Fetal monitoring at home in high-risk pregnancy. An integrated clinical and economic evaluation
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Citation for published version (APA):

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Towards a framework for evaluation of non-health outcomes. Measurement and implications for cost-effectiveness analysis

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8.1. Introduction

People may regard life as a sequence of choices. Choice is the outcome of selecting one option out of a set of mutually exclusive alternative options, each with its own specific consequences, either advantageous or disadvantageous. Decision making is the process to arrive at a choice. Although decision making may apply to many fields in everyday life, here we concentrate on a specific class of decisions, viz. decisions in health care.

The theory of choice has been developed in economics. The basic economic model assumes that people know what they want (the axiom of connexity or completeness). A recent experiment shows a lack of support for incompleteness after decision support. Indeed, when choices are not straightforward at first sight — as often the case when issues are unfamiliar, complex, or when direct experience is lacking — decision support may be needed.

Decision making could take the following form: a set of alternatives is identified; information on the characteristics and consequences of each alternative is gathered; judgements (valuations, weighing) regarding the alternatives are made and compared relative to each other in terms of a (multi-)objective function; and choice is made. Information may be obtained from varying sources: past experience, experience from others, retrospectively collected observations, disclosure of existing information, or prospective data collection. Information is an aid rather than a substitute of decision making. Usually, additional aspects that are difficult to represent may play a role in decision making.

That difficulty is also present in many medical decisions. Although medical decisions are usually taken from a genuine clinical decision making perspective, we believe that the economic perspective can also be applied to medical decisions. In case of decisions regarding the diagnosis or treatment for particular patient groups or health conditions, decision support has been formalized by means of randomized clinical trials which are aimed at outcome-based decision support, and by economic evaluation ('medical technology assessment') which is aimed at efficiency-based decision support. Despite many useful results, standard application of these techniques has also revealed limitations.

Whether or not domiciliary antenatal fetal monitoring should be initiated instead of conventional in-hospital monitoring, represented a choice of the type mentioned above. While evaluating domiciliary monitoring, several problems in the conventional application of evaluation methods emerged. Firstly, our evaluation concerned two patients, the pregnant woman/mother and the fetus/infant instead of one (i.e. the fetus/infant as primary patient). Secondly, a set of unrelated outcome concepts with quite different timing existed (e.g. safety of pregnant woman, safety of mother, maternal morbidity, complications of interventions, neonatal sequelae). And finally, we found a strong effect of other factors than conventional morbidity and mortality measures ('non-health' outcomes) in decision making.
The latter finding justifies a thorough discussion as to which position these outcomes have in standard evaluation methodology. In our case, the care setting – home or hospital – seemed to provide ‘benefits’ or ‘value’ per se, playing a role in patient’s considerations when they were asked to choose between alternative monitoring options. Probably an array of many such ‘non-health’ outcomes exists (e.g. information, communication, caregiver’s attitude), not only within the context of our study but also in the provision of health care in general. This raises questions as: can these ‘non-health’ outcomes be measured and if yes, how? Which reference values are valid? How can values be incorporated into one overall judgment?

We expect that the role of non-health outcomes in public and individual decision making, in policy setting and, consequently, in decision support techniques, will increase:

- with little left to gain in terms of mortality, aspects other than survival increase in importance when choices between health care options have to be made;
- with increasingly educated and informed patients changing patients into health care consumers, the legally supported trend toward shared decision making and the development of individualized health care (taking into account non-health aspects of care) will be more frequent and more persistent;
- the conventional boundaries between the domains of health and health care on the one side and all other domains on the other, will gradually fade and maybe disappear (e.g. food technology, employment, sports).

In section 8.2, we address the classification of objectives and outcomes of health care services. Based on the framework presented in section 8.2, we introduce the distinction between process and outcome and address the borderline between health outcome and non-health outcome in section 8.3. In section 8.4, we discuss how non-health outcomes may be dealt with in view of existing evaluation techniques. In section 8.5, we discuss the position of non-health outcomes relative to cost-utility and cost-effectiveness analysis as (economic) decision support models. We conclude with section 8.6.

8.2. The objectives and outcomes of health care

The structure of clinical evaluations essentially is as follows. Given a defined medical problem, i.e. a problem that society expects to be solved by medical care, one or more relevant alternative options are compared in terms of the quantified health-related consequences these alternatives have for representative groups of patients. In its most simple form, outcome measures recorded at the individual patient level are quantified in a dichotomous way (cured yes or no; presence or absence of adverse outcome) which are aggregated over the individual patients (proportion cured; proportion adverse outcome) and statistically tested to arrive at an overall recommendation for the patient group as a whole. This consequentialistic approach focusses solely on the extent to
which the goals are *ultimately* achieved, irrespective of patients' characteristics or the health services delivery process ('path independency').

This basic structure can be represented more formally. Two mutually exclusive alternatives A and B with outcomes O(A) and O(B), respectively, are ranked according to their magnitude. If "more of O(.)" is considered preferable, then the following conclusion can be drawn: if O(B) is larger than O(A) then alternative B is preferred to alternative A. Note that the preference ordering is relative. Firstly, there is no zero anchor; in fact, the alternatives are ranked relative to each other. Secondly, there is no external reference as to how O(A), O(B) or any of their derived measures such as O(B)−O(A) or O(A)/O(B) relate to other health interventions or commodities for which preferences can be expressed (C and D). That is, the decision being made is 'local', not 'global'.

In clinical evaluations, the health outcome concept O(.) has two characteristics. Firstly, O(.) is *health-related* outcome, implying that the consequences of (medical) alternatives are confined to the 'health domain'. Secondly, outcome is usually operationalized as a set of independent outcome measures (primary, secondary outcomes) which may be measured repetitively over time. The definition of multiple outcome measures gives the health concept a multidimensional feature. As such, the health outcome concept has evolved from a one dimensional event-like outcome into essentially a two-dimensional continuous concept of mortality and morbidity (defining hypothetical "mortality-morbidity"-space). To support decision making, the mortality-morbidity health concept can be reduced to one composite health outcome measure (e.g. quality-adjusted life years (QALYs)). The composite health outcome measure O*(.) can then be used to rank alternatives O*(A) and O*(B) as to recommend which of two interventions A and B is the preferred one.

From an empirical point of view, there are more aspects than only health-related outcome that count in societal and individualized decision making. Specifically, *different aspects* may be relevant for *different actors* involved in the delivery of health care, such as those in need for health care (patient group), those in potential need for health care (preventive target group), health care professionals and institutions, health (and other) insurance companies, the government, administrative bodies and authorities, and manufacturers of all kinds of medical supplies.

For our purpose, we have simplified the complex interactions between these actors into a simple supply-demand model, shown in Table 1. At the supply side, the production of all services in society is distinguished into health services and non-health services. Next, the delivery of health services is further classified in terms of their primary objective which may be medical, non-medical, or a mix of medical and non-medical. At the demand side, the outcomes that result from the health and non-health services supply are categorized into health-related and non-health-related outcomes.
# Classification of objectives and outcomes in health care

Table 1 illustrates that the primary aim of health services delivery is to improve health but that health care may also provide outcomes other than health. Health services with a primary medical objective produce primary health-related outcomes (cell 1.1). For example, pharmaceutical treatment may reduce morbidity which obviously is a health-related outcome, but also induce side effects, defined here as secondary health-related outcome (cell 1.2). The way the pharmaceutical is administered (injection, tablets) may be considered to produce a non-health effect (cell 1.4).
The health care system also delivers services with a primary non-medical objective. Services are provided by health care but their primary aim is basically non-medical and the resulting outcomes can be considered primary non-health-related (cell 2.3). Examples are reproduction and elderly homes. The primary outcome of reproductive support is a successful pregnancy. The primary outcome of elderly homes is to maintain independent, dignified living (autonomy). Although a successful pregnancy and independent living, strictly speaking, are non-health related (that is, cannot easily be translated as a point in 'morbidity/mortality'-space), they definitely are the intended outcome of the health service delivered. Health care aimed at achieving non-health outcome may even generate secondary health-related effects (cell 2.2), e.g. complications associated with screening for Down's syndrome.

Occasionally, health services may have mixed objectives, e.g. the treatment of ectopic pregnancy. The primary aim is to avoid maternal mortality which is a primary health-related outcome (cell 3.1). The side-effects of treatment can be considered secondary health-related outcomes (cell 3.2). Reduced reproductive capacity, a specific 'side-effect' of tubectomy, can be regarded a non-health related effect (cell 3.4). The side effects of methotrexate treatment, however, can be considered a secondary health-related outcome. Another example is genetic screening which not only delivers test information and potential health benefits for the screenee, but also information regarding the family and, possibly, future offspring. From a methodological point of view, such mixed cases are difficult fields of research.

Society also delivers services which typically are non-medical but nevertheless have an impact on health. For example, the primary aim of water utility companies is to safeguard a continuous supply of clean water (cell 4.3), which in turn reduces the health risk due to water pollution (cell 4.2). Although health economics usually excludes cases like cells 4.2 and 4.3, this arbitrary choice is not always justified.

Table 1 illustrates that conventional clinical evaluations which compare alternative health services in terms of health related outcome (i.e. predominantly cells 1.1 and 1.2, occasionally 2.2, 3.1 and 3.2) are an extreme reduction of what matters in real decision making. Note that even Table 1 itself is an extreme abstraction of the complex interactions among actors and their objectives.

Two conclusions can be drawn from Table 1:

- Health services, irrespective of their primary objective, not only deliver health-related outcomes but also non-health-related outcomes. The latter category not only includes the secondary, unintended effects of health care but also incorporates non-health related outcome as intended primary objective, primary in the sense of playing a dominant role in actual decisions.
- The array of benefits and disadvantages of alternative health care interventions is often much larger than the analysis and evaluation of health-related outcomes suggest.
The remainder of this chapter is devoted the concept, meaning and measurement of non-health outcomes.

### 8.3. Outcome versus process; health outcome versus non-health outcome

Several researchers have already suggested that the outcome domain of health interventions can be divided into a domain of health-related outcome, consisting of mortality and morbidity outcome, and a domain of non-health outcomes. Berwick and Weinstein speak of 'non-health' outcomes which may be either relevant or irrelevant to decision making ('decisional non-health' versus 'non-decisional non-health'). Donaldson and Shackley prefer to label these effects 'process utilities' in order to distinguish between the conventional utility concept (the valuation of health states defined by a position in "mortality-morbidity"-space) and the valuation of aspects other than mortality or morbidity. A similar problem was encountered by Pigou about 1920 when he tried to distinguish the concept of welfare into economic welfare and non-economic welfare.

The conventional model of health care is to deliver health services to a patient in a suboptimal health state in order to achieve a more favorable health state or prevent a deterioration of the current health state (cure, primary, secondary, tertiary prevention). This model is reflected in Donabedian's structure-process-outcome model. Process is the transitory phase in which a patient with a suboptimal health state is 'transformed' into a patient with improved health. From this view, health improvement is the intended health-related outcome of the health care delivery process (disregarding cell 2.3). Table 1 presented above has shown that the 'outcome' concept is ambiguous: some outcomes that are the unintended 'by-product' of the medical input-output process but which, nevertheless, cannot be considered health-related (cells 1.4, 2.4, and 3.4). Apparently, when combining the process-outcome view with the classification of Table 1, there are outcomes which are related to health and outcomes that are related to the process of health services delivery. The latter ones correspond to the secondary non-health related outcomes (cells 1.4, 2.4, 3.4). The cells 2.3 and 3.3 take an intermediate position. Although these effects are also non-health related, they are not process-related because of their intentional nature.

If we accept this view, then non-health outcome may be defined tentatively as: the secondary, non-health related, unintended outcomes of health care delivery which cannot be captured in terms of mortality or morbidity. Non-health outcomes can be characterized as follows:

- Non-health outcomes originate from the the delivery of health services and, as such, can be considered the consequence of the process of health care.
- Improving health status implies that a patient must pass through the process of health services delivery and by doing so, the patient cannot avoid nor avert non-
health outcomes. I.e. health outcome and non-health outcome are the result of joint production ('multiproducts').

- As the health services delivery process is a transitory stage, non-health outcomes must also be transitory effects. The duration of the process and the existence of non-health outcomes over time do not necessarily parallel each other.
- Contrary to the health outcomes, non-health outcomes have no self-evident interpretation. They may be regarded advantageous to one individual and disadvantageous to another patient.

What constitutes the borderline between health and non-health is still an issue. The borderline that separates health from non-health, though important from the conceptual point of view, may be difficult to draw. Obviously, non-health outcomes include all effects that are not covered by the definition of health (disregarding cells 2.3 and 3.3 in Table 1). From the clinical perspective, health may be defined as the absence of mortality and morbidity. It depends on the clinical problem at hand which (quantifiable and statistically testable) outcome measures are selected to operationalize ‘mortality-morbidity’-space. From a more general philosophical perspective, health may be defined as:

“...a state of complete physical, psychological and social well-being and not merely the absence of disease or infirmity” (WHO definition)."^{14}

In medical research, predominantly (health) psychologists have operationalized this health concept in questionnaire derived measures of health. In their view, health-related quality of life (HRQoL), i.e. the health-related aspects of overall quality of life, is the individual's self-reported judgement of the level of health-related well-being.\^{15} HRQoL
is usually operationalized by items in the domains physical functioning, psychological or mental health, and social functioning. Hence, the health status measurement approach has adopted the WHO-view on health.\textsuperscript{16} Therefore, if we equate the morbidity aspect of health with HRQoL, by definition we define non-health as the aspects not covered by HRQoL. Obviously, the WHO health definition and the commonly applied HRQoL-operationalizations are much broader than the clinical mortality-morbidity perspective.

Several HRQoL-instruments have been developed (MOS-20, RAND SF36, NHP, SIP) and each of these instruments claims to measure health status or HRQoL validly and reliably, though not without problems. Firstly, although all of these instruments share a common core, viz. health operationalized around physical functioning, mental health and social functioning, the operational differences between them are considerable. Secondly, it is likely that neither of these instruments represents the perfect operationalization of the health or HRQoL concept, assuming that such a perfect operationalisation exists. Therefore, aspects of 'true' health may erroneously not have been measured or aspects of non-health may mistakenly have been measured.\textsuperscript{16} Donaldson and Shackley have argued that the strict partition of health and non-health is particularly difficult regarding the mental health domain.\textsuperscript{8}

Even if an instrument would be available that perfectly operationalizes the concept of health, then still it would not be possible to measure health perfectly for reasons of limited responsiveness. Moreover, there is no consensus as to how responsiveness should be measured.\textsuperscript{17} Hence, an empirical approach to disentangle health and non-health is unlikely to be of great help.

For conceptual and empirical reasons (Table 1 and Figure 1), we claim the existence of a domain of non-health outcomes alongside the 'conventional' mortality-morbidit y domain. Although some outcomes can unambiguously be regarded as health outcome whereas others definitely are non-health, the exact borderline between them is rather unclear. This leaves a 'grey zone', maybe large, maybe small, where effects can either be defined as health-related or as non-health-related, depending on the arguments put forward. It is unclear as to what extent conceptual arguments and empirical methods can be of use in separating health from non-health.

The acknowledgement that a non-health outcome domain exists, implies a reconsideration of the outcome concept and of its commonly applied measurement tools. From a conceptual point of view, 'pure' health states do no longer exist; only 'states' composed of health outcomes and non-health outcomes do exist. From an empirical point of view, the strict partition between health and non-health is less important. What is important is the recognition that all aspects, irrespective of their health or non-health nature, may play a role when medical decisions, either at the individual or societal level, have to be made.
8.4. Management of non-health outcomes

Decision making can deal with non-health outcomes in different ways, depending on the presence or absence of these effects, their importance relative to health outcome and their role in decision making. Figure 2 provides an overview.

**Figure 2.** The measurement of non-health outcomes

We acknowledge that different societal actors may hold different views regarding the preferred position of non-health outcomes in Figure 2. Here, we adopt the most generic case: non-health outcomes exist, by definition they are not included in health states, and they may be considered in decision making.

*Valuing non-health outcome*

Conventional economic choice behavior can be modelled with the aid of an individual (economic) utility function $U(.)$ or valuation function $V(.)$. To avoid ambiguity between the terms utility and valuation, we adopt the term that is used in the medical decision sciences to represent valuation under certainty, i.e. valuation $V(.)$. $V(.)$ may represent individual welfare or indicate choice. The specification of $V(.)$ is a model on what determines welfare or choice for this specific individual; it is not a model on what should be considered welfare or what should determine choice.

The generally accepted model on the demand of health is the Grossman model.\textsuperscript{18} Typical of the model is that the durable capital stock health produces an output of heal-
thy time each period ('healthy days'). The (neoclassical) life-time valuation function is consists of the service flow healthy time (ht), obtained from the health stock, and of a composite consumption good (Zt):

\[(1a) \quad V = V(h_{t-1}, h_t; Z_{t-1}, Z_t)\]

Each period, new health investment increases the health stock while depreciation lowers the health stock. It is further assumed that consumers produce health investments (lt) and other commodities (Zt):

\[(1b) \quad l_t = l_t(Xh_t, Th_t, E_t) \quad \text{and} \quad Z_t = Z_t(Xz_t, Tz_t, E_t)\]

where Xh represents health care input, Xz market goods input, Th time spent in investing health, Tz time spent in producing Z and E the stock of human capital (education). The model may be extended to a full neoclassical model after which (1a) is optimized subject to several constraints (among others (1b), a time budget and income budget) and conditions for optimality are derived.

For our purposes, we use a simplified approach, interpreting \(V(.)\) not as an individual life-time utility function but as an indicator of choice with which trade-offs may be modelled. We assume that individuals acquire 'value' through consumption goods (X) and the holding of money (Y); supply labor services (L) lowers 'value'. To acquire consumption goods (X), individuals must spent money (Y). Cash balances are increased through labor income.

\[(2) \quad V(X; L; Y)\]

(Noted that time may be included in (2) by separating an individual’s life span in a sequence of time-dependent \(V(.)\), i.e. the intertemporal valuation function.) Health status (H) may be considered one of the elements of X. For our purposes, we explicitly separate H from X and assume that an individual holds \(V(.)\) as presented in (2), for a given health state H. That is, for every H, there is an individual \(V(.)\):

\[(3) \quad V(X; L; Y | H)\]

Conventional economic theory is concerned with the relations between X, L, and Y, holding H constant. In other words, the economic theory adopts model \(V(.)\) in (3). The conventional health-economic perspective, however, concentrates on H as the dominant factor and its relations with X, L and Y (see (1a) and (1b)):

\[(4) \quad V(H | X; L; Y)\]

Based on the arguments put forward in sections 8.2 and 8.3, if non-health outcome
exists and is considered in decision making, then (4) can be extended with the incorporation of a non-health outcome \( z \). For simplicity, \( z \) is introduced here as if there is only one non-health outcome. In fact, it may represent an array of heterogeneous non-health outcomes.

(5) \( V(H; z \mid X; L; Y) \)

Compared to Grossman's model, the existence of \( z \) implies two adaptations. Firstly, \( U \) now becomes:

\[
(1a') \quad V = V(h_0, \ldots, h_t; z_0, \ldots, z_t; Z_0, \ldots, Z_t)
\]

and, secondly, added is the production of a non-health outcome in health investment:

\[
(1b') \quad z_t = I_t(Xh_t, Th_t, E_t)
\]

\( V() \) as specified in (5) offers opportunities to measure \( z \) in terms of \( H, X, L \) or \( Y \). If we relate this general microeconomic format to cost-utility analysis – the most generic and commonly used economic evaluation framework –, the framework without indirect costs (i.e. value of lost production) is based on the model \( V(H \mid Y) \). If indirect costs are included then \( V(H; L \mid Y) \) is applied. In the next section, we will discuss how \( V(z) \) can be measured in the context of cost-utility analysis. Two options to measure non-health outcome \( V(z) \) will be explored: one which measures non-health outcome \( z \) in terms of money \( (Y) \), i.e. the WTP/WTA-approach, and one which measures non-health \( z \) in terms of health outcome \( (H) \), i.e. a trade-off of health versus non-health (“willingness to suffer/willingness to get well”) approach.

**WTP/WTA-approach**

Assume two alternative clinical strategies (1,2), generating health outcomes \( H_1 \) and \( H_2 \) and non-health outcomes \( z_1 \) and \( z_2 \), respectively. From the perspective of an individual, the associated \( V() \) are:

(6) \( V_1(H_1; z_1 \mid X; L; Y) \) and \( V_2(H_2; z_2 \mid X; L; Y) \)

The difference in valuations \( V_1 \) and \( V_2 \) is caused by the differences in health outcomes \( H_2 \) and \( H_1 \) and by the differences in non-health outcomes \( z_2 \) and \( z_1 \). First we establish whether \( z_1 \) is preferred to, indifferent to, or not preferred to \( z_2 \), assuming that health outcomes \( H_1 \) and \( H_2 \) do not differ \( (H_1 = H_2 = H) \). That is:

(7) \( V_1(H; z_1 \mid X; L; Y) \) is compared to \( V_2(H; z_2 \mid X; L; Y) \)

and ranked in order of preference.
If $V_1 \geq V_2 \Rightarrow z_1$ is preferred to $z_2$, and
if $V_1 \leq V_2 \Rightarrow z_1$ is not preferred to $z_2$.

Assume that $z_2$ is preferred to $z_1$ ($V_1 \leq V_2$); then according to the WTP-approach, $z_2$ relative to $z_1$ is valued as:

\begin{align*}
(8) \quad V_2(H ; z_2 \mid X ; L ; Y - \Delta Y) &= V_1 \quad \text{where } -\Delta Y \text{ is the sum to be paid}
\end{align*}

Alternatively, according the WTA-approach, $z_2$ relative to $z_1$ is valued as:

\begin{align*}
(9) \quad V_1(H ; z_1 \mid X ; L ; Y + \Delta Y) &= V_2 \quad \text{where } +\Delta Y \text{ is the sum to be accepted}
\end{align*}

Aggregation of the individual $+\Delta Y$ (or $-\Delta Y$) depending on the valuation method used) values provides an estimate of the net value of $z_2$ relative to $z_1$, expressed in terms of money.

Several WTP/WTA have been developed in economic theory\textsuperscript{19,20}, which may modify (8) and (9) without changing their basic structure. The development and discussion of these variants fall outside the scope of this Chapter. WTP and WTA usually result in different estimates, illustrating among others the difference between a gain and a loss.

We have developed an experiment on the basis of (8) which will be reported in Chapter 9. This study reveals, among others, that it $z$ (the stimulus which is to be valued) is derived from patients' experiences whereas $+\Delta Y$ is a hypothetical sum of money to pay (the calibrator of the response). Using $Y$ as calibrator inevitably involves template bias.\textsuperscript{5} Aspects of the WTP/WTA approach will be further addressed in Chapter 11 (General discussion, section 11.2.1).

**Health versus non-health trade-off**

This trade-off is based on the same idea as the WTP/WTA-approach but now compensation is not requested (or asked, respectively) in terms of money ($Y$) but in health consequences $\Delta H_1$ or $\Delta H_2$. In analogy to (7), individuals are asked to rank $z_1$ and $z_2$ in order of preference. Again, assume that $z_2$ is preferred to $z_1$, then $z_2$ relative to $z_1$ is valued as

\begin{align*}
(10) \quad V_2(H - \Delta H ; z_2 \mid X ; L ; Y) &= V_1 \quad \text{where } -\Delta H \text{ is the quantity of health sacrificed}
\end{align*}

Or alternatively,

\begin{align*}
(11) \quad V_1(H + \Delta H ; z_1 \mid X ; L ; Y) &= V_2 \quad \text{where } +\Delta H \text{ is the quantity of health accepted}
\end{align*}

In (10) essentially a 'willingness to accept a health sacrifice' is described, as $-\Delta H$ must be sacrificed in order to gain $z_2$ instead of $z_1$. In contrast, (11) gives a description of the 'willingness to accept a health compensation' in exchange for the willingness to sacrifice the preferred non-health $z_2$. 
As with WTP/WTA, several operational variants of (10) and (11) may be developed. Their elaboration falls outside the scope of this Chapter. Similar to WTP/WTA, we do not expect symmetric results to health gains (\(+\Delta H\)) and health losses (\(-\Delta H\)). Furthermore, the use of health as calibrator may introduce bias (template bias).\(^5\)

Regarding the issue of ‘valuation under certainty’ versus ‘valuation under uncertainty’, one should separate uncertainty with respect to the outcome (i.e. the presentation of stimulus) and uncertainty with respect to the valuation method or calibrator (the measure of response, i.e. the standard gamble). The valuation of non-health outcome (z) is subject to the same methodologic difficulties encountered in the valuation of health, particularly regarding the issue of ex ante versus ex post valuations.

From the economic-theoretical point view, there are no objections why non-health outcomes should not be made measurable, if we want to include them in individualized decision making and in societal decision support models like cost-effectiveness analysis and cost-utility analysis. The approach we have offered extends the use of accepted techniques to value health outcomes H to the domain of non-health-outcomes z. These imply the use of H or Y as calibrator to arrive at a valuation for z. Several framing options are available, awaiting further empirical research to learn which of them turns out more feasible and valid than others. In Chapters 9 and 10 we have conducted two such experiments, a willingness to pay (money) experiment and a willingness to accept (health loss) experiment, respectively.

Now we have demonstrated that non-health outcomes exist in theory, that there are no theoretical reasons why non-health outcomes should not be measured, and that a format to structure the measurement procedure is available, we discuss in the final section the opportunity to include non-health outcomes in cost-effectiveness or cost-utility analysis.

8.5. Non-health outcomes and cost-utility analysis

Cost-effectiveness analysis (CEA) and cost-utility analysis (CUA) are the two most prevalent health-economic decision-support models at this moment. Although contested by some, both models are considered to represent societal preference for alternative medical interventions. Both in CEA and CUA, societal preference is presented as the ratio of the difference in costs between two alternative medical interventions versus the difference in health effects produced with these interventions (the cost-effectiveness ratio and cost-utility ratio, respectively). Typical of CEA is that health effects are measured in terms of a one-dimensional health outcome, e.g. life years gained or cases detected. Contrary to CEA, health effects in CUA are expressed in terms a composite health outcome, quality-adjusted life years, which consists of mortality (life years gained) and morbidity (adjustment for health-related quality of life). The respective ratios are:
According to these models, which strategy is preferred from the societal perspective is not self-evident. It is a choice as to whether the gain in health effects \( E_t - E_0 \) or \( \text{QALY}_t - \text{QALY}_0 \) is worth the cost difference \( C_t - C_0 \).

Cost-benefit analysis (CBA) differs fundamentally from CEA and CUA in two respects. Firstly, CBA allows the incorporation of 'other value created' not necessarily related to the health state (e.g. reassurance, information) while the inclusion of 'other value created' in CEA or CUA is not self-evident. Secondly, both costs and health effects in CBA are measured in terms of one unit, often money. As alternatives can be ranked in terms of the net benefit (benefit minus costs), it makes no difference whether an additional factor – ‘other value created’ or non-health outcome – would be added to the benefits or subtracted from the costs. Eventually, in this case, the net benefit and thereby societal preference is not altered. However, the addition of an extra term works out differently in CEA and CUA because societal preference is expressed in terms of ratios (see (12)). Adding the valuation of non-health outcome to the denominator or, alternatively, to the numerator yields different ratios which may affect societal decision making. The same problem occurs in CBA when the cost-benefit ratio is used instead of the net benefit. It should be noted that there is no advantage in applying the cost-benefit ratio to the net benefit in case of 'local' decision making. Whereas the inclusion of non-health effects in either the cost-side or the health-effects side is somewhat trivial in CBA, it is a rather complicated issue in CEA and CUA because the numerator and denominator differ fundamentally in terms of content, measurement and methodology.

Here we use the CUA model as the point of departure for being the most widely used framework. If we accept that non-health outcomes exist, the following questions can be asked: firstly, should non-health outcomes be incorporated in CEA or CUA? and, secondly, if yes: should they included in the numerator (costs-side) or denominator (health effects-side)?

Regarding the first question, there are several options to deal with non-health outcomes in CUA. Firstly, non-health outcomes should be fully discarded because this class of effects is primarily unrelated to health (a conceptual argument). This viewpoint partly reflects current practice although a separate account alongside CUA or – if regarded important – a conditional analysis may suffice here. In our view, discarding these effects is not in agreement with the societal perspective which states that all costs and all effects throughout society should be included. Hence biased decision-support may occur.

Secondly, non-health outcomes may be discarded not because they are irrelevant for health decision-making but because they are difficult to measure (an operational argument). E.g., the borderline between health and non-health is unclear, non-health outcomes often are highly subjective effects, or they are difficult to quantify. Each if these arguments may be true. A counterargument is that health (status) and health-
related quality of life are also highly subjective and difficult to quantify. Nevertheless, we have developed a methodology and instruments to measure them. Various studies have shown that they can be measured successfully. Using adapted valuation techniques from health status measurement, the experiments shown in Chapters 9 and 10 will show that they can be measured.

Thirdly, non-health outcomes should not be treated as an independent class of effects alongside health outcomes because they are already incorporated in either the costs or the health effects (a conceptual argument). Relatively large consensus on the definition of costs exists. Obviously, an item or an effect considered a sacrifice may be included as a cost. Whether or not a non-health outcome is reasonably included in health-related quality of life depends on how one views the boundary between health and non-health and the different health concepts (see section 8.3). Defining health as a point in mortality-morbidity space, we believe that the class of non-health effects is definitely not captured by that health concept. Using health-related quality of life as health definition, we are aware that these effects may have been captured by the quality of life adjustment. After all, the health-related quality of life definition is broader than the morbidity-mortality definition and possibly captures more effects than only health. However, we regard it highly unlikely that all societal effects can be reduced eventually to health-related quality of life. If health-related quality of life is supposed to measure the health-related part of overall quality of life then, by definition, ‘non-health-related quality of life’ must also exist.

Finally, non-health outcomes may or should be addressed in CUA insofar these effects have not been included already in the costs or health effects. Several options are available as how this might be achieved. Much depends on the precise interpretation of the cost-utility ratio as measure to evaluate societal preference (see (12)). Whether non-health outcomes belong in the numerator or in the denominator determines the method to value of non-health outcomes. Firstly, if they should belong in the numerator, i.e. alongside the costs, then non-health outcome must be reconciled with costs which are usually expressed in money. This would imply a WTP/WTA-approach to value non-health outcome. Secondly, if they should belong in the denominator, alongside the health effects, then the valuation method depends on the dimension used to express health outcome. For example, if effectiveness is expressed in terms of CUA, the inclusion of non-health effects would imply a trade-off between non-health outcome and life years, between non-health-outcome and health status, or between non-health outcome and QALYs. In case of CEA, the trade-off would depend on the relevant health outcome measure used, e.g. cases detected or mean Prechtl score.

Several interpretations of the cost-utility ratio can be given. Firstly, the ratio represents monetary effects (costs) versus non-monetary effects (health effects). This option holds no fundamental view on whether non-health outcomes should be incorporated in the numerator or denominator. If methods exist to value non-health in monetary and in non-monetary terms, then this valuation-oriented argument cannot decide whether non-health outcomes should be included in the numerator or denominator.
Secondly, the ratio may reflect non-health effects ('costs') versus 'health effects'. According to this view, not only costs (health care resource use or resources sacrificed to improve health) belong in the numerator but also all other effects that are not covered by the health concept. This would imply the incorporation of non-health outcomes in the numerator of the ratio. Disadvantageous non-health outcomes are added to the costs, beneficial non-health effects are subtracted from the costs. Current practice shows that if adjustments for non-health outcomes are made, these are usually incorporated in the costs-side. It is unclear, however, if this choice reflects a fundamental view on the meaning of the cost-utility ratio, or if the valuation method is decisive.

Thirdly, the ratio reflects inputs ('costs') versus outputs ('health effects') as if CUA represents a medical input-output model. Outputs are the result of the delivery of health care, inputs are the resources that must be devoted to achieve these outputs. Non-health outcome is the consequence of the delivery of health care delivery and, according to this view, should therefore be included in the denominator.

Moreover, the ratio may reflect process-related effects ('costs') versus outcome-related effects ('health effects'). Whether non-health outcomes belong in the numerator or denominator depends on the classification of non-health effects. According to this view, process-related non-health outcome belongs in the numerator and primary non-health related outcome belongs in the denominator (see Table 1).

In the abovementioned options, it is assumed that non-health outcomes are included either in the denominator or numerator. If a heterogeneous vector of non-health outcomes exists, some elements may be included in the costs-side and while others may be incorporated alongside the health-effects, depending on the nature of these elements.

Although each of these interpretations may be defended, we feel that options 2 (non-health versus health) and 4 (process versus outcome) come closest to the generally accepted interpretation. There is no strong consensus as to which interpretation may be correct one, assuming that a correct interpretation exists. Two cases from the literature are illuminating. Firstly, Russell et al. define the societal perspective as follows: “[Applying] the societal perspective, the analyst considers everyone affected by the intervenon and counts all significant health outcomes and costs that flow from it, regardless of who experiences the outcomes or costs.” And: “The measure of health needs to be comprehensive and to include longer life, better function, and unwanted side effects. Costs include not only medical and other resources, but also the time of patients and unpaid caregivers.” (page 6).22 From this view, the denominator of the ratio should only capture the primary and secondary health-related outcomes from Table 1, leaving no other place than the numerator (costs-side) as the place to incorporate non-health outcomes. In fact, this represents the second option. Support for this view is given by Garber et al.: “Health is an important component of individual utility, but not the sole consideration.”(page 31). And “[The conflicting role between individual welfare and aggregate health] illustrates a fundamental difference in values between
the implications of defining the output of health care in terms of its contribution to overall well-being and instead, defining it in terms of its contribution to health itself." (page 32). According to the former (overall well-being) view, non-health outcomes may belong in the denominator; according to the latter (strict health) view, there is no other place than include them in the numerator.

A second case concerns the debate on productive costs. Brouwer et al. argued that "... Productivity costs suggest that these are costs expressed in monetary terms and not health effects, expressed in non-monetary terms." This comes close to our options 1 and/or 2. Furthermore, they conclude that "...productivity costs reflect the full costs of lost production from a societal perspective, which cannot be captured in the quality of life measure ..." , i.e. they belong in the numerator for being difficult to measure, ignoring the possibility of a trade-off.

We conclude that the position of non-health outcome in CUA is unlikely to be solved as long as the debate on the interpretation of CUA and the societal perspective continues.

8.6. Conclusion

Although non-health outcomes are difficult to define, it is likely that a class of non-health outcomes exists. Non-health outcomes may be relevant in individual and societal decision making, which supports their inclusion in cost-effectiveness or cost-utility analysis. From a theoretical point of view, the 'projection' of non-health outcomes on health-related outcome (i.e. 'morbidity-mortality'-space) may be preferable though this depends in part on the interpretation of the cost-utility ratio and counterarguments are available. Whether they should belong in the numerator, alongside the costs, or in the denominator, alongside the health effects, remains an issue. In the meanwhile empirical research may provide more evidence as to which valuation technique(s) is (are) appropriate.
References


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TOWARDS A FRAMEWORK FOR EVALUATION ON NON-HEALTH OUTCOMES


