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Review article

Human health benefits and burdens of a pharmaceutical treatment: Discussion of a conceptual integrated approach

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ABSTRACT

The effects of a pharmaceutical treatment have until now been evaluated by the field of Health Economics on the patient health benefits, expressed in Quality-Adjusted Life Years (QALYs) versus the monetary costs. However, there is also a Human Health burden associated with this process, resulting from emissions that originate from the pharmaceutical production processes, Use Phase and End of Life (EoL) disposal of the medicine. This Human Health burden is evaluated by the research field of Life Cycle Assessment (LCA) and expressed in Disability-Adjusted Life Years (DALYs), a metric similar to the QALY.

The need for a new framework presents itself in which both the positive and negative health effects of a pharmaceutical treatment are integrated into a net Human Health effect. To do so, this article reviews the methodologies of both Health Economics and the area of protection Human Health of the LCA methodology and proposes a conceptual framework on which to base an integration of both health effects. Methodological issues such as the inclusion of future costs and benefits, discounting and age weighting are discussed. It is suggested to use the structure of an LCA as a backbone to cover all methodological challenges involved in the integration. The possibility of monetizing both Human Health benefits and burdens is explored. The suggested approach covers the main methodological aspects that should be considered in an integrated assessment of the health effects of a pharmaceutical treatment.

1. Introduction

As our modern society is facing an ever growing need for health care, the challenges encountered in this research field are legion (Khanna, 2012). Due to earlier successes in medicine, the life span of the average citizen has increased significantly, creating new health problems in the form of elderly diseases (Olshansky et al., 2005). Pharmaceutical companies constantly strive to develop new solutions to tackle these arising obstacles, though the success rate of pharmaceutical development rarely exceeds 1% (Pammolli et al., 2011). When confronted with regulatory issues concerning safety, accessibility and pricing, a selection process is put in motion throughout the complete pharmaceutical supply chain (Kola and Landis, 2004). Early on, pharmaceutical companies evaluate medicines in development phases on safety and efficacy to receive initial approval of controlling institutions such as the Food and Drug Administration (FDA) in the United States or the European Medicines Agency (EMA) in Europe. In a later phase, during the course of the debate for patient reimbursement, governments consider the incremental health benefit and budget impact of a medicine compared to the available alternatives (Mauskopf et al., 2007). The health effect of a pharmaceutical treatment on patients is traditionally benchmarked by the research field of Health Economics, weighting the amount of Quality-Adjusted Life Years (QALYs) that can be won through a certain treatment against the monetary costs, resulting in the Incremental Cost-Effectiveness Ratio (ICER) (Gold et al., 1996). Compared to the societal and economic aspects of healthcare, the evaluation of ecological issues is lagging behind. Indeed, the pharmaceutical industry has been criticized over the years for its high waste-to-product ratio, even though its products lead to a higher level of health for the population (Jimenez-Gonzalez et al., 2011). A new approach is needed towards health care which also incorporates environmental effects. The discipline of Life Cycle Assessment (LCA)

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may rise to the challenge, as it provides a holistic framework for assessing the environmental performance of various production systems (Finnveden et al., 2009; Jimenez-Gonzalez and Overcash, 2014). By qualitatively and eventually quantitatively evaluating the resource use and emissions of any system, the damage to three commonly accepted Areas of Protection (AoP): Natural Resources, Natural Environment and Human Health can be calculated (Udo de Haes et al., 1999). For the latter, LCA employs Global Burden of Disease (GBD) figures of the World Health Organisation (WHO) to map the disease-oriented Disability-Adjusted Life Years (DALYs) that are a result of the use and emission of toxic compounds (WHO, 2004, 2013; Huijbregts et al., 2005). Through Multi Criteria Decision Analysis (MCDA) specifically the Area of Protection Human Health employing the disease-oriented concept of DALYs could be weighed against the patient-based approach of QALYs, combining the two public health concepts into a broader sustainability analysis. While the two perspectives of Human Health benefits and burdens have similar goals in terms of quantifying health, to this date they have not been used for a combined assessment of a pharmaceutical treatment. Therefore we perform an analysis of the methodological similarities and differences of both concepts. In this article, available methods for valuing patient outcomes resulting from a pharmaceutical treatment and the associated evaluation of Human Health burdens in LCA are reviewed. Methods with which to integrate both aspects are discussed in order to provide a methodological framework for a conclusive impact assessment of both Human Health benefits and burdens. This framework will enable a holistic assessment of the Human Health effects of a medical treatment Boxes 1–3).

2. Human health benefits: valuing patient outcomes

2.1. Introduction

The scientific field of Health Economics specialises in the assessment of the difference in health effects and costs of two medical interventions. A part of this evaluation is qualitatively and quantitatively expressing the health status of an individual or group. This health state envelops all levels an individual can experience in terms of physical, mental and social health. Looking at health as having multiple dimensions rather than a simple life or death approach enables the comparison of different interventions based on their incremental health effects. The critical part of valuing outcomes is assigning a numerical value to each and every particular health state an individual could experience. This direct patient preference measurement can be conducted by the use of several techniques that determine the perceived Health-Related Quality of Life (HRQoL) of an individual in any given health state. This can be achieved by questioning a large group of either patients or healthy individuals regarding a multitude of health states and having them assign preferences to each one (Gold et al., 1996).

2.2. Health state preferences

2.2.1. Quantification

There are generally two semi-quantitative approaches for assigning a quality weight or so-called preference to different health states. The first is a psychological approach, which envelops ranking and rating scale methods. These are easy to grasp for respondents because of their similarity to everyday choices. However, it shows that people have difficulties assigning numerical values to different health states. Therefore two specific methods are generally used (Gold et al., 1996).

- The paired-comparison, where respondents are required to indicate their preference for one out of two proposed health states. When a statistically sufficient amount of paired comparisons are completed, this enables a ranking of the health states under consideration. However, the weakness of this method lies in the fact that relatively few health states can be rated this way, because of the exponentially large amount of paired comparisons needed when increasing the number of health states under comparison (Fanshel et al., 1970).
- The category rating and Visual Analogue Scale (VAS) are direct methods that map preferences for health states by asking people to directly assign a numerical value to each health state, typically on a scale from 0 (worst imaginable health state or death) to 100 (best imaginable health state or perfect health) (McDowell, 1987).

The second approach to assign preferences to health states is based on the expected-utility theory.

The utility approach gauges the preference for a certain health state based on the difference in utility perceived by the respondent between a suggested health state and perfect health. Utility signifies the quality of a health state measured on a scale of 0–1, where 0 is the worst imaginable health state or death and 1 is the best imaginable health state. In some methods it is possible to assign negative values to health states that are considered worse than death. There are two main methods that are based on this approach.

- The standard gamble asks respondents to choose between an assured continuation of life in a currently proposed non-optimal health state and the possibility of regaining full health, signifying an intervention. However, when choosing for the full health option, there is a chance that the intervention might go wrong, followed by the theoretical death of the respondent. This chance of death can be varied, and for worse proposed health states the respondent will typically allow for a bigger probability of death when there is a possibility to cure the affliction. When the respondent reaches indifference between the two options, the probability of not dying during the intervention represents the utility of the proposed health state (Torrance, 1986).
- The time trade-off method requires the respondent to indicate whether he would prefer living e.g. 10 years in a certain non-optimal health state or a lower amount of years in perfect health. This second amount of years can be varied, and when the patient is indifferent between the two options, the amount of years that the respondent would want to live in perfect health represents the utility of the non-optimal health state (Torrance et al., 1972).

The semi-quantitative methods to assign preferences to health states are cumbersome to use, and require a lot of time to administer to a cohort of subjects large enough to ensure statistical relevance. Therefore, multi-attribute health state classification methods have been developed that offer a more direct utility measurement based on the semi-quantitative techniques. Multi-attribute methods provide a fixed set of health states, therefore obviating the time-intensive process of repetitively defining preferences. These health states are subdivided in attributes based on physical, mental and social health and envelop several dimensions or levels of severity ranging for instance from ‘no problems’ to ‘moderate problems’ and ‘severe problems’. Respondents are asked to evaluate their condition through a questionnaire on a fixed set of attributes. Depending on the amount of attributes and dimensions of the method, this leads to a fixed amount of possible outcomes of the questionnaire. All these possible outcomes have been assigned a utility value based on the health preference methods previously described. An overview of the most commonly used multi-attribute health state classification methods is given in Table 1 (Drummond et al., 2005) (Box 1).

The multi-attribute health status methods enable a fast scre-