	Support inclusion	Support inclusion
Other decisive factor	Technical description and physician			
Performance indicators	SF budget neutrality	Therapeutic value; Macro budget neutrality and >3 months of application	Therapeutic value	Therapeutic value, relative cost-effectiveness
Information needs				
Outcome	SF microbudget costs	Therapeutic value; macro budget costs and application	Therapeutic value	Relative C/E Societal costs QALYs /morbidity
Comparator	?	Alternative intervention	Alternative intervention	Usual care Usual care
Follow-up	?	?	?	Long term
Time availability	?	?	<2 years	<2 years
Expected performance	Assistive device budget: approx. US $3,000/patient treated Other budgets: cost reduction	Some evidence for spasm reduction and arm function improvement Macrobudget: US $750/patient treated after 3 years	Some scientific support for spasm reduction and arm function improvement	Higher effectiveness and reduced costs after 3 years

[a] SF = Local sick fund.
[b] CvZ = Health Care Insurance Board.

neuroprosthesis in the reimbursement guidelines by the Health Care Insurance Board. It was also concluded that macro-budgetary impact as well as clinical effectiveness should also be studied in order to influence the decision makers.

In a pre-assessment, cooperation of intended users is considered crucial. In case 1 it was noticed that the sick fund representative could not give an in-depth view on the decisional context. Although this could be explained by the strategic context of specific decision making, it is obstructive to future CEA impact analysis. In the second case it appeared that the overall cooperation of intended users was low. In such cases expert opinion seems valuable, although this might not fully represent the decision makers' view. One of the explanations may be that decision makers have little experience regarding economic evaluation approaches and decision context (23). For instance, it appeared difficult for the intended users to state performance indicators (health effects) in precise terms. The same accounts for the relationship between costs and effects, or relative cost-effectiveness. Regarding the preferred evaluation design, all intended users were somewhat uncertain and they could only point out global demands. It might also be argued that performing a pre-assessment could change decision makers' behavior, since they would become more aware of the decision to be taken.

Different explanations can be given regarding the mismatch between information needs and CEA results. Most obvious are the different interests in healthcare and the absence of incentives for healthcare providers and insurers for efficient behavior (3;9;14). The compartmentalization of specific budgets does not facilitate efficient allocation of resources and often will lead to a cost-minimizing behavior within each compartment. This was particularly the case in the low back pain rehabilitation program, where it did not appear possible to shift budgets from extramural health care to inpatient rehabilitation, for example.

There are some other findings that suggest that CEA results do actually correspond with the prescription policy regarding medicines. George et al. (10) produced a league table of drugs considered for reimbursement by the Australian Pharmaceutical Benefits Advisory Committee (PBAC) and reviewed whether this table was consistent with findings of economic efficiency. They concluded that the PBAC was broadly consistent with the use of economic efficiency as a criterion (10). Although the contribution of George et al. showed that decisions about the inclusion of drugs in the benefit package are largely consistent with cost-effectiveness information, it is still required to further improve the use of CEA information.

The healthcare developments in the Netherlands and other countries are intended to further decentralize responsibilities. It is expected that insurance companies will increasingly act as commercial companies with a financial interest in the contracts they sign with health-care providers. Originally, healthcare insurers had no financial interest, and it is expected that there will be an increasing demand for and use of cost-effectiveness information in contracting healthcare providers. On the other hand, it is probably very difficult for insurance companies to compare cost-effectiveness information of different treatment strategies and to support decision making (19). From this point of view as well as from the present study, it can be concluded that it is worthwhile to undertake some efforts to further educate healthcare decision makers in the use of cost-effectiveness information.

Also, it may turn out productive to critically appraise the process of technology development and assessment itself. Elsinga and Rutten (9) and Hummel et al. (13) have put forward that one of the problems of medical technology assessment is that the technology is often evaluated while the technology is in an advanced stage of diffusion, i.e., the Collingridge controversy (9;13). This implies that it is hardly possible to actually influence the introduction and implementation of the technology, because it is already diffused to healthcare professionals. Some authors have proposed alternative methods to improve the process of technology introduction and diffusion. These methods are merely based on

improving actual study design. For instance, Sculpher et al. proposed to follow an iterative approach in economic evaluation, starting with a review of the literature on costs and effects in early stages of clinical research (21). It is then possible to anticipate the study requirements in later stages of clinical research. The present study shows that pre-assessments provide valuable information concerning the design of a CEA in obtaining an appropriate fit between the CEA results and the decision makers' actual information needs.

Rather than improving the actual study designs, it is also possible to investigate the process of technology development. Hummel et al. (13) introduced a more rigorous method to improve the process of technology development. They propose to follow a hierarchical model of technology development with which it is possible to support discussions about different factors that influence technology development and diffusion (13). The method anticipates the different stakeholders that are involved in the development and diffusion of the technology. These constructive approaches may very well be used to overcome the gap between different healthcare responsibilities in early stages of technology development.

POLICY IMPLICATIONS

The present study suggests that a pre-assessment may provide useful information about the actual information needs of decision makers, and thus can be used to further optimize cost-effectiveness studies. Due to decentralization of healthcare responsibilities it is to be expected that insurance companies will become more concerned with the cost-effectiveness criterion, and they might also use it as a competitive force. Decision makers need to be involved in early stages and need to be educated in using cost-effectiveness information.

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