Expert Review of Pharmacoeconomics and Outcomes Research

TITLE:

"Estimating Health Effects in Quality-of-Life Terms: An Application to Health Losses Due to Road Crashes".

AUTHOR name and affiliations:

Patricia Cubí-Mollá (University of Alicante)

Correspondence:

Patricia Cubí-Mollá
Departamento de Fundamentos del Análisis Económico
Universidad de Alicante
Ctra. San Vicente del Raspeig, s/n
03080 ALICANTE (Spain)
Tlf: +34965903400 Ext. 3026
patriciac@merlin.fae.ua.es

SUMMARY:

Nowadays, measures of disability and health-related quality of life are becoming important, even essential, parameters in the evaluation of treatment and prevention strategies for reducing the burden of injury. The estimation of the health effect induced by these policies should contemplate several important aspects: the proper definition of "health effect", at individual and aggregate levels; the correct selection of a health metric; the accurate estimation of the short-term effect (direct health gain/loss) and long-term effect (total of health gain/loss along the life path of the individual) that injuries may produce; and the suitable selection and management of databases. This

review article focuses on the particular topic of road crashes, but the analysis can be extended to any sort of injury.

KEYWORDS: Health-Related Quality of Life; Health Measures; Injuries; Road Crashes; Health Effect.

BODY:

Introduction

In 2001, injuries represented 12% of the global burden of disease [1]. The category of injuries worldwide is dominated by those incurred in road crashes. In 2004, over 50% of deaths caused by road crashes were associated to young adults in the age range of 15-44 years, and traffic injuries meant the second-leading cause of death worldwide among both children aged 5-14 years, and young people aged 15-29 years [2]. In addition, road crashes are expected to be the main origin of the projected 40% increase in global deaths resulting from injury between 2002 and 2030 [3].

Evaluation of policy or clinical interventions is an essential aspect of injury prevention, aimed to reduce the burden of injury. Evaluations are usually performed through the estimation of cost-effectiveness ratios,[1] which are obtained by taking the cost of the treatment and dividing it by the “health gains” the treatment produces [5].

[1] A discussion about different methodologies for evaluating health interventions (cost-utility analysis, cost-benefit, etc.) can be found in [4]

The cost of the treatment is calculated in monetary terms. Some standards must be adopted, in order to make different studies comparable. The Panel on Cost-Effectiveness in Health and Medicine convened some guiding principles referred to the assignment of costs, by adopting a societal perspective (e.g. to include costs to the health care sector, costs to the individual and broader societal costs) [6].

The concept of “health gain” has experienced a significant development during the past few decades. Most of the analyses about policy interventions in the case of road injuries interpret “health gain” as: reduction of the number of crashes, reduction of the number of fatalities, reduction of the number of people seriously and/or slightly injured. They are contemplated by means of absolute figures (e.g. [7]), or in terms of relative risks (e.g. [8]). Elvik [9] presents a good review of the evaluation of policy interventions.

Selecting one or another of the aforementioned ways of interpreting health gains is highly linked to the difficulties in properly estimating several dimensions related to the evolution of the individuals affected. Let us mention their pre-injury status, their health status after the crash, their evolution, and the final or chronic health status observed in the affected individuals.

In dealing with the pre-injury status, in our case we do not deal normally with institutionalized individuals, that is, we are not in a case where policy interventions are defined over targeted subpopulations with a well-known health state (as it happens, for instance with cancer treatments, effectiveness of dialysis programs, etc.). In those cases it is plausible to obtain proper information about the pre-injury status of the patients. In the context of injuries, nonetheless, it is especially difficult to analyse the effectiveness of prevention control (burning, road crashes, falls, poisoning, etc.), since the pre-injury status of the individual is usually unknown.

As a consequence, to properly analyse the effectiveness of prevention control in road crashes, we have to deal with five fundamental problems. First, we may choose an adequate metric to evaluate health status. Second, we have to select a way of properly estimate pre-injury health status, direct health effect of an injury, and post-injury chronic loss of health of any plausible individual affected by a crash. Third, we should decide if it is plausible to aggregate individual results in some number expressing the effects on the population, considering two dimensions: adding health losses of individuals with the same order of seriousness (fatal/non-fatal) [10], or even the rationality of expressing the total loss of health for non-fatal and fatal injured individuals into a single figure [11]. Forth, we must choose carefully the source of information, testing for the completeness and reliability of the data. Fifth, the lack of a gold-standard methodology requires the application of some criteria that could assess the validity of the results.

In dealing with the first goal, a metric to evaluate population general health status is needed [12]. The World Health Organization (WHO) in 1946, defines health as follows: "*Health is not only the absence of infirmity and disease, but also a state of physical, mental and social well-being*" [13]. Previous broad definition captures essential elements of quality of life, which underlies most human health metrics [14]. Based on this definition, it is also clear that life expectancy or mortality-based measures are no longer being considered adequate as measures of a population's health.

Once a metric is established, analyzing health effects requires exploring some aspects in detail. First, how can we estimate the pre-injury health status? Can we presume it, or should we establish a comparison group? Second, how can we capture the chronic health loss of the people injured? How long after the traffic crash should we take for considering the damage as having a chronic effect? Closely related to that point, it is also crucial establishing how to measure the total health effect throughout the life path of individuals. In other words, how to combine direct health effects with life expectancy. Shall we assume that the people affected would keep a constant health loss along the rest of their life path? Finally, we shall consider whether the accident may also have effects on the expected number of years of life of the individuals injured in the crash, namely, if their life expectancy diminishes or not.

The lack of information about previous question induces researchers to commonly use some specific simplifying assumptions. For instance, it is quite common to consider pre-injury status as one of "perfect health", and the immediate post injury status as a chronic one, when estimating the health effects of injuries [10], [14]. The life expectancy of the affected people is usually obtained from external information, and is taken as a fixed amount for men and women, without controlling for other crucial factors as can be age or region [14]. Moreover, when computing effects or road crashes on injured individuals, it is usually assumed that the accident does not change their life expectancy [15]. All these simplifying assumptions, nonetheless, have as a consequence a rough approximation to the actual magnitude of the injury effect on health.

The possibility of improving previous rough approach is linked to the availability of more extensive and reliable databases. Even though they are certainly improving, we are far from achieving a complete set of data that comprises all valuable information for an accurate analysis.

This paper explores some ways of answering previous questions, improving the extra-simplified analysis: first, the best appropriate metrics to quantify a health status; second, how to estimate the direct health effect of an injury; third, how to estimate the effect on the full life-path of a particular individual; four, how to estimate the burden of some particular type of injuries on the population health; and finally, how to obtain the finest estimation of health losses, always with the restrain of the availability and quality of data.

Box 1: Definitions and abbreviations of explained terms.
• Health-related quality of life (QoL): physical, mental and social well-being • Post-injury health state: health state of the individual that has been seriously injured by a road crash • Pre-injury status: health state of the injured individual, previous to the road crash • Potential health state: health state that the injured individual would attain he did not suffered the road crash. • Direct health effect: difference between the potential and post-injury health states. • Life path: health evolution of a person from birth to death

Table 1: Problems at evaluating health effects, and proposed solutions	
Unknown potential health state	• Estimation of pre-injury status • Use of comparison groups
Combining direct health status with life expectancy	• Assume that the post injury health state is a chronic health state • Assume that life expectancy does not change because of the injury
Aggregating health effects among dissimilar groups of individuals	• Introduce age-weighting factors • Interpret health values as indexes
Incomplete databases	• Use of different sources of data as complementary.
Lack of a gold-standard methodology	• Then-tests (control for a response shift) • Follow some criteria of validity

Appropriate metrics

A wide variety of metrics are used to quantify the burden of illnesses and injuries to population (an exhaustive description of these measures can be found in [12], [16], [17], among others). In general terms, let us classify the different sorts of measures into two groups, depending on the way they approach the problem: (i) estimate the amount of good health, versus (ii) assess the degree of functional limitation. It is important to underline that such these groups embrace (a) health status measures (which do not indicate preferences for health states), and (b) preference-based measures (defined by means of preference-based methods as Time Trade-Off or Standard Gamble). The literature suggests that non-preference-based measures should not be applied in the context of decision analysis or economic evaluations (e.g. cost-utility analyses) [12]

Measures in the first group (i) focus on the impact of the injury over the general health state of the individual, comprising a variety of indexes or metrics that define "health". Health status measures (a) as Visual Analogue Scale (VAS), Self-Assessed Health (SAH), Euroqol five-dimensional descriptive system (EQ-5D) or Short-Form Health Survey (SF-36); and preference-based measures (b) such as Health Utility Index (HUI-3, the current version), quality of well-being (QWB), or Euroquol five-dimensional index (EQ-5D index), can be placed within such approach. These metrics reflect the quality of health states both from a physical and a psychological aspect. The preference-based measures can combine the effect of death and nonfatal consequences into a summary measure that typically ranges from 0 (representing death) to 1 (representing optimal health) and where any number reflects the relative preference for particular health states. Instead of self-reported scores, these metrics provide community values for the health states. Previous characteristic can, on the one hand, complicate interpersonal comparisons among subjects (and therefore the consistency of aggregation procedures), and, on the other hand, securing data from some targeted groups of population as can be children, elderly or unconscious.

Metrics in the second group (ii) try to estimate the seriousness of the injuries. The preference-based measures (a) attempt to reflect the degree of functional limitation of the people injured (e.g. Functional Capacity Index (FCI), Disability weights). The non-preference measures (b) quantify the seriousness of the injuries by attending to the mortality risk or life threat (e.g. Abbreviated Injury Scale (AIS), Injury Severity Score (ISS), ICD-9 Injury Severity Score (ICISS), Anatomic Profile Score (APS), etc.). These sorts of metrics are considered as external to the patients, and are constructed from the clinicians and researchers point of view; are easy to obtain, and examine in detail the characteristics of the concrete injury. Nonetheless, not all metrics in this group have been clearly validated [18], and moreover they present some other disadvantages, as can be not allowing for heterogeneity, problems with co-morbidities, and not taking into account the psychological dimension.

Of the scales that have been reviewed, those that belong to the second group are the most commonly used to asses health losses due to injuries. However, several studies suggest that an individuals' injury and acute psychological responses are strongly linked and so both play important roles in determining quality of life and disability outcomes (e.g. [19]). Although measures of severity in the second group provide some understanding of the relative seriousness of injuries in terms of threat to life, they still fall short in measuring resource utilization and the long-term impact of nonfatal injuries on the person, his or her family, and society at large. These considerations have challenged the field to move beyond counting injuries by severity alone to measuring their direct impact on health-related quality of life.

Yet, the use of health state outcomes as a method for describing the consequences of traffic injuries from diverse perspectives (effects for health at individual level, at aggregate level, for public health, or at decision-making process), must be performed carefully. The wide set of alternatives that have been already mentioned (selection of health measures, ways of combining quality of life to length, etc.) demand an assessment of the validity of the results. Elvik (1995) [10] summarizes the different criteria of validity that could be set at measuring the consequences of traffic injuries, that are: statistical validity (errors and variations of mean values); internal validity (logical descriptions of health states, specially at self-assessment); theoretical validity (coverage of all dimensions of health, and their contribution to the general health state, as well as coherency with the medical theory); external validity (agreement of results between different indexes or studies); and practical relevance (the extent to which the results can be applied to decision-making).

Evaluating the direct health effect

Once the health metric has been selected, it is time to estimate the direct health effect of a road crash. Now image that an individual has a traffic accident, and we can evaluate his/her *post-injury health status*. Let us imagine the health state of this individual under the unreal scenario in which the accident did not happen (*potential health status*). The actual loss of health would equal the difference between the values associated to the *post-injury* and *potential health states*.

The *post-injury health status* is assumed to be well-known by the analyst. If the chosen metric corresponds to the second group (seriousness of the injuries), it is relatively easy to obtain trauma care information, from hospital databases as can be Hospital Discharge Registers. If the aim consists on measuring the QoL, health-related surveys are the most common choice. Both sources may be complementary, that is, some specific surveys can embrace questions from which measures as AIS, ISS, etc. can be deduced; and, on the other hand, in hospitals, residences and trauma centres it is more and more usual to distribute a questionnaire to patients about their QoL. Notice that the selection of the source influences on the temporal scenario that is taken for evaluating the health effect. The survivor is expected to recover gradually, but maybe not achieving his/her previous health state. Thus, in some cases data from hospitals may report health states in a point in time previous to where the affected individual has restored his/her health at a maximum. By using those data as a proxy of the final chronic health state of the individual, the health impact of the injury can be biased.

Now, what we called *potential health status* is unidentified, since it is a priori impossible to know what would the state of health of the individual have been does the accident not occurred. The problem is how to approximate the unknown *potential* health status.

Many authors consider the health state prior to the accident (*pre-injury status*) as a proxy of the *potential* health state. Nonetheless, even under such an assumption, it happens that the evaluation of a pre-injury health status could be quite complicated, due to the availability of data. Because of that, the majority of earliest studies in this area used to consider the pre-injury health state as being of "perfect health" [10], [14]. However, under that assumption what was obtained meant a rough approximation to the actual magnitude of the loss due to the injury.

A different and more recent strategy for approximating the *potential* health state of the people injured consists on obtaining information from other people, rather than the injured individual per se. In other words: imagine that we can find information (dated prior to the accident) about the health state of an individual or a group of individuals who did not suffered a road traffic crash; assume that the individual (or group of) is highly comparable to the injured one, since they coincide in several factors (maybe age, gender, studies...). Therefore, the health state of that individual or *comparison group* can be taken as a proxy of the *potential* health state of the victim.

The approaches commented above (*pre-injury status* and *comparison group*) are highly connected, and can be easily combined. In fact, the use of *comparison groups* to approximate the *pre-injury status* is the most common choice nowadays [16]. This methodology is mainly based on the use of population norms that provide some benchmark against which to compare pre-injury outcomes. This methodology is improving, and norms are computed for groups of population with different characteristics among them, becoming finest partitions of the total population. Nowadays, it is recommended to use at least changed health baselines for men/women and different age-groups.

We must remark that the selection of a *comparison group* should be performed carefully. As we mention in the introduction, real data show that traffic crashes are not random, but they are more likely to happen to people with particular features (for instance men aged 15-29). Therefore the health state of the *comparison group* and the *post-injury health state* of the victim cannot be unconditionally contrasted. In the case where extra information about the people injured is available (e.g. socio-economic variables), the comparison group can be defined quite accurately by using some statistical techniques, usually embraced in the literature of “treatment effects” [20]. The more appropriate the comparison groups are defined, the more accurate the estimation is.

Combining values for health with life extension

Once we have chosen the way of measuring the quality of a concrete health state, and the health effect valuations have been determined, we must deal with the question of how to estimate the total health effect through the life path of the individual. In order to do so, it is commonly considered a generic age-health profile for any affected individual, representing the valuation of his/her life path from birth to death [21]. The decreasing shape of the curve is based on the rationality of deterioration of health with aging. By considering a continuous metric for QoL that ranges from zero (death) to one (perfect health), the area under the curve from t to t' stands for the total valuation of the health state over that portion of her lifetime $[t,t']$ [see Fig 1].

Assume that the individual suffers a major injury in time T. When computing the health effects of that injury, most cost-effectiveness studies implicitly make the following assumptions:

A1 The post injury health state is a chronic health state

A2 Life expectancy does not change because of the injury

The use of previous assumptions implies a rough approximation to the actual magnitude of the injury.

Figures 1 and 2 illustrate the cases of a non-fatal and a fatal road crash, respectively. The largest irregular curve defined from birth to death represents the *potential* health status of an individual, from birth to life expectancy. An injury occurs at time T, which deteriorates the health of the individual. In the scenario of a non-fatal injury, the valuation of the post-injury status (w_1) remains decreasing from T to death. If the accident causes death, the post injury status goes down to zero. The value w_0 stands for the estimated *potential* health status. In both figures we assume that *potential* health valuation is known, and thus, the value w_1- w_0 represents the direct health effect, presumably unbiased.

Figure 1: Possible bias in the evaluation of non-fatal injuries

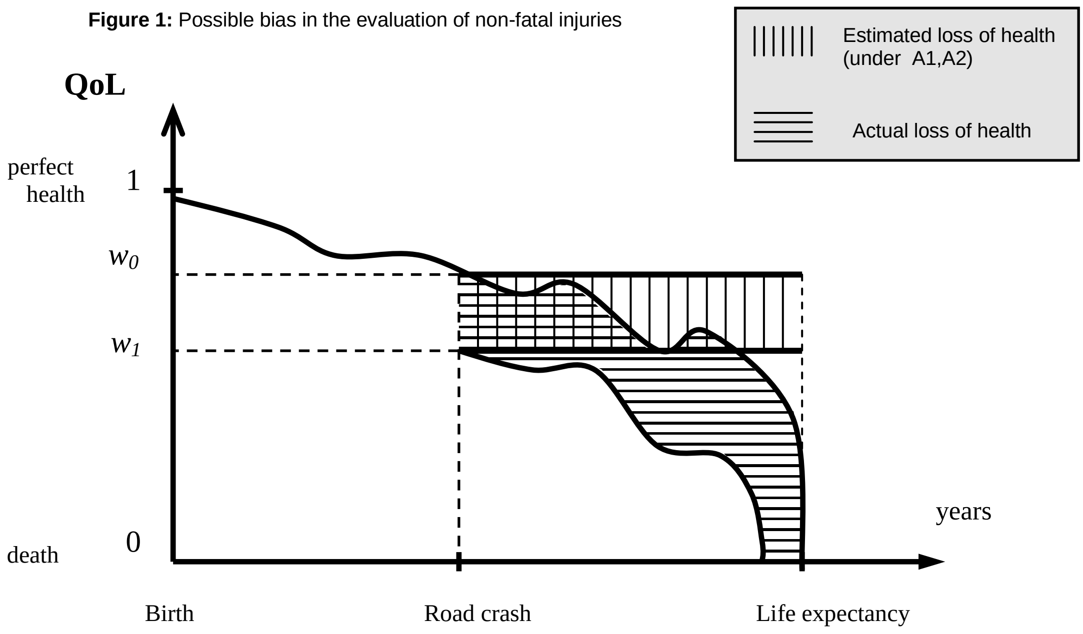
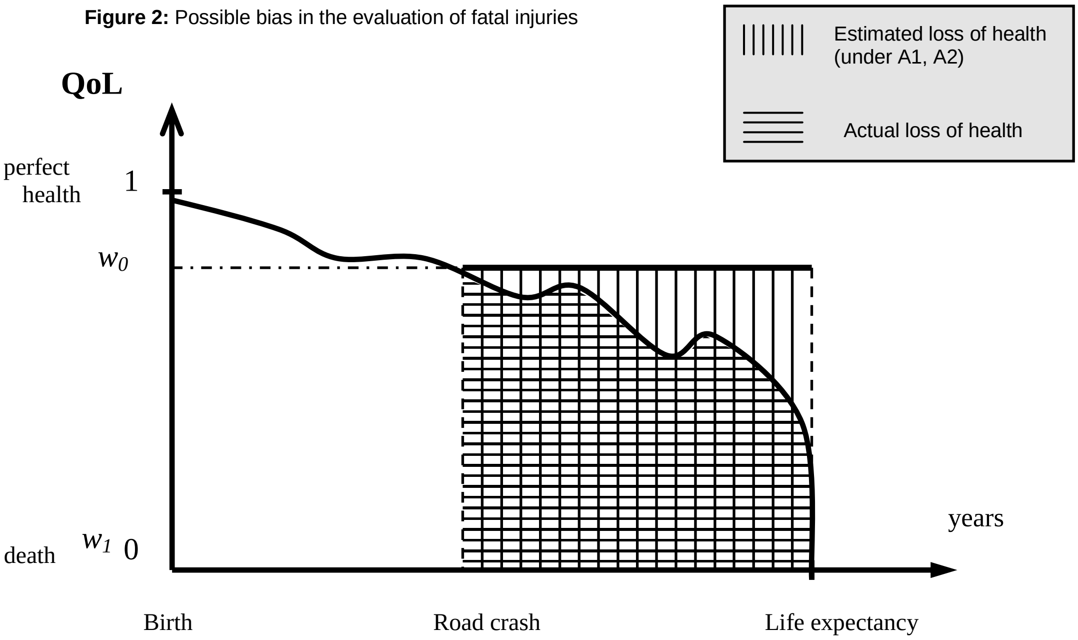


Figure 2: Possible bias in the evaluation of fatal injuries



The area between the curves that represent the *potential* health state and the *post-injury* health state (the horizontal axis, in case of fatal crashes), would represent the true health losses due to the collision, from the moment the accident happens up to the individual's death (if non-fatal crashes), and from the moment the accident happens up to his/her life expectancy, in case of a fatal crash. Under assumptions (A1)-(A2), the estimated health status turns into a constant function- the potential health profile equals w_0, and the post injury status equals w_1, from T to *life expectancy*-. The area of the rectangle defined by these constant functions is an estimation of the health loss.

The difference between both areas does not clearly indicate whether the health effect is biased or not. Indeed, the effect of the injury may imply a "change of level" in health (that is, the handicap induces a constant decrease by age at the same rate it would have decreased had the accident not occurred). Thus, the conventional methodology would be likewise compelling, by adjusting for the proper direct health effect. However, in the case of fatal injuries, where the estimated injury status is taken as the null function (Figure 2), Assumptions A1 and A2 lead to overestimating the actual health loss.

Aggregating health effects among individuals

Quality-adjusted health measures can be interpreted into two different ways: as utilities and as health indices. The utilitarian interpretation identifies the aggregation problem as a major one: all traditional welfare aggregation problems stand here in a prominent way. Under the extra-welfarist interpretation, however, the metrics are interpreted as health indices rather than health utilities, solving the aggregation problem. Even taking into account that aggregation procedures are linked to the selected instrument, there is still a lack of consensus about the form of combining results from different groups of population.

For instance there is a debate on the use of the age-weighting function originally proposed in the Global Burden of Disease study [22], still most widely applied in DALY calculations. Also, the so-called “fair innings” argument claims that everybody should enjoy the healthiest life possible, but until a certain age (70-75 years) [23]. Other general discrepancies can be found when talking about aggregating the effects of mortality and morbidity into a single figure [10]. Also, it is worth mentioning the “worst-off first” criteria and the notion of double jeopardy (the idea that disable people are disadvantaged twice in aggregate data). An exhaustive discussion of these distributional and ethical considerations can be found at [11]

Data

Besides the previously mentioned theoretical difficulties, another major issue deals with the availability of data.

Mortality and morbidity data are usually collected form diverse sources of information: police databases, hospital discharge registers, forensic reports, health surveys, insurance companies, and so on. These databases should be taken as complementary, not only because any of them just provide with partial data, but also because of the differences in the data collection methodology, giving rise to differences in results (see, for instance, [24]).

If we focus on the evaluation of QoL lost due to non-fatal crashes, securing proper data is still a big deal. The days immediately after the road crash are considered critical for the injured. The survivor is expected to recover gradually, but maybe not achieving his/her previous health state. The ideal is to estimate the chronic sequelae that a traffic crash can produce in the affected, and to evaluate the impact of these sequelae in their daily living. In the most advantageous scenario, the post-injury health status can be obtained directly from the people injured. However, some authors defend that adaptation to a moderately disabling chronic illness is associated with a response shift, [25]. Therefore it is recommendable the use of then-tests to collect this information [26].

Besides the difficulties of obtaining state-independent health measures, there is still the problem of estimating the *potential* health state from external comparison groups. These comparative health values are mostly obtained from Health Surveys. However, health information is usually available at an ordinal level [27], with questions as: “In your opinion, how is your health in general?", where respondents must choose one category, normally: "very good", "good", "fair", etc. Therefore, such questions do not provide the cardinal health scale needed for estimating the generic life path.

Since categorical measures of health are one of the most commonly used indicators in socioeconomic surveys, a wide variety of methods has been developed with the aim of dealing with the proper cardinal counterparts of ordinal health measures (e.g. [27], [28]).

Related to the estimation of health losses, databases are becoming more complete. CARE (European Road Accident Database), IRTAD (International Road Traffic and Accident Database) or CCIS (Co-operative Crash Injury Study) are examples of the improvement in the data collection, and they include a wide set of variables related to road crashes that some decades ago were ignored. However, there is still hard work to do before achieving a complete set of data that comprises any valuable information (details of the accident, joint with description of the health state of the injured individual, etc.). Meanwhile, the short-term objective consists in obtaining the finest estimation of health losses but with the restrain of the availability of data

EXPERT COMMENTARY

Nowadays, measures of disability and health-related quality of life are becoming important, even essential, parameters in the evaluation of treatment and prevention strategies for reducing the burden of injury. Hence the evaluation of the costs and benefits of such novel instruments is essential. In order to pursue this task, and for allowing a comparison among analysis of different measures, we should express the total toll of deaths, injuries and *sequelae* derived from traffic accidents in a simple metric, that could estimate the total loss of health that could be avoided.

Several measures have been developed in this direction. For a start, monitoring health-related quality of life can be enhanced by establishing equivalences between cardinal and categorical health variables, since the former are the preferred measures for cost-effectiveness analysis, but the latter is more frequently enclosed in surveys. Also, overcoming typical assumptions, as could be considering health states as chronic or pre-injury health status as perfect health, can be considered as a great step forward. For instance, given the lack of pre-injury measures, the use of appropriately defined comparison groups should be crucial for the study of trauma outcomes.

FIVE-YEAR VIEW

Political and non-governmental institutions are showing an increasing interest in the prevention of road-traffic injuries and deaths. Moreover, we can assist nowadays to the beginning of a systematic and accurate collection of data related to road crashes and health states. All these factors will allow for an improvement in the estimation of health effects, what will lead us to a better knowledge of the significance of the problem.

In a near future is also possible –and desirable- that health and road policies will base their decisions on cost-effectiveness analysis. Finally, and maybe one of the most crucial pieces, it is possible that we will witness to great changes in general population attitude, since we are gradually becoming aware of the actual risk concerned to road crashes.

KEY ISSUES

- Road crashes are nowadays a major public health problem.
- Estimation of health losses due to road crashes is crucial for evaluating policy prevention strategies.
- Health-related quality of life metrics are becoming essential measures for evaluating the actual impact of a road crash on the people affected.
- The direct health effect of a road crash is unobservable: some assumptions are needed.
- The estimation of the pre-injury health state of the individual as well as the definition of comparison groups is decisive for the evaluation of the direct health effect.
- A suitable way of evaluating the total loss of health in the life path of the people injured is needed.
- Standards of aggregating health losses among dissimilar groups of population must be adhered to.
- A complete set of data that comprises any valuable information related to road crashes is needed.

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