

## **Valuing Health and Longevity in Regulatory Analysis: Current Issues and Challenges**

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# Valuing Health and Longevity in Regulatory Analysis: Current Issues and Challenges

**Lisa A. Robinson and James K. Hammitt**

**ABSTRACT:** Economic valuation of health risks plays an important role in informing decisions about environmental, health and safety regulations, indicating the extent to which those affected by a policy or program would agree to exchange income for the benefits it provides. For mortality risks, this willingness to pay is typically expressed as the “Value per Statistical Life” or VSL. The VSL is not the value of a particular individual’s life. Instead, it measures the rate at which individuals are willing to substitute income for small reductions in their own mortality risks within a defined time period. Currently, US agencies rely on similar research but apply varying VSL estimates, raising concerns related to both the standardization and the differentiation of their values. More standardization seems desirable if agencies continue to follow similar approaches. However, the differences in the risks and populations addressed across agencies suggests that greater differentiation in their VSL estimates is desirable, given that preferences for exchanging income for risk reductions vary depending on these characteristics. The approaches used to value nonfatal illnesses and injuries are more diverse, largely because willingness to pay estimates are lacking for many outcomes of concern. Analysts often use estimates of monetized quality-adjusted life years or averted costs as rough proxies. While more willingness to pay research is needed for nonfatal risks, in the interim the methods used to develop these proxy measures could be improved based on recent research and expert panel recommendations.

## **Valuing Health and Longevity in Regulatory Analysis: Current Issues and Challenges**

Economic valuation of health risks plays a major role in informing decisions about environmental, health and safety regulations, especially as governments around the world increasingly require assessment of regulatory impacts. Regulatory analysis in some form has been mandated in the United States for over 30 years (OMB 1997), and is gradually being implemented in the OECD member countries (OECD 2009). For regulations designed to reduce the risk of illness, injury or premature mortality, counting the number of cases averted is an important initial step in understanding the impacts of alternative policies. Such counts do not convey the relative severity of each outcome, however, nor can they be meaningfully aggregated across different types of effects. Taking the next step of valuing health outcomes in monetary terms provides additional useful insights.

Valuation is particularly informative when it addresses trade-offs that are similar to those involved in regulatory decisions. Such decisions require choosing whether to devote resources to achieving health risk reductions, or to allow individuals, firms, or government agencies to use these resources to provide other desirable goods and services. When based on the affected individuals' willingness to pay (WTP) for risk reductions, monetary valuation indicates their preferences for trading income (or wealth) for health improvements. These values can be used to determine whether the benefits of alternative regulatory actions are likely to be commensurate with their costs, and also to identify which action, if any, is most likely to maximize the net benefits to society. In combination with other considerations – such as whether the impacts are distributed equitably, and the implications of nonquantifiable effects and other uncertainties – these findings help support sound decisions.

Individual WTP for risk reductions is likely to differ from the medical costs or productivity losses associated with incurred cases of illness, injury or premature

death. The cost of treating a health condition is not the same as the value of reducing its risk of occurrence. For example, treatment does not necessarily return the individual to his or her original health state. WTP often exceeds medical costs and productivity losses by a significant amount because it reflects the value of averting pain and suffering and other quality of life impacts.

Because health risk reductions are not directly bought and sold in the marketplace, economists generally use data on related marketed goods or observed behavior (“revealed preferences”) or data from survey research (“stated preferences”) to estimate their value. For example, risk is one of many attributes of different housing locations, job choices, and motor vehicle options. Economists often study related decisions, using statistical methods to separate the value of risk differences from the value of other attributes. Alternatively, they may develop a survey that describes the risk of concern and asks respondents to indicate their WTP for reducing it.

Approaches for valuing health risks in regulatory analysis are well established and widely used. Typically, premature mortality and nonfatal illnesses or injuries are valued separately, because only a few empirical studies integrate consideration of both types of effects. Thus this article first summarizes the valuation of mortality risks, then discusses nonfatal risks. It focuses primarily on US practices, describing the approaches used as well as key challenges.

## ***Valuing mortality risks***

As introduced above, health risk reductions are generally valued by estimating individuals’ willingness to exchange income for the risk change, based on revealed or stated preference studies. For mortality, this WTP is typically expressed as the “Value per Statistical Life” or VSL.<sup>1</sup>

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<sup>1</sup> Both WTP and willingness to accept (WTA) compensation are consistent with the framework for benefit-cost analysis. However, WTA is used less

## ***The VSL concept***

Most regulations lead to relatively small changes in health risks at the individual level, often expressed as “statistical cases” for ease of presentation. A statistical case, or statistical life, involves aggregating small risk changes across several individuals. For example, a 1 in 10,000 risk reduction affecting 10,000 individuals can be expressed as a statistical case (1/10,000 risk reduction x 10,000 individuals = 1 statistical case), as can a 1 in 100,000 risk reduction affecting 100,000 individuals (1/100,000 risk reduction x 100,000 individuals = 1 statistical case). For most regulations, the specific individuals who would avoid illness or injury, or whose lives would be extended by the policy, cannot be identified in advance. A regulation that is expected to “save” a statistical life is one that is predicted to result in one less death in the affected population during a particular time period. “Saving” a statistical life is not the same as saving an identifiable individual from certain death.

The value of these small risk changes, expressed as the VSL, can be calculated by dividing individual WTP for a small risk change by the risk change (see Hammitt 2000). For example, if an individual is willing to pay \$600 for a 1 in 10,000 reduction in his or her risk of dying in the current year, the VSL is \$6 million ( $\$600 \div 1/10,000 = \$6 \text{ million}$ ). Alternatively, individual WTP for small risk reductions can be aggregated across a population. A \$6 million VSL also results if each member of a population of 10,000 is willing to pay an average of \$600 for a 1 in 10,000 annual risk reduction ( $\$600 \times 10,000 = \$6 \text{ million}$ ).

Analysts often estimate the value of mortality risk reductions based on revealed preferences, most frequently using wage-risk studies (also referred to as compensating wage differential or hedonic wage studies).<sup>2</sup> In these studies,

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often in practice due to difficulties in its measurement. Thus this article refers to WTP throughout for simplicity.

<sup>2</sup> Viscusi and Aldy (2003) discuss this approach as well as other revealed preference methods in detail, and summarize related studies.

researchers compare earnings across workers in different occupations or industries who face varying levels of on-the-job risks, using statistical methods to control for the effects of worker qualifications (such as education and experience) and other factors (such as nonfatal job risks) on this relationship. The objective is to estimate the additional compensation a worker requires to accept a more dangerous job, among the set of jobs for which he is qualified.

In recent years, researchers have completed an increasing number of stated preference studies that estimate these values. Such studies include contingent valuation surveys, which ask respondents to indicate their WTP for risk reductions associated with specific scenarios, and conjoint analyses (or choice experiments), which disaggregate the attributes of the scenarios, asking respondents to make several choices among alternatives to explore their trade-offs. Many of these studies focus on traffic safety or other types of accidents; some consider illnesses associated with air pollution or other contaminants. While revealed preference studies are often viewed as more credible because they are based on actual behavior, they address scenarios that differ from those of concern in many regulatory analyses. Stated preference studies are hypothetical but have the advantage of allowing researchers to tailor the scenario to the risks of concern.

## ***Current practices***

Because the scenarios studied in empirical research often differ in significant respects from the risks associated with many regulations, analysts usually apply estimates derived from one scenario (such as job-related accidents) to a somewhat different scenario (such as air pollution, food safety, or homeland security regulations). This “benefit transfer” approach requires carefully considering the quality of the available research (the data and methods used) as well as the suitability of the estimates (the extent to which they consider populations and risks similar to those addressed by the regulation). While in some cases analysts may be able to quantitatively adjust the primary research results to better fit the regulatory scenario, they often must explore the implications of the resulting uncertainties qualitatively due to the limitations of the research available.

The use of a benefit transfer approach for valuing mortality risks in regulatory analysis is well-established. Analysts generally follow a two step process. First, they develop a best estimate (or range of estimates) of the base VSL from the available research literature. Second, they determine whether to adjust this base estimate quantitatively to reflect differences between the scenarios studied and the regulatory scenario.

Table 1 summarizes the base VSL estimates used by major US regulatory agencies. The US Office of Management and Budget's (USOMB's) guidance for regulatory analysis (USOMB 2003) notes that the available research suggests that the VSL is generally between roughly \$1 million and \$10 million (no dollar year reported). While it allows agencies some discretion in determining which VSL estimate best fits their regulations, most use central values somewhat above the middle of this range when expressed in 2007 dollars. Of these agencies, the US Environmental Protection Agency (USEPA) historically has been responsible for the majority of the regulations that include quantified mortality risk reductions, and has devoted considerable attention to the valuation of these risks (Robinson 2007). The US Department of Transportation (USDOT), the US Food and Drug Administration (USFDA), and the US Department of Homeland Security (USDHS) have also promulgated a number of such regulations in recent years. Other agencies generally rely on approaches similar to those followed by these agencies.

**Table 1: Base VSL estimates used in US regulatory analyses**

Agency	Reported VSL Estimates	
	(range, dollar year) <sup>a</sup>	Basis
Office of Management and Budget 2003 guidance	<b>\$1 million-\$10 million</b> (no dollar year reported)	Available research, allows agency flexibility
Environmental Protection Agency	<b>\$7.5 million</b>	Viscusi (1992, 1993) literature review

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2000 guidance <sup>b</sup>	(\$0.9 million-\$21.1 million, 2007 dollars)	
Department of Transportation 2008 guidance	<p><b>\$5.8 million</b></p> <p>(sensitivity analysis: \$3.2 million, \$8.4 million; probabilistic analysis: standard deviation of \$2.6 million, 2007 dollars)</p>	<p>Mrozek and Taylor (2002), Miller (2000), Kochi et al. (2006), Viscusi and Aldy (2003) meta-analyses;</p> <p>Viscusi (2004) wage-risk study</p>
Food and Drug Administration 2007 analyses <sup>c</sup>	<p><b>\$5 million, \$6.5 million</b></p> <p>(varies, no dollar year reported)</p>	<p>Viscusi and Aldy (2003) meta-analysis</p>
Department of Homeland Security 2008 analyses <sup>d</sup>	<p><b>\$6.3 million</b></p> <p>(\$4.9 million-\$7.9 million, 2007 dollars)</p>	<p>Viscusi (2004) wage-risk study</p>
Other agencies	<p>Economically significant rules addressing mortality risks infrequent, approaches generally similar to the above</p>	

Notes: Estimates presented in 2007 dollars because some agencies have not yet updated their estimates for subsequent years.

a. The USDOT and USDHS base estimates include the effects of income growth over time as well as inflation as of the year 2007. The USEPA adjusts for income growth separately in each analysis depending on its target year; the value in the table reflects the effects of inflation only.

b. The USEPA estimates are reported in 1997 dollars and inflated to 2007 dollars by the authors using the US Consumer Price Index ([http://www.bls.gov/data/inflation\\_calculator.htm](http://www.bls.gov/data/inflation_calculator.htm)). The USEPA is now updating its guidance.

c. As reported in USFDA 2007.

d. Based on Robinson (2008) as reported in US Coast Guard (2008a, 2008b). Previous USDHS analyses use VSL estimates of \$3 million and/or \$6 million.

These base estimates are derived from selected literature reviews and meta-analyses, which are dominated by wage-risk studies conducted largely in the US and other high income countries.<sup>3</sup> The differences across agencies reflect the particular estimates they choose from these studies, rather than tailoring of the values to the particular populations or risks each addresses. The agencies do, however, adjust their base estimates quantitatively for some differences between the underlying studies and the scenarios addressed by their rules. These adjustments reflect changes in real income over time, any significant delays between changes in exposure and changes in mortality incidence (latency or cessation lag), and some external costs (e.g., insured medical costs) not likely to be included in estimates of individual WTP. The agencies differ in how they implement these adjustments, as described in detail in Robinson (2008) and in the references cited in Table 1.<sup>4</sup>

Other countries vary in their practices. For example, the European Commission's 2009 *Impact Assessment Guidelines* discuss a number of different approaches to valuation, and suggest that countries use the methodology that is appropriate to the circumstances. The *Guidelines* indicate, however, that the VSL has been estimated at 1- 2 million Euros in the past (no year indicated), and suggest that this range be used "if no more context specific estimates are available" (European Commission 2009, Annexes, p. 43).

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<sup>3</sup> The USEPA (2000a) values are based on 26 estimates, 21 of which are from wage-risk studies. The Viscusi and Aldy (2003) and Mrozek and Taylor (2002) meta-analyses only include wage-risk studies. While Miller's (2000) meta-analysis includes stated preference studies in some model specifications, his "best" estimates are based only on wage-risk studies. The Kochi et al. (2006) estimate used by the USDOT is based on 42 wage-risk studies and 18 stated preference studies.

<sup>4</sup> Robinson (2008) has been updated and published in abbreviated form as Robinson et al. (2010).

## ***Major issues and challenges***

The VSL has been a controversial issue for many years, due largely to the confusion between placing a monetary value on a particular individual's "life" and reporting the average value that we each place on small reductions in our own mortality risks. The latter is exhibited almost daily as we trade-off small risks for convenience (e.g., by driving too fast) or spend money on safety products (e.g., bike helmets) rather than other goods and services. This controversy is reflected in the senior discount debate (discussed below) as well as in several texts that oppose valuation (e.g., Ackerman and Heinzerling 2004) and in recent debates about decreases in values that reflect the results of new research (see Viscusi 2009, Robinson 2009). Cameron (2009) suggests that, to address these problems with semantics, the VSL should instead be referenced as the "willingness to swap alternative goods and services for a microrisk reduction" (p. 2) in a particular type of risk.

In addition to these sorts of communication issues, the summary of current practices above raises concerns related to both the standardization and differentiation of the VSL estimates used in regulatory analysis. First, the commonalities in practices across US agencies raise the question of whether more standardization is desirable, as long as these agencies are relying on similar approaches. Second, the differences in the risks and populations addressed by these agencies suggests that greater differentiation in the VSL estimates may be desirable, given that preferences for exchanging income for risk reductions may vary depending on these characteristics. At least in the near term, the first issue may be somewhat easier to resolve than the second, because increased tailoring of the estimates is inhibited both by concerns about equity and by limitations of the available research.

### ***Standardization***

As discussed above, US agencies are currently relying on the same general body of literature for their base VSL estimates – primarily wage-risk studies conducted in the US and other high income countries. However, the estimates vary across agencies because they were developed at different times, based on the individual studies,

literature reviews, and meta-analyses then available. Agencies have also made different decisions about which estimates to select from these studies and about how to apply the estimates in their regulatory assessments.

This application of different base estimates despite the commonalities in the approaches suggests that more harmonization may be beneficial, both in reducing the confusion that can result from the application of different values and in increasing the quality and efficiency of the process for developing these values. For example, Viscusi (2009) suggests that a panel of scientific experts should periodically meet to review the evidence and update the VSL estimates used in regulatory analysis. This type of process could be used to determine whether agencies should continue to rely on a common set of studies for their base estimates, and, if so, to develop a standard base estimate to be applied across all agencies. To the extent that the agencies are each adjusting these base estimates for some of the same factors (e.g., income growth, cessation lag or latency, and external costs), standardization may also be desirable for these adjustments.

The USEPA already follows an approach for developing its VSL estimates that involves extensive use of independent experts: funding new primary research, periodically evaluating the available evidence, and submitting recommendations to its Science Advisory Board for review (e.g., Stavins et al. 1999, Stavins et al. 2000, Cropper et al. 2007). Extending this approach to address the estimates used across agencies would result in more comparable analytic results, allowing decisionmakers and others to more clearly distinguish differences in impacts without the potential confusion caused by the application of different VSLs. It would also reduce duplication of effort across agencies, while providing the additional insights that stem from consultation among experts from different policy areas. The main challenge to implementing this approach is overcoming the institutional and other barriers to cross-agency collaboration, which may be difficult given the longstanding tradition of independently developing VSL estimates.

### *Differentiation*

The use of standardized estimates across agencies is a second-best option that results from deficiencies in the research base and other concerns. While increased harmonization may be desirable as long as the agencies continue to rely on similar approaches to estimate the VSL, standardization means that the economic analyses will fall short of the goal of reflecting the preferences of those affected by the regulations. Empirical research suggests that the VSL is likely to vary depending on the characteristics of those affected and of the risks themselves, yet agencies currently tailor their estimates to reflect very few of these differences.

At least in theory, this tailoring could be achieved by moving away from relying primarily on wage-risk studies for base estimates, and instead relying on studies that explicitly address the populations and risks that each agency regulates. Recent reviews, including those cited in Table 1, suggest that the research base may be insufficient to support such an approach at this time. An alternative would be to implement additional adjustments to the base estimates to better reflect the differences in the populations or risks addressed, based on research currently available.

The challenges to implementing such adjustments vary somewhat depending on whether the goal is to reflect differences in the individuals affected or differences in the nature of the risks. US agencies generally do not adjust their VSL estimates for differences across population subgroups, despite evidence that individuals' WTP for their own risk reductions varies depending on characteristics such as age and income. This reluctance to make adjustments in part stems from the significant controversy that erupted over the so-called "senior discount:" the USEPA's use of lower estimates for older individuals in sensitivity analysis conducted for air pollution rules prior to 2004 (see Robinson 2007). While there is some evidence that the VSL declines at older ages, recent work suggests that this relationship is uncertain (Hammitt 2007, Aldy and Viscusi 2007, Krupnick 2007). As a result, two US expert panels advised against making VSL age adjustments (Cropper et al. 2007, National Academy of Sciences 2008), indicating that more research is needed. US government agencies now use the same VSL for all affected individuals, regardless of age.

In the case of income, the research evidence is more consistent, but adjustment of the VSL to reflect income differences is inhibited by equity concerns. Several studies suggest that, in the US, a one percent change in income is likely to lead to about a 0.4 to 0.6 percent change in the VSL (e.g., USEPA 1999, Viscusi and Aldy 2003).<sup>5</sup> While several US agencies use these elasticity estimates to adjust the VSL for changes in real income over time, none of the agencies make adjustments for cross-sectional income differences. Instead, the VSL is based on the average income of the individuals included in the underlying valuation studies, regardless of the income levels of those affected by the regulations.

In the US, the use of estimates based on averages is often viewed as providing more equitable treatment, or equal protection, for different groups in policy decisions. However, whether this approach is in fact equitable depends on how one views the incorporation of individual preferences in these analyses. Some regulations disproportionately affect individuals who differ significantly from the average in terms of age, income, or other characteristics.<sup>6</sup> If these individuals have preferences for spending on their own risk reductions that differ from the population average, an analysis based on the average VSL will not reflect their preferences. In addition, these population averages are anchored in the distribution of health, income and other characteristics that existed at the time of the underlying studies, and this distribution will change over time.

Interestingly, adjustments for population characteristics appear less controversial in other countries. For example, while the current Canadian guidance for impact assessment does not discuss age adjustments (Treasury Board 2007), Canadian agencies have included these adjustments in some regulatory analyses (e.g., Chestnut et al. 1999) without the sort of public outcry that resulted in the US.

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<sup>5</sup> As discussed in Robinson and Hammitt (2009), these elasticity estimates appear low when transferring VSL estimates across countries in different stages of development. In this context, elasticity estimates greater than 1.0 appear reasonable.

<sup>6</sup> For example, the USEPA's air pollution regulations primarily reduce mortality among individuals over age 65 (e.g., USEPA 2006).

Adjustments for risk characteristics appear less controversial than adjustments for population characteristics because they avoid these sorts of equity concerns. However, these adjustments are hampered by limitations in the research literature. Agencies generally adjust only for delays between exposure and incidence, by discounting the VSL over the lag period.<sup>7</sup> Some recent studies suggest that illness-related deaths are likely to be valued differently than the injury-related deaths included in the wage-risk studies (e.g., Van Houtven et al. 2008, Cameron and DeShazo 2009) while others (e.g., Hammitt and Haninger 2010) find no difference. Some research also suggests that risks that are viewed as less controllable, voluntary and familiar may be valued up to twice as high as other risks (Robinson et al. 2010). However, more research is needed to determine the appropriate adjustment factors.

## **Valuing nonfatal risks**

The approaches used to value nonfatal illnesses and injuries in regulatory analysis are more diverse than those used to value mortality. This occurs largely because estimates of WTP are lacking for many of the nonfatal risks associated with environmental, health and safety regulations. Analysts often use other measures as rough proxies, including monetized estimates of quality-adjusted life years or estimates of averted costs, as discussed below.

### ***Conceptual approach***

As introduced earlier, WTP is the maximum amount of income (or wealth) that an individual would willingly exchange for a beneficial outcome, and is the most appropriate measure for use in benefit-cost analysis. However, regulatory agencies

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<sup>7</sup> Recent studies support the use of discounted values for delayed impacts (e.g., Viscusi and Aldy 2003, Hammitt and Liu 2004, Alberini et al. 2006, Van Houtven et al. 2008), although the estimates of the amount (or rate) of the discount vary.

often rely on alternative approaches when WTP estimates are not available. One such approach involves monetizing estimates of Quality-Adjusted Life Years (QALYs).<sup>8</sup> These measures integrate the effects of health states on the quality of life over time and longevity. They were originally developed as nonmonetary measures for use in cost-effectiveness analysis and in comparing health status across populations.

Estimating QALYs is generally a two-step process.<sup>9</sup> First, the impact of a condition on health-related quality of life (HRQL) is represented on a scale anchored at “0” and “1,” where “0” represents a state viewed as equivalent to dead and “1” represents a state equal to perfect or full health. Better health states are scored closer to “full health;” i.e., closer to a value of 1.0. Second, this estimate is multiplied by the duration of the condition to determine the associated QALYs. For example, a health state that has an HRQL score of 0.9 and lasts for two years is equivalent to 1.8 QALYs (0.9 HRQL x 2.0 years = 1.8 QALYs).

To use these estimates in benefit-cost analysis, they must be assigned a monetary value. Regulatory agencies often estimate the value per statistical life year (VSLY) by dividing an estimate of VSL by the estimated number of (discounted) life years remaining for the average individual studied. They then use this average as the value of a QALY.

This approach only roughly approximates the value of risk reductions for two reasons. First, the studies cited earlier on the relationship between the VSL and age suggest that the VSLY is not a constant; the two expert panels that recently reviewed this issue recommended against the use of a constant VSLY (Cropper et al. 2007, National Academy of Sciences 2008). Second, QALY estimates reflect different types of trade-offs than WTP estimates (see Hammitt 2002). QALYs are based on the trade-

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<sup>8</sup> US regulatory agencies commonly rely on QALYs; disability-adjusted life years (DALYs) are used in some international studies. Detailed information on the construction and use of DALYs is available on the World Health Organization website: <http://www.who.int/>.

<sup>9</sup> For more information on the use of these measures in regulatory analysis, see Institute of Medicine (2006).

off between different health states and their duration, independent of income or wealth. In contrast, WTP estimates are based on the trade-off between spending on health risk reductions or on other goods and services. Thus WTP estimates are more consistent with the types of trade-offs involved in regulatory decisions.

A second alternative is to rely on avoided costs as a proxy for WTP, either alone or in combination with monetized QALYs. At minimum, these costs typically include expenditures on medical treatment (i.e., direct costs). In some cases, the value of lost productivity (i.e., indirect costs) is also assessed, based on the effects of injury or illness on paid and often unpaid work time.<sup>10</sup> Other expenditures, such as those related to insurance administration and litigation, may be included as well. These estimates are for incurred cases rather than for *ex ante* risk reductions, addressing an outcome that differs from the effects of potential regulations. Moreover, the costs of treating an illness or injury are not necessarily related to an individual's WTP to avoid the illness or injury: being injured and treated is typically worse than not being injured. In theory, the cost of appropriate treatment may be less than, equal to, or greater than WTP to avoid the illness or injury. Some comparisons suggest that WTP may often exceed the cost of illness by a factor of three to six (USEPA 2000b, Appendix B).

Because estimates of avoided costs exclude the value of avoiding pain and suffering and other quality of life impacts, analysts at times add estimates of monetized QALYs to capture these additional effects. Combining these estimates does not, however, address the other limitations of each approach. In contrast, it may be appropriate to add avoided costs when relying on WTP estimates, if the avoided costs would be paid by third parties (such as insurance companies) and hence not incorporated into individual WTP.

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<sup>10</sup> The approach used to estimate these indirect costs is often referred to as the "human capital" method.

## ***Current practices***

When valuing nonfatal risks in regulatory analyses, the USOMB recommends that agencies apply estimates of individual WTP, supplemented by estimates of any net changes in economic costs to society (i.e., avoided costs) that are not captured in the WTP values (USOMB 2003). When WTP estimates are not available, the USOMB notes that agencies may apply monetized estimates based on health utility studies (such as QALYs). However, a committee of independent experts (Institute of Medicine 2006) subsequently recommended against this latter approach.

Generally, the USEPA applies WTP estimates to the extent possible and relies on averted cost estimates (including medical costs and lost productivity) only when necessary (e.g., USEPA 2009). In contrast, the USFDA and USDOT routinely use monetized QALYs in their analyses. The USFDA first estimates the QALY gains associated with each regulatory option, then monetizes them using a constant value per QALY, testing the effects of a range of estimates to reflect associated uncertainties (e.g., USFDA 2007). The USDOT follows a somewhat different approach.<sup>11</sup> It first categorizes injuries by severity, then calculates both the economic costs and monetized QALY losses associated with injuries in each category (e.g., Blincoe et al. 2002). While the USFDA approach is not standardized across analyses, the USDOT applies the same values in all its analyses once they are established for each transportation mode (e.g., trucks, automobiles).

## ***Major issues and challenges***

While reductions in the risks of premature mortality tend to dominate the benefit estimates for many regulatory analyses, regulations also often lead to significant changes in the risks of nonfatal illnesses and injuries. The lack of WTP estimates for

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<sup>11</sup> US National Highway Traffic Safety Administration (NHTSA) 2007 provides an example of this approach; however, the nonfatal injury values had not yet been updated for the USDOT's revised VSL estimates (see Table 1), and the agency is currently revising its approach for estimating QALYs.

many such risks means that the analytic results may not accurately reflect the affected individuals' preferences for reducing these risks. Thus more research on these values is clearly needed.

However, new primary research studies often take several years to complete. In the interim, the methods used to estimate avoided costs and monetized QALYs could be improved based on recent work. In particular, detailed cross-agency guidance on developing avoided cost estimates could encourage greater consistency as well as more accurate estimation. Recent improvements in costing methods for medical care could help inform the development of this guidance (Yabroff et al. 2009). In addition, the approaches used to estimate QALYs could be improved through implementation of the recommendations of a recent expert panel (Institute of Medicine 2006). Finally, it may be possible to use emerging research, such as Hammitt and Haninger (2009), to develop valuation functions for QALYs that move away from reliance on a constant VSLY.

## ***Summary and conclusions***

As introduced above, WTP is the maximum amount of income (or wealth) that an individual is willing to exchange for a beneficial outcome, reflecting trade-offs similar to those involved in regulatory decisions. Given constrained resources, regulators must decide whether it is preferable to increase expenditures on risk-reducing policies, or to allow the funds to be used for other desired goods and services.

For mortality risks, valuation estimates based on individual WTP are well established. Related controversies stem largely from the confusion caused by referencing the "value of life," indicating the need for clearer communication of the underlying concepts. Other key challenges include promoting greater consistency across agencies when they rely on similar research and analytic approaches, and determining whether and how these estimates should be better tailored to the populations and risks that each agency regulates. For nonfatal risks, the key challenge is the need to develop WTP estimates for a greater variety of injuries and illnesses. In the interim, the methods used to develop averted cost and monetized QALY estimates

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as rough proxies could be improved based on recent research results and expert panel recommendations. Improving the methods for monetary valuation will enhance the information available to analysts and decisionmakers when comparing the costs and benefits of alternative policies.

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