Valuing Morbidity
White Paper

Date Published: July 28, 2020

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ABSTRACT

The assessment of health risks to the public plays a fundamental role in the evaluation of many U.S. Nuclear Regulatory Commission (NRC) regulations. The NRC's cost-benefit analyses often rely on the monetization of averted health detriment risks of radiation exposure to quantify the benefits associated with proposed safety improvements. Health economists currently have no clear consensus on the best method for estimating the value of nonfatal health risks and morbidity impacts. The staff conducted a literature review of other Federal agency guidance, recent regulatory analyses, and academic viewpoints on this issue to support the development of NRC guidance on the monetary valuation of nonfatal cancers and cancer morbidity risks. The literature review focused on Federal and international agencies whose primary purpose is to regulate public health and safety, with attention paid to recent regulations that value nonfatal cancers or cancer morbidity. This literature review found significant variation across agency practice in the approach to valuing nonfatal health risks.

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ABBREVIATIONS AND ACRONYMS

AAAM	Association for the Advancement of Automotive Medicine
AIS	Abbreviated Injury Scale
ARBRP	Arsenic Rule Benefits Review Panel
CDC	Centers for Disease Control and Prevention
CFOI	Census of Fatal Occupational Injuries
DfT	United Kingdom Department for Transport
DHS	U.S. Department of Homeland Security
DOC	U.S. Department of Commerce
DOI	U.S. Department of the Interior
DOT	U.S. Department of Transportation
EPA	U.S. Environmental Protection Agency
ERS	Economic Research Service
FDA	U.S. Food and Drug Administration
FHA	Federal Highway Administration
HHS	U.S. Department of Health and Human Services
HSE	United Kingdom Health and Safety Executive
HRQL	health-related quality of life
HUD	U.S. Department of Housing and Urban Development
IOM	Institute of Medicine
MAIS	maximum abbreviated injury scale
NRC	U.S. Nuclear Regulatory Commission
OECD	Organisation for Economic Cooperation and Development
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
q	a measure of the level of environmental quality or health risk
QALY	quality-adjusted life year
SAB	Science Advisory Board
USDA	U.S. Department of Agriculture
VSL	value of a statistical life
WHO	World Health Organization

INTRODUCTION

One of the primary goals of U.S. Nuclear Regulatory Commission (NRC) regulations is to provide reasonable assurance of adequate protection of public health and safety. Reductions in human health risks are often the dominant component of measured benefits in cost-benefit analyses of NRC regulations. However, these benefits are among the most challenging to monetize because the value of increased safety cannot be estimated directly from market pricing and requires nonmarket valuation[1] techniques. Historically, research on the economics of the health benefits of regulations has focused on society's willingness to incur the costs of small reductions in mortality risks (i.e., the value of a statistical life (VSL)) (HSE, 2007). The valuation of morbidity and nonfatal health risks has received less attention due in part to the complexity of identifying a single method for valuing a myriad of illnesses, each characterized by its own unique symptoms, temporal profiles, and outcomes. While health economists have identified the valuation of morbidity risks as an area in need of further research (Hoffman and Anekwe, 2013), at present there is no consensus on how this should be done.

The NRC staff undertook this literature review to support the development of updates to NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," and NUREG-1530, "Reassessment of NRC's Dollar per Person-Rem Conversion Factor Policy." The agency received public comments on the draft NUREG-1530, Revision 1, issued August 2015, which identified that the NRC needs to update the method it uses to value nonfatal health risks (NRC, 2017). As explained in SECY-17-0017, "Proposed Revision to NUREG-1530, - Reassessment of NRC's Dollar per Person-Rem Conversion Factor Policy," issued January 30, 2017, the dollar per person-rem conversion factor no longer includes the valuation of morbidity effects. As a result, the NRC set out to review the current state of practice for valuing morbidity and nonfatal health risks. The objective of this white paper is to document the NRC's review and serve as the basis for selecting an approach to the valuation of nonfatal cancer risks. This approach and the resulting valuation estimates will be detailed in an appendix to the revised NUREG/BR-0058. While the monetary valuation of morbidity risks is comprised of two components, (1) risk quantification and (2) monetary valuation of an avoided statistical case of illness, the focus of this paper is solely on the monetary valuation component. The quantification of risks (i.e., the selection of a cancer risk coefficient) will also be addressed in the appendix to NUREG/BR-0058.

Accordingly, the scope of this paper is threefold:

(1) Survey the various methods of morbidity valuation that may be applied in cost-benefit analysis.

(2) Review the approaches to monetary valuation of nonfatal health risks used by other U.S. Federal agencies and international governing bodies.

(3) Summarize the advantages and limitations associated with the various approaches and practices.

The literature review begins with an examination of the basic concepts and economic foundations that underlie current approaches to the valuation of health risks. This is followed by

[1] Nonmarket valuation refers to those approaches used to estimate the public's valuation of resources not generally expressed in the marketplace (Champ et al., 2003). This is commonly done for regulations that involve public goods such as environmental resources (e.g., clean air and water, biodiversity).

an overview of the most common methods used to monetize injury and illness risks, their advantages and limitations, and a sampling of recent academic viewpoints on the application of these approaches in the context of cost-benefit analysis.

The following section explores the current state of practice in the Federal Government. The section begins with an overview of Governmentwide guidance issued by the Office of Management and Budget (OMB) and then describes current agency-specific guidance and gives recent examples of regulatory analyses that value nonfatal health risks. It also discusses the practices of international organizations.

BACKGROUND

Cost-benefit analysis is the principal analytical framework used to evaluate public expenditure decisions. U.S. Federal agencies have used cost-benefit analysis widely since Executive Order 12291, "Federal Regulation," dated February 17, 1981, required cost-benefit analysis on all Federal Government projects costing $100 million or more. Federal agencies now routinely measure a wide range of welfare impacts on a monetary scale—not merely financial effects or the loss of marketed goods, but also the risk of death, physical injuries, or disease, and environmental damage.

THEORETICAL FOUNDATIONS

In the context of government policy analysis, cost-benefit analysis is founded on a branch of economics known as "welfare economics" (Olsen et al., 1999). Welfare economics uses microeconomic techniques to evaluate well-being at the societal level, where social welfare or well-being is the aggregation of individuals' personal welfare or well-being (IOM, 2006). The fundamental value judgment of standard welfare economics is that social ranking of alternative policies should be based on individuals' preferences (Champ et al., 2003). According to welfare theory, individuals are their own best judge of their welfare, and personal well-being is increased with the satisfaction of individual preferences; therefore, when one individual's preferences are satisfied, social welfare increases (Olsen et al., 1999).

Although the amount of welfare that a person expects to derive from their preferences cannot be measured directly, it can be roughly inferred based upon the theory that a rational consumer will not spend money on an additional unit of a good or service unless its marginal utility[2] is at least equal to or greater than that of a unit of another good or service. If we assume that individuals are rational, fully informed, and seek to maximize utility, then the choices they make are, by definition, those that maximize expected utility, and, therefore, the price of a good or service is related to its marginal utility. Standard welfare economics rests on this concept, which assumes that expected utility can be inferred from the preferences that individuals reveal in their market choices (Dolan and Kahneman, 2007). For this reason, maximum willingness to pay represents the theoretically correct measure of "strength of preference" for, or value of, a commodity (Baker et al., 2014).

[2] The word "utility" has two distinct meanings—it can refer either to the hedonic experience of an outcome or to the preference or desire for that outcome. These have been labelled "experienced utility" and "decision utility," respectively. Economists abandoned experienced utility early in the twentieth century in favor of a new interpretation, in which utility represents "wantability." A person's decision utilities are revealed by their choices. It is this second interpretation that lies at the heart of the methods that economists have developed to value nonmarket goods, such as health (Dolan and Kahneman, 2007).

An important distinguishing feature of willingness to pay estimates in the context of valuing health risks is whether the estimates were obtained from an ex-ante or an ex-post perspective. For willingness to pay estimates to be a measure of expected utility, the values must be based on an ex-ante perspective. That is, when valuing health risk reductions, estimates should be based on the willingness of healthy individuals to pay to reduce the risk of incurring some illness in the future (Freeman, 2003). In contrast, ex-post values would represent the willingness of individuals already suffering from an illness to pay to be restored to a healthy state. As cost-benefit analyses of NRC regulations are ex-ante analyses, the elicitation method should be consistent with this perspective.

METHODS OF HEALTH BENEFITS VALUATION

According to Freeman (2003), health risks can reduce well-being through four channels: (1) medical expenses incurred to treat an illness, (2) lost wages from an inability to work, (3) defensive or averting expenditures to mitigate the risks, and (4) disutility or pain and suffering associated with symptoms of the disease and side effects of treatment. A comprehensive willingness to pay estimate would capture all these elements. However, in practice, the various methods used to estimate willingness to pay vary in the extent to which they capture these components.

The most common approaches used to approximate willingness to pay for avoided health risks can be classified broadly into three categories: (1) methods that elicit individual willingness to pay based on either revealed preference or stated preference studies, (2) methods that measure the direct financial and human capital costs of being ill, and (3) proxy methods. Figure 1 shows this classification.

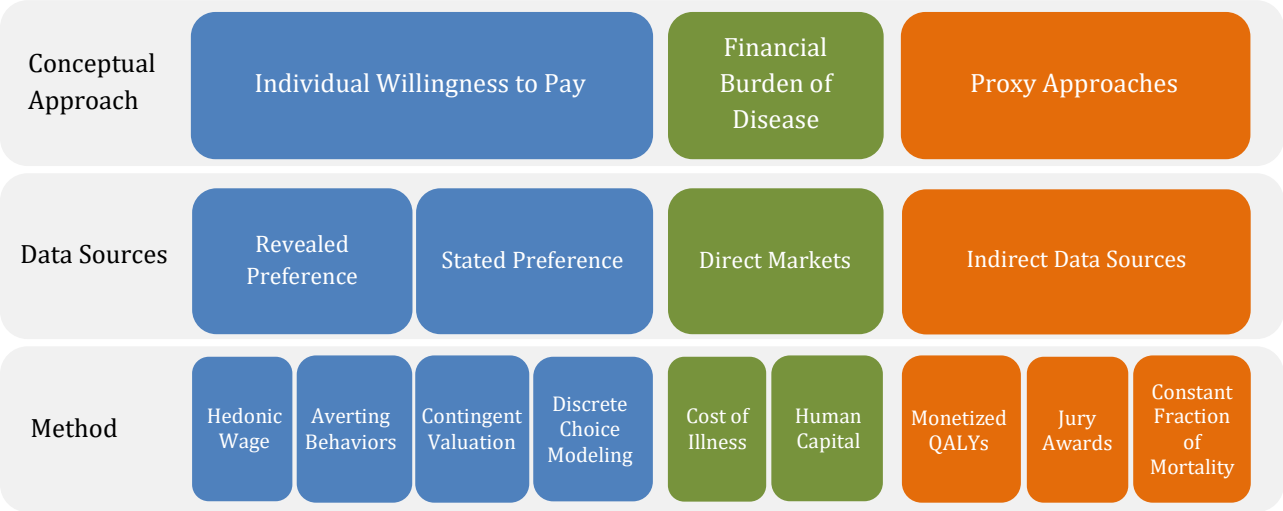

Figure 1. Classification of Alternate Approaches to Morbidity Valuation

The principal distinction among these methods is based on the source of the data (Mitchell and Carson, 1989). Economists have developed procedures to estimate decision utilities using revealed preference techniques and stated preference studies where direct markets do not exist, as in the valuation of public goods or of states of personal health. In practice, high-quality revealed preference and stated preference studies for valuing many nonfatal illnesses are scarce, and policy analysts have turned to costs of illness or human capital approaches and

proxy measures such as monetized health-related quality of life measures. The following sections discuss these approaches in more detail.

Revealed Preference

Revealed preference studies analyze individuals' choices in related, or surrogate, markets to impute the value of nonmarket goods. A key element in the theoretical framework of revealed preference techniques is the individual utility-maximizing behavior model that relates an individual's choices to changes in the level of environmental quality or health risks. If a behavioral relationship between observable choices and health risk, *q*, can be specified and estimated, this relationship can be used to calculate the marginal rate of substitution between *q* and some observed choice variable with a known monetary value, thereby revealing the marginal value of changes in *q* (Freeman, 2003). The advantage of these methods is that the data come from observations of people acting in real-world settings where people must live with the consequences of their choices. However, since a reduction in health risk is not purchased directly, its value must be separated from the other characteristics of the choice variable, which requires large data sets and the use of advanced statistical techniques. The two most common revealed preference methods used in health valuation are hedonic wage studies and the averting behavior method.

Hedonic Wage

The hedonic wage approach estimates the marginal willingness to pay for reduced safety risks using labor market data to deduce the value that workers place on different levels of occupational hazards. Also known as "compensating wage differentials," this method has been used extensively to value mortality risk reductions and is often the preferred method to deduce the VSL. Assuming an individual is free to select a job, it is expected that the worker will weigh the wage versus the utility provided by the job. One important component of that utility is the safety of the job. This requires a reliable source of data on injury risks. Many characteristics may affect the wage, and many confounding factors[3] such as prestige and work-life balance may affect financial compensation for a hazardous occupation, making it a challenge to isolate the wage-risk tradeoffs. The regression methods used to estimate the implicit value wage-risk premium must be carefully controlled for these factors.

The benefit of this method is that it is based on real market data and observable choices that individuals make. One criticism of this approach is that it assumes that workers are fully aware of the types of risks and their magnitude associated with the job when that may not always be the case. Another concern is whether the values derived from labor market studies, which are based on the working-age population of healthy adults, can be extended to other populations at risk such as children and the elderly (Champ et al., 2003). Age, gender, education level, and wealth are all expected to influence the value of willingness to pay for risk reduction. Therefore, the willingness to pay values derived from hedonic wage studies may not accurately reflect attitudes toward risk across all demographics. The primary challenge of applying this approach to valuing nonfatal illnesses is that accurately determining these risk levels for various occupations is often more difficult than for fatal risks. While the Census of Fatal Occupational Injuries by the U.S. Bureau of Labor Statistics provides a comprehensive and rigorously verified accounting of fatal occupational injuries that is often used to estimate the VSL (Viscusi, 2013),

[3] In statistics, a confounding factor is a third variable that influences both the dependent variable and the independent variable being studied to distort the association between the two. Not being aware of or accounting for the confounding factor can result in a false correlation.

no comparable database exists for nonfatal injuries and illnesses. Consequently, the use of this method is far less prevalent in computing nonfatal risks than the stated preference methods that better isolate nonfatal health risks.

Averting Behavior

The averting behavior (or defensive behavior) method deduces willingness to pay from the behaviors of individuals and the expenditures made to mitigate or avoid health and safety risks. This method assumes that a rational person will take defensive behaviors as long as the value of the damage avoided exceeds the cost of the defensive action (Champ et al., 2003). Instead of using labor market data, the averting behavior method typically relies on consumer market prices. For example, someone living in an area with poor air quality might purchase an indoor air purifier to reduce the risk of developing symptoms induced by poor air quality. An analyst would then establish a relationship between the price of the averting good and the perceived risk reduction of that good. From this information, the marginal willingness to pay for a change in health risk can be calculated. This method of risk valuation has been used extensively in studies of actions to avoid environmental risks such as contaminated water supply studies, hazardous waste contamination, and radon in homes (EPA, 2000a).

The major obstacle to using the averting behavior method is joint production. Joint production occurs when a defensive behavior or expenditure impacts individual welfare through more than just a single outcome such as the length or risk of illness. Under an assumption that the averting behavior has no other impact on utility besides reducing the health impact, the averting behavior method can provide a useful lower bound on willingness to pay (Abrahams et al., 2000). However, this assumption is rarely satisfied, and expenditures on the averting good cannot be viewed as a lower bound on willingness to pay because part of the expenditure is measuring willingness to pay for something other than health risk reduction. For example, substituting bottled water for tap water affects not only exposure to contaminants but also the taste and odor of the drinking water. Other defensive expenditures, such as smoke detectors and bicycle helmets, reduce both the risk of death and the risk of injury. While there are many approaches to controlling for joint production in the estimation of willingness to pay, a common practice is to acknowledge and dismiss it (Champ et al., 2003), assuming these factors are independent.[4]

Stated Preference

Stated preference methods involve surveying people on the value they place on a good or service in a hypothetical, or simulated, market. When valuing health risks, this approach involves presenting study participants with hypothetical risk decisions and eliciting the values that they would be willing to pay to achieve some risk reduction. This method has been used extensively for estimating the values of public goods, such as environmental air and water quality, and is used most often by Federal and state agencies with environmental responsibilities (Carson, 2000). The advantage of this approach is that the analyst can construct surveys to analyze the specific risk of concern and can include those health risks that cannot be tied easily to consumer or labor market transactions. In addition, the surveys can provide participants with detailed information about the health risks they are valuing and include questions to gauge their understanding of this information.

[4] Studies of water contamination typically do not account for taste differences between bottled water and tap water (Champ et al., 2003).

Contingent Valuation

The most widely used stated preference method is contingent valuation, where the estimates obtained are contingent on the information provided to the respondent in the survey (Hoyos and Mariel, 2010). The contingent valuation method consists of constructing questionnaires with well-defined health states, detailing proposed changes, and using this information to directly elicit the respondents' willingness to pay for the hypothetical changes. These surveys typically describe the health risk to be reduced and a proposed method for paying for the reduced risk, such as increased taxes or a one-time payment. They often include socioeconomic and attitudinal questions. Common elicitation formats used to evoke the monetary valuations include "open-ended," "referendum," and bidding game approaches. The open-ended format asks the respondent for the highest amount of money they would be willing to pay for a health risk reduction. In theory, this would directly elicit an individual's maximum willingness to pay. However, in practice this format frequently tends to draw zero values (also known as a protest[5]) and nonresponses, indicating that participants may have difficulty with this format (Wattage, 2011). With the referendum, or closed-ended format, discrete choice questions ask participants whether they would be willing to pay a specified amount for a change in risk. Many practitioners prefer this format as it simplifies the decisions that participants must make and mimics the types of choices people would have to make in a market situation (i.e., whether to purchase or not to purchase a good or service). The bidding game format is similar to the single closed-ended format except that, based on the participant's response to the willingness to pay, the value will be adjusted iteratively until the participant either changes from a negative to a positive response or from a positive to a negative response. Research has shown that this method is susceptible to "starting point bias," where final bids are influenced by the magnitude of starting bids (Boyle et al., 1985).

Due to the hypothetical nature of these surveys, there is some question as to the accuracy of these values (Champ et al., 2003). Participants may have less incentive to carefully consider their choices because they do not have to pay the amounts stated in these surveys. In addition, the contingent valuation method is susceptible to bias. Participants may intentionally try to influence the outcome of the survey with their responses due to their general attitudes toward issues such as environmental protection. One source of bias comes from individuals' desire to express their feelings about the act of giving toward a social good to gain some sense of moral satisfaction. This effect, known as the "warm-glow" effect,[6] might result in a participant expressing a positive willingness to pay value for a social good, independent of the characteristics of the social good or whether the participant values it (Carson, 2000). However, Chestnut et al. (1996) found that estimates of willingness to pay to avoid angina resulting from contingent valuation questions were of the same general magnitude as estimates calculated from patient reports of actual expenditures and perceived episodes avoided, suggesting that contingent valuation can elicit accurate estimates of willingness to pay.

Discrete Choice Modeling

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5 A type of bias is the protest in which the respondent always chooses the status quo in the choice questions and agrees or strongly agrees with the statement that their household should not have to pay any amount for the specified social good (EPA, 2015).

6 Warm-glow effect refers to a type of bias in which the respondent always chooses the most expensive option in the choice questions and agrees with the statement that it is important to achieve the specified social good no matter how high the costs (EPA, 2015).

In choice modeling, participants are asked to choose among different alternatives rather than asked direct valuation questions. With discrete choice experiments, researchers present participants with different scenarios, each with different levels of attributes from which to select. Participants' choices demonstrate implicit tradeoffs between the different attributes in each choice set. These tradeoffs are then analyzed to estimate the effect of each attribute on individual utility. One of the advantages over contingent valuation is that choice experiments tend to reduce the number of zero responses due to ethical protests (Hoyos, 2010) and may minimize the warm-glow effect. Instead of being faced with the decision of whether one would be willing to pay for a social good or health risk reduction, participants are simply choosing between alternatives. Additionally, choice experiments allow for estimating not only mean willingness to pay but also the implicit price or marginal willingness to pay for different attributes (Mahieu et al., 2014).

Cost of Illness

Cost of illness estimates provide a measure of the economic burden of a disease on an individual and society by summing the resource and opportunity costs of being ill. These estimates are prevalent in health economics literature as they are directly measurable and present a useful metric of the impact an illness has on public programs such as Medicare and Medicaid. While the types of costs included in these estimates vary, few cost of illness studies attempt to monetize the intangible costs of pain and suffering (Pike and Grosse, 2018). Instead, these estimates most commonly capture the direct medical costs of treatment and the indirect costs due to lost wages or lost production (Jo, 2014).

The cost of illness is calculated using either a prevalence-based method or an incidence-based method (Tarricone, 2005). Prevalence-based estimates are derived from all costs within a single year incurred by all individuals who have an illness (cross-sectional). Incidence-based estimates attempt to measure lifetime costs by estimating the direct and indirect costs for each year of illness weighted by the probability of the individual's survival by year (longitudinal data). In contrast to collecting data over a lifetime, incidence-based cost of illness is often modeled by creating a cohort of people with the illness and requires more assumptions than prevalence-based cost of illness. However, incidence-based estimates are the correct method for calculating cost of illness when estimating the value of disease prevention (CDC, 2017).

Using cost of illness alone in cost-benefit analysis is criticized primarily because it is an incomplete measure of the total value of induced morbidity.[7] Cost of illness does not account for willingness to pay estimates and individual preferences for the avoidance of pain and suffering associated with illness. Although the cost of illness may provide a reasonably close approximation of individual willingness to pay for minor illnesses (Guh et al., 2008), it may also significantly underestimate willingness to pay for illnesses associated with a significant amount of "dread" due to the pain and suffering associated with the illness and treatment. In most nonfatal cancer cases, cost of illness is not an appropriate measure of the burden of disease, but it may provide a lower bound on the value for illness (EPA, 2000a).

[7] Induced morbidity refers to a loss of quality of life brought about by external factors other than aging. Because this type of morbidity may be avoided or its effects mitigated through averting behaviors, any valuation estimate of this type of morbidity should include averting costs.

Proxy Measures

Proxy measures have been developed for various injuries and illnesses in cases with no existing estimates for health risk. The Consumer Product Safety Commission's Injury Cost Model, which estimates the cost to society of injuries associated with consumer products, draws from jury awards as the primary data source to monetize pain and suffering. These estimates come from a regression analysis of 1,986 jury awards and settlements to the victims of nonfatal injuries due to consumer products (Lawrence, et. al., 2018). Internationally, the Organisation for Economic Cooperation and Development (OECD) has generalized the results of past cost-benefit analyses to monetize the nonfatal component of a health risk as a constant fraction of the total value of the health risk. This white paper discusses this approach in more detail in the International Practices section. The most prevalent proxy method currently in use leverages existing estimates of summary measures of disease outcome known as quality-adjusted life years (QALYs).

Monetized Quality-Adjusted Life Years

The QALY is a metric that reflects both the quality of life and the longevity associated with a particular health state combined into a single number. QALYs are the most common metric for standardization of the impact of morbidity; they have been used extensively for cost-effectiveness analysis of different medical interventions and as a measure of disease burden in health care policy (IOM, 2006). The number of QALYs remaining for an individual living with a particular health state is computed as the product of the remaining years of life expectancy and a health-related quality of life (HRQL) weight between 0 and 1, which represents the quality of life as compared to full health. For example, half a year lived in perfect health (HRQL = 1) would be equivalent to 0.5 QALY. Conversely, an individual who lives for 1 year with impaired health with a HRQL of 0.5 would also equate to 0.5 QALY. The QALY is a useful metric that combines both the quality of life impacts and length of life impacts of a medical intervention or illness into a single number so the total benefits can be compared directly.

Figure 2 illustrates how the benefits of avoiding a statistical case of illness can be represented using QALYs. In this figure, the top line represents the health profile of an average individual in the absence of a specific illness. The bottom line represents the health profile of an individual who experiences a reduction in quality of life and life expectancy upon being diagnosed with an illness. The QALYs gained from the reduction in an illness risk that results in avoidance of a single case are the difference between the areas under the two curves.

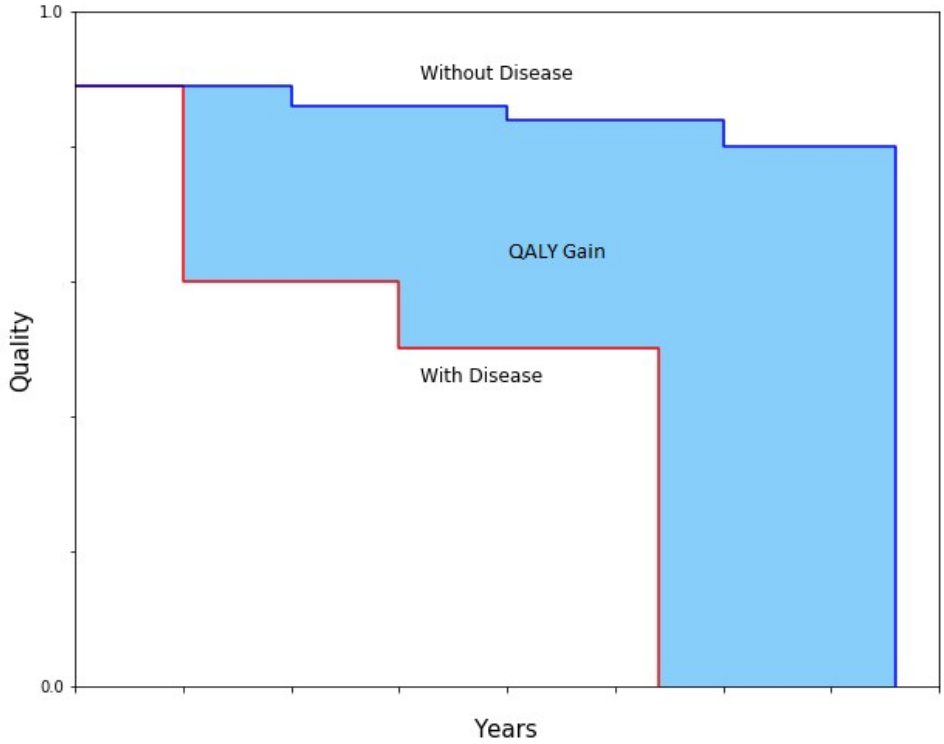

Figure 2. QALY Gain from an Avoided Illness

The number of illnesses and illness profiles is potentially infinite, and it is simply not practical to conduct primary research to elicit willingness to pay for each possible health outcome.[8] To address this problem, a set of principle and shared attributes can be selected to describe every illness state. Cameron (2014) refers to this as measuring willingness to pay by describing each possible illness in terms of its levels of a small number of common attributes. This method of quantifying morbidity has been practiced extensively in health economics but not directly applied to cost-benefit analysis.

Some researchers have challenged the validity of the assumptions that underlie QALYs (Smith et al., 2009). The QALY approach assumes that the value of being in a given health state is independent of the time spent in that state (e.g., living with a chronic illness for 2 years has twice the utility value of being in that health state for 1 year). Another controversial assumption is that all QALYs gained are equal without regard for whom they accrue (e.g., a QALY gain for a child is equal to a QALY gained by an elderly person near the end of life). Some argue that QALYs may vary greatly based on the baseline health status of the individual and personal characteristics, such as age. In addition, variation in the elicitation techniques for valuing health states has resulted in differing QALY values depending on the methods used (Nord et al., 2009). Despite this controversy, QALYs remain widely used and regarded as the best available metric for quantifying the benefits of medical interventions as part of cost-effectiveness analysis.

[8] Cameron (2014) refers to this problem as the "curse of dimensionality." This phrase is commonly used to describe the phenomenon that arises when analyzing and organizing data in high-dimensional spaces. As the dimensionality increases, the amount of data needed to identify any statistically significant result often grows exponentially with the dimensionality.

A principle challenge in the application of QALYs to cost-benefit analysis is deciding how these measures should be monetized. One method is to amortize the VSL over the average remaining life span of the population of interest to determine a VSL year. The unit value of a QALY, an equivalent year lived in full health, is then set equal to the VSL year. Another method is based on the incremental cost-effectiveness of medical care in the United States. In the United States, the ratio of $50,000 per QALY gained by a medical intervention has been used as a threshold for determining the intervention's cost-effectiveness (Owens, 1998). However, this threshold value has little technical or empirical grounding (Neumann et al., 2014).

Braithwaite et al. (2008) attempted to update this value by inferring upper and lower bounds on society's willingness to pay for healthcare based on the costs and benefits of modern health care and unsubsidized health. This study cited surveys and polls indicating that most of the U.S. population believe that the United States is spending too little on health care and most frequently identified it as the economic sector that should have the highest priority for future growth. From this, it was reasoned that most of the U.S. population are willing to pay the incremental costs of prior health care advances. Therefore, estimates of the cost-effectiveness of recent advances in modern health care were used as a lower bound in Figure 2. Alternatively, before passage of the Affordable Care Act, the purchase of health insurance was low among U.S. adults who did not have access to employer- or government-subsidized insurance plans. This unwillingness to pay for unsubsidized health insurance is used as an upper bound estimate for the decision rule. Sensitivity analyses were performed on the upper and lower bounds, resulting in a range between $109,000 and $297,000 per QALY saved (Braithwaite et al., 2008).

The validity of using monetized QALYs as a proxy for willingness to pay in cost-benefit analysis has been debated. From the U.S. Environmental Protection Agency's (EPA's) Advisory Council on Clean Air Compliance Analysis (2004)—

> The Council's reservations about QALYs stem primarily from concerns about QALY weights on health state attributes being inconsistent with the utility-theoretic models that underlie benefit-cost analysis unless excessively strong assumptions are made. All members agree that there should be no attempt to develop utility-based monetary valuations for QALYs (such as WTP [willingness to pay] per QALY) as these are conceptually inconsistent approaches.

In 2004, the OMB and other Federal agencies asked the National Academy of Sciences' Institute of Medicine (IOM) to address several technical questions surrounding cost-effectiveness and cost-benefit analyses, namely with regard to the use of HRQL measures. The IOM (2006) did not recommend monetizing QALYs, stating that "willingness to pay and HRQL valuation and measurement have developed out of distinct disciplinary and methodological traditions. Given their different theoretical underpinnings and the different types of tradeoffs they consider, it is misleading to combine them." Despite these recommendations, the OMB does allow for the practice of monetizing QALYs in the absence of sufficient willingness to pay studies (OMB, 2003).

Comparison of Methods

Table 1 summarizes common methods for health effects valuation. The three methods most often used to value morbidity due to environmental factors are the cost of illness, contingent valuation, and averting behavior (EPA, 2000a). Several studies have compared the relative magnitude of values produced by these approaches. One study (Dickie et al., 1987) compared

contingent valuation and averting behavior method estimates to avoid symptoms of ozone exposure and found that contingent valuation bids frequently exceeded averting behavior estimates by factors between 5 and 10. Richardson et al., (2010) estimated the value of decreased morbidity from wildfire smoke using all three methods. The values estimated using the contingent valuation and averting behavior methods were found to be comparable, whereas the cost of illness value was at least an order of magnitude less.[9]

Chestnut et al., (1996) compared cost of illness to willingness to pay estimates for small changes in angina frequency and found that, despite negligible changes in cost of illness for very small changes in angina frequency, subjects had significant willingness to pay to avoid increases in frequency.[10] Alberini and Krupnick (2000) compared willingness to pay from contingent valuation surveys to cost of illness associated with minor respiratory symptoms and estimated the ratio of willingness to pay valuation to the cost of illness estimate at 1.61 to 2.26. Cropper et al., (2004) estimated that the household willingness to pay valuation to prevent malaria in Ethiopia is approximately twice the cost of illness estimate.

In the United Kingdom, the Health and Safety Executive (HSE) compared willingness to pay for nonfatal road injuries from a study that used direct elicitation methods to those inferred using the monetized QALY approach. Adjusting for inflation, the HSE found the QALY approach produced values that are approximately one-third to one-quarter, depending upon severity, of the values that were previously estimated using contingent valuation methods (HSE, 2007).

While theoretical and empirical evidence confirms that cost of illness underestimates the value of willingness to pay to avoid illness, it is important to note that revealed preference and stated preference estimates of willingness to pay may not be complete measures of the value of avoided illness to society. Freeman (2003) addresses this as follows:

> Although individual willingness to pay is the correct starting point for analyzing health-related values, there is one important respect in which society's valuation of changes in health might diverge from that of the affected individual. Society has developed several mechanisms for shifting some of the costs of illness away from the individual who is ill and onto society at large. These mechanisms include medical insurance, which spreads the costs of treatment among all policyholders, and sick leave policies, which shift at least part of the cost of lost work days onto the employer and ultimately onto the consumers of the employer's products. An individual's expressed willingness to pay to avoid illness would not reflect those components of the costs of her illness that are borne by or shifted to others. However, the value to society of avoiding her illness includes these components. Empirical measures of the value of reducing illness must take account of these mechanisms for shifting costs.

To address this problem, some analysts sum the cost of illness and willingness to pay to capture the total social welfare cost of an illness (Hunt and Ferguson, 2010), with the understanding that this may result in double counting. The OMB affirms this stance, as discussed in the section of this white paper on Office of Management and Budget Guidance.

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9 Individual willingness to pay using contingent valuation resulted in estimates of between $75 and $98 per symptom day, while willingness to pay deduced from averting behavior resulted in estimates of between $43 and $94 per symptom day. The cost of illness value was estimated to be $3 per symptom day (Richardson et al., 2010).

10 This study estimated willingness to pay using both the contingent valuation method and the averting behavior method.

Willingness to pay approximations using either stated preference or revealed preference methods remain the most desirable measure of social benefit gained from health risk reductions because they align with the principles of welfare economics and utility theory. Most of the literature agrees that it is appropriate to include costs of illness along with willingness to pay to capture the entire benefit of morbidity risk reductions, but care must be taken to avoid double counting. Despite willingness to pay as the preferred method of valuation, proxy measures such as monetized QALYs are a viable option when high-quality willingness to pay studies are absent for a given health effect.

Table 1. Common Approaches to Morbidity Valuation

Approach	Method	Description	Remarks
Revealed Preference	Hedonic Wage	Estimates wage-risk tradeoffs from labor market data using hedonic regression methods.	Based on observed behavior. Extensive data are needed to relate small changes in safety attributes to wages. Assumes workers have prior knowledge of job risks and their magnitudes.
	Averting Behavior	Estimates willingness to pay to avoid illness using observations of defensive expenditures taken to prevent or mitigate illness.	Based on observed behavior, and consumer price data are readily available. Requires complex statistical methods to isolate the value of safety risk reductions from other attributes of products. Difficult to measure consumer perceptions of effectiveness of defensive behavior.
Stated Preference	Contingent Valuation	Estimates willingness to pay by asking survey respondents directly about the value they place on risk reduction.	Surveys can be constructed to analyze the specific risk of concern. Participant choices may not be reliable because of the hypothetical nature of a survey.
	Discrete Choice Modeling	Estimates willingness to pay based on survey responses to choices between discrete alternatives with different levels of attributes related to risk.	Avoids protest responses. Allows for simulation of market choices. Participant choices may not be reliable because of the hypothetical nature of a survey.
Direct Markets	Cost of Illness	Estimates financial costs attributed to the disease that are incurred by society and the individual, which include— – medical and treatment costs – lost productivity costs and lost wages – value of lost leisure time due to treatments or incapacitation	Costs and wage estimates are obtained directly from market data. Does not attempt to approximate willingness to pay as it is not based on individual preferences. For many diseases, cost of illness significantly underestimates willingness to pay as it does not account for the value of pain and suffering.
Indirect Data Sources	Monetized QALYs	Assigns a monetary value to the existing QALY health utility metric, which combines a health state's impact on quality of life and life expectancy.	QALY values exist for a vast number of illnesses and health states. Methods used to monetize the QALY lack theoretical or empirical support (IOM, 2006).

OFFICE OF MANAGEMENT AND BUDGET GUIDANCE

The OMB provides guidance to Federal agencies on conducting regulatory analyses. The OMB is the largest component of the Executive Office of the President and helps a wide range of executive departments and agencies across the Federal Government implement the commitments and priorities of the President. The OMB issues Executive orders and Presidential memoranda to agency heads and officials, the mechanisms by which the President directs specific Governmentwide actions by executive branch officials. Within the OMB, the Office of Information and Regulatory Affairs reviews all significant Federal regulations by executive agencies to ensure that economic and other impacts are assessed as part of regulatory decisionmaking.

OMB Circular A-4, "Regulatory Analysis," dated September 17, 2003, provides the OMB's guidance to Federal agencies on the development of regulatory analysis as required under Section 6(a)(3)(c) of Executive Order 12866, "Regulatory Planning and Review," dated September 30, 1993. This Governmentwide guidance broadly defines what is expected of a "good" regulatory analysis but affords agencies substantial flexibility in the individual methods and tools used to conduct these analyses. OMB Circular A-4 contains the most extensive and broadly applicable regulatory analytical requirements, but it does not apply to independent regulatory agencies. The statutes that provide rulemaking authority to independent regulatory agencies often require them to consider regulatory costs and benefits, and they often have less explicit requirements for cost-benefit analysis, if any (Carey, 2014). Because of the Commission's previously expressed desire to meet the spirit and intent of Executive orders related to cost-benefit reform and decisionmaking, the NRC voluntarily complies with Executive Order 12866 (NRC, 2020).

In discussing the key concepts needed to estimate costs and benefits, OMB Circular A-4 states that opportunity cost is the appropriate concept for valuing the costs and benefits associated with a regulation and promotes the principle of willingness to pay as the preferred method of measuring opportunity cost. OMB Circular A-4 provides a detailed discussion on how costs and benefits should be monetized for major health and safety rulemakings. The circular advises that both the individual willingness to pay and external costs to society due to increased medical costs or loss of production be considered:

> When monetizing nonfatal health effects, it is important to consider two components: (1) the private demand for prevention of the nonfatal health effect, to be represented by the preferences of the target population at risk, and (2) the net financial externalities associated with poor health such as net changes in public medical costs and any net changes in economic production that are not experienced by the target population. Revealed preference or stated preference studies are necessary to estimate the private demand; health economics data from published sources can typically be used to estimate the financial externalities caused by changes in health status.

With regard to proxy measures, OMB Circular A-4 specifically identifies health utilities as an alternative approach:

> If data are not available to support monetization, you might consider an alternative approach that makes use of health utility studies.... This health utility information may be combined with known monetary values for well-defined health states to estimate monetary values for a wide range of health states of

different severity and duration. If you use this approach, you should be careful to acknowledge your assumptions and the limitations of your estimates.

While the OMB emphasizes the preference of willingness to pay studies over health utilities (e.g., QALYs), the guidance allows for the use of these measures in the absence of high-quality willingness to pay or cost of illness estimates. Therefore, each agency needs to make its own determination as to whether suitable estimates from stated preference or revealed preference studies exist to support monetization of the health risks of concern.

The following section discusses the approaches used at selected U.S. Federal agencies.

FEDERAL AGENCY PRACTICES

Several agencies within the U.S. Government are responsible for regulations that affect health risks to the public. Currently, these agencies use a variety of methods for valuing nonfatal health risks as part of a regulatory analysis. The NRC staff performed a literature review of current guidance and recently conducted regulatory analyses. As part of this review, the staff summarized at least one recent case study where nonfatal health risks were valued. Overall, the review revealed significant variation in agency practices, which are detailed below.

In selecting agencies for the focus for this review, the staff looked at agencies that publish high volumes of regulations that often consider human health benefits in their regulatory actions. The staff examined each agency's submissions to the Unified Agenda to see how many regulations the agencies were actively working on at any given time and how many of those rulemakings might consider human health impacts. Figure 3 provides a snapshot from the OMB Office of Information and Regulatory Affairs of the Federal agencies with the most regulatory actions currently under review as of August 7, 2019. While these numbers represent all rulemakings, regardless of whether they consider human health effects, this information provided a starting point for identifying agencies for this review.

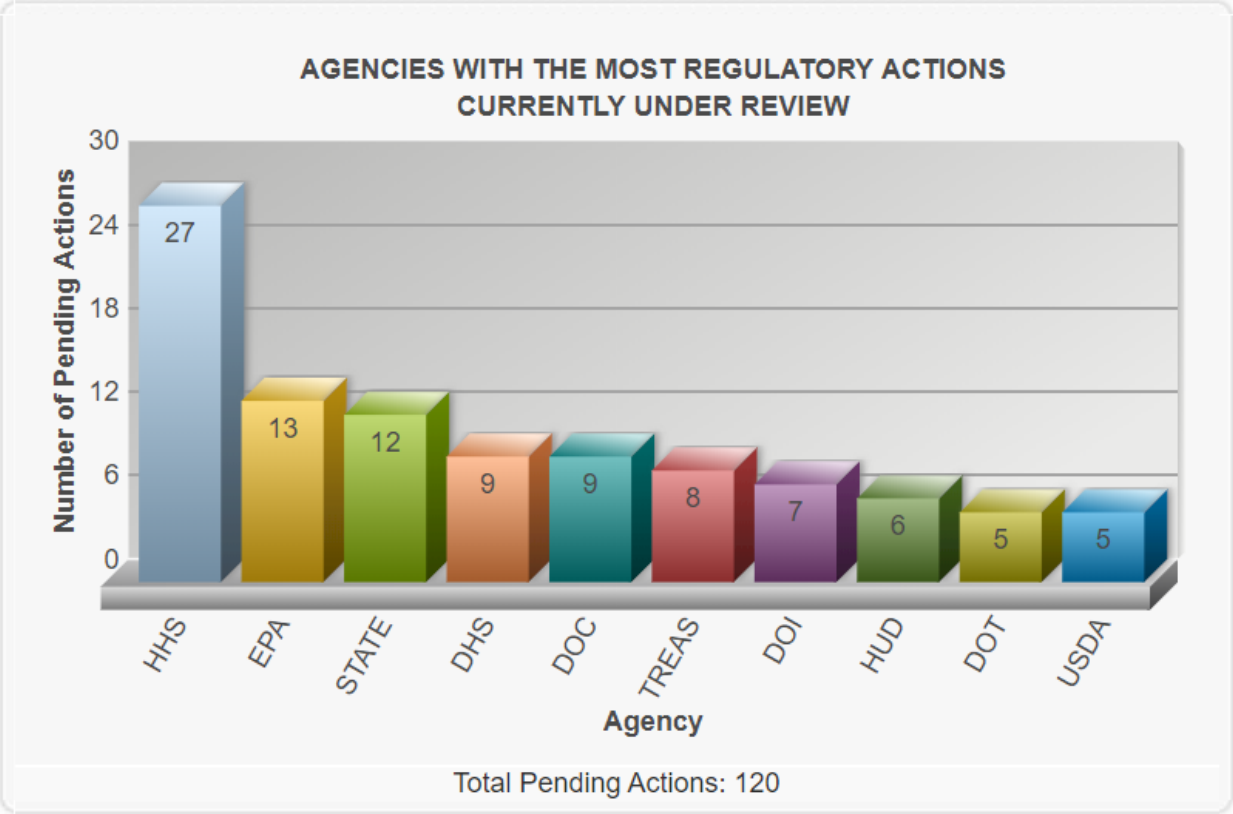

Figure 3. Agencies with the Most Regulatory Actions Under OMB Review as of August 7, 2019

Source: Office of Information and Regulatory Affairs (https://www.reginfo.gov/public/)

For consistency with NRC guidance on the valuation of mortality risk reduction (NRC, 2015), which used other agency's practices for benchmarking, this literature review looked at the agencies cited in the guidance. To identify recent regulatory analyses for this review, the staff used the OMB's database of historical regulatory plans and Unified Agendas. This database contains each agency's current rulemaking activities from proposed to final rulemakings. The NRC staff reviewed the historical and current Unified Agendas from fall 2010 for those rules that potentially quantify and value human health impacts. As a result of these considerations, the staff chose to focus its review on the U.S. Department of Health and Human Services (HHS), the EPA, the U.S. Department of Transportation (DOT), the U.S. Department of Labor, and the U.S. Department of Agriculture (USDA).

U.S. Department of Health and Human Services

The HHS is a cabinet-level department of the U.S. Government whose mission is to enhance and protect the health and well-being of all Americans (HHS, 2014). As such, reducing health risks is one of the primary goals of HHS regulations.

Guidelines

In 2016, the HHS issued "Guidelines for Regulatory Impact Analysis," which addressed the valuation of health risk reductions (HHS, 2016). This guidance recommends that the reductions in fatal risks and nonfatal risks should be estimated separately and the results summed. In

keeping with this recommendation, the guidelines have separate sections valuing morbidity risk reductions and mortality risk reductions. In valuing morbidity, the HHS states the following:

> Analysts should first review the literature to determine whether suitable WTP [willingness to pay] estimates of reasonable quality are available. If not, they should use monetized QALYs as a proxy....

While acknowledging that willingness to pay studies are the preferred approach to morbidity valuation, the guidance recognizes that gaps in the literature exist for many health effects. For this reason, it focuses on a methodology for using monetized QALYs to value morbidity. According to the guidance, the expected QALYs due to a health risk are calculated as follows:

- Estimate the number of QALYs for a given case by multiplying the health state's HRQL estimate with time spent in that health state.
- The resultant expected QALYs are weighted by multiplying the HRQL in each future year of life by the probability of surviving that year using survival probabilities obtained from the Centers for Disease Control and Prevention (CDC) life tables (CDC, 2018) and discounted using the same rates as recommended for monetary values.
- Resulting QALYs are summed across health states and illnesses associated with a hazard.

This approach is taken for an individual both with and without an illness to calculate the QALY gain by avoiding the illness. Figure 4 summarizes criteria for selecting appropriate HRQL estimates in the HHS guidelines.

1) QALY estimates should be based on research that addresses the risks and populations affected by the regulation.
2) The description of the effects of the health state on quality of life should be based on information from those who have experienced the condition (such as patients).
3) The preference weights placed on the health states should be based on a survey representative of the general U.S. population.
4) The "without new regulation" baselines (with the condition) should be compared to a realistic estimate of "with-regulation" health status, which takes into account factors (such as age and co-morbidities unrelated to the regulated hazard) that may lead those affected to be in less than perfect health once the regulation is implemented.
5) The implications of related uncertainties should be discussed and addressed quantitatively if significant.

Figure 4. Criteria for Selecting QALY Estimates for Use in Cost-Benefit Analysis

Source: HHS, 2016

To monetize the saved QALYs, the HHS recommends developing a constant dollar per QALY value by dividing the VSL by the expected future QALYs remaining for the average-aged individual reported in the VSL studies. This approach differs from the VSL year approach in that expected future QALYs are generally less than expected remaining life years, based on the

assumption that health tends to deteriorate with age.[11] Analysts should base the life expectancy on the average age of the individuals upon which the underlying VSL studies are based. Additionally, the value of future years is discounted.

Cost-savings that are not reflected in the QALY measure may be added to these values, including those that accrue to third parties (such as savings in insured medical costs). While analysts may add in medical costs paid by third parties, they should not add estimates of lost productivity or income to avoid potential double counting.

Recent Regulatory Impact Analysis

Within the HHS, the Food and Drug Administration (FDA) is responsible for protecting public health through the regulation of food, pharmaceuticals, and medical devices (HHS, 2020).

Since the issuance of the HHS "Guidelines for Regulatory Impact Analysis" in 2016, the FDA published a proposed rule that assessed the value of a reduction in both fatal and nonfatal oral cancer risks. The FDA's "Tobacco Product Standard for N-Nitrosonornicotine Level in Finished Smokeless Tobacco Products (Proposed Rule)," dated January 23, 2017 (FDA, 2017a), would establish a product standard that would require all finished smokeless tobacco products to comply with a limit for N-nitrosonornicotine to be marketed and distributed for sale in the United States. The primary benefits of this rule would be reduced health risks to consumers. While the FDA noted that the rule would reduce cases of other types of cancer, it focused its quantitative estimations on reduced oral cancer risks.

In the preliminary regulatory impact analysis for this proposed rule (FDA, 2017b), the FDA used a monetized QALY approach to quantify the value of reduction in time spent suffering from oral cancer and its effects. The FDA made the following assumptions to assess the different health costs associated with oral cancer:

- The impact of cancer on the HRQL was considered for a 62-year-old individual (median age of diagnosis of oral cancer).
- Upon diagnosis, the health costs of cancer are incurred for an entire year. For this period, an HRQL of 0.68 is assigned, taken from a cost-effectiveness analysis of oral cancer screening (Dedhia et al., 2011).
- An individual with cancer is assumed to have a yearly recurrence risk of 19.1 percent within 5 years of the initial diagnosis. This rate is derived from a retrospective study on the recurrence rate of oral squamous cell carcinoma (Ermer et. al., 2015).
- Cancer patients who are treated and remain cancer-free for 5 years incur a reduction in HRQL, resulting in an HRQL of 0.75 (Rogers et al., 2006).
- Survival probability was based on data published in the National Cancer Institute's Surveillance, Epidemiology, and End Results Program's Cancer Statistics Review for 1975–2012 (Howlander et al., 2015).

[11] Hanmer et al. (2006) generated nationally representative values for the U.S. adult population: seven common HRQL scores stratified by age and gender. The authors used data from the Medical Expenditure Panel Survey and the National Health Interview Survey.

To calculate the present discounted QALY gains from avoided cancer morbidity, the FDA subtracted the HRQL from the assumptions above from the baseline weights for each year between 62 and 100 years of age. The difference in HRQL was multiplied by the baseline survival probabilities associated with each age and either the probability of recurrence or 5-year survival from the assumptions. A discount rate was applied to the resulting QALY difference and summed across each year of life. To monetize the estimated QALY gains, the FDA calculated a dollar per QALY for each year after publication of the rule by dividing the VSL by the sum of the present discounted QALYs remaining for a 40-year-old person. The FDA produced low, primary, and high dollar per QALY values based on low, middle, and high VSL values.

U.S. Environmental Protection Agency

The EPA's mission is to protect human health and the environment. The EPA seeks to accomplish its mission through research, public outreach, and developing and enforcing regulations on a wide range of environmental topics (EPA, 2019a). The EPA regulates the manufacturing, processing, distribution, and use of chemicals and other pollutants. In addition, the EPA is responsible for determining safe tolerance levels for chemicals and other pollutants in food, animal feed, and water.

Guidelines

In 2010, the EPA published "Guidelines for Preparing Economic Analyses" to provide an overarching framework for economic analyses (EPA, 2010). The EPA's National Center for Environmental Economics developed this guidance in consultation with economists from across the agency. All chapters underwent an external peer review before finalization, either through the EPA's Science Advisory Board (SAB) Environmental Economics Advisory Committee or through independent reviews by external experts. The guidelines incorporate recent advances in theoretical and applied work in the field of environmental economics and provide guidance on analyzing the benefits, costs, and economic impacts of regulations and policies. The EPA revises these guidelines periodically to incorporate new information pertinent to environmental policymaking and economic analysis, with the most recent update issued in 2014.

The EPA guidelines provide extensive discussion on the underlying concepts of benefits valuation, but they do not prescribe a methodology for valuing morbidity effects. Instead, it discusses the available methods and provides considerations for the analyst in selecting an approach. The EPA states that individual willingness to pay is the preferred measure of valuation, citing three commonly used methods of willingness to pay estimation in an environmental context: stated preference, averting behavior, and cost of illness. In addition, the guidance also mentions that risk-risk tradeoff studies can be linked to willingness to pay estimates to provide an approximation of willingness to pay for certain illnesses. The guidance cautions against the practice of monetizing health state indices, citing the recommendations of the IOM (2006) and Hammitt (2003).

Recent Regulatory Impact Analysis

The EPA uses surrogate illnesses to approximate willingness to pay for avoided nonfatal cancer illnesses. In a 2000 economic analysis for the Arsenic in Drinking Water Rule (EPA, 2000b), the EPA used the willingness to pay to avoid chronic bronchitis estimated by a 1991 study (Viscusi

et al., 1991) as a surrogate for bladder cancer. A subsequent EPA SAB[12] review panel reviewed the economic analysis for the Arsenic in Drinking Water Rule and expressed reservations about the valuation methods used for avoided cancer morbidity. The panel noted that the willingness to pay study cited consisted of a very small sample size and questioned the appropriateness of using benefits transfer of a noncancer illness to estimate the value of a cancer case. The SAB referenced a more recent study (Magat et al., 1996) that estimated the willingness to pay to avoid nonfatal lymphoma and noted that this may be more comparable with bladder cancer. The SAB recommended the use of the willingness to pay and the cost of illness values for bladder cancer as upper and lower bounds in an uncertainty analysis, with a discussion of the meaning and potential implications of these two estimates (SAB, 2001). The EPA used the Magat et al., (1996) estimate for nonfatal lymphoma in the economic analysis for the Stage 2 Disinfectants and Disinfection Byproducts Rule (EPA, 2005). In this rulemaking, the EPA valued a nonfatal case of bladder cancer using two surrogates, avoiding a case of curable lymphoma and avoiding a case of chronic bronchitis. The results using both willingness to pay estimates were presented for the analysis.

The EPA has continued to use this approach when valuing nonfatal cancer risks related to regulations. A more recent economic analysis dealing with the regulation of methylene chloride in consumer paint and coating removal provided a more extensive discussion of the approach to nonfatal cancer valuation (EPA, 2019b). This analysis estimated the benefits of avoided cases of liver cancer, lung cancer, and benign mammary gland tumor cases. This analysis delineated fatal cancers from nonfatal cancers by the cause of death: nonfatal cancers are defined as those cases in which the individual will die from something other than the cancer.[13] For nonfatal cancers, the EPA uses both the willingness to pay and the cost of illness approaches. In the nonfatal liver and lung cancer case, the EPA used the same two surrogate estimates applied in the Arsenic in Drinking Water Rule and the Stage 2 Disinfection Byproducts Rule: one based on the willingness to pay to avoid chronic bronchitis and another on the willingness to pay to avoid nonfatal lymphoma. The methylene chloride economic analysis provides a detailed discussion of why these two proxies were used, including the precedent set by the earlier rulemakings, as well as a qualitative discussion of why these two surrogates provide reasonable estimates of willingness to pay for cancer risks.

U.S. Department of Transportation

The DOT is responsible for setting safety regulations for all major modes of transportation in addition to maintaining and developing the Nation's transportation systems and infrastructure. The DOT operates through several administrations, such as the Federal Aviation Administration, the National Highway Traffic Safety Administration, and the Federal Highway Administration (FHA).

Guidance

The DOT has published guidance on the valuation of fatal and nonfatal injuries since 1993 and has issued memoranda periodically to adjust these values for real income growth and inflation (DOT, 2013). In this guidance, the DOT acknowledges that, in principle, the value of preventing

[12] The EPA SAB provides a mechanism for the agency to receive peer review and other advice designed to make a positive difference in the production and use of science at the EPA. One of the primary responsibilities of the SAB is to review the quality and relevance of the scientific and technical information being used as the basis for agency regulations (EPA, 2019c).

[13] The terms "fatal" and "nonfatal" do not reflect the type or severity of the cancer. This is simply a way of categorizing the cancer cases to apply different value estimates.

injuries should be estimated by the potential victims' willingness to pay. However, citing the lack of willingness to pay studies for the range of injuries under consideration, the DOT offers a standardized method for developing coefficients for each injury category to scale the VSL (DOT, 2016). Each type of injury is rated on a scale of QALYs, in comparison with the alternative of perfect health. These scores are grouped according to injury severity using the Abbreviated Injury Scale,[14] yielding coefficients that can be applied to the VSL to assign each injury class a value corresponding to a fraction of a fatality. Table 2 presents the current coefficients.

Table 2. Relative Disutility Factors by Injury Severity Level

MAIS Level	Severity	Fraction of VSL
MAIS 1	Minor	0.003
MAIS 2	Moderate	0.047
MAIS 3	Serious	0.105
MAIS 4	Severe	0.266
MAIS 5	Critical	0.593
MAIS 6	Unsurvivable	1.000

Source: DOT, 2016

The estimated QALY values used to derive the values in Table 2 are based on a "preference-based" instrument first developed in 1995, known as the Injury Impairment Index. The Injury Impairment Index was developed to measure QALY losses through six health dimensions and was uniquely derived from preference weights used in other instruments. The Injury Impairment Index QALY values were updated in a 2010 report to the National Highway Traffic Safety Administration (Spicer and Miller, 2010), which provides more information on how these QALY scores are calculated for injuries. In addition to these QALY-based scores, the FHA and National Highway Traffic Safety Administration consider "economic" or human capital costs due to injury (FHA, 2005).

U.S. Department of Labor

As part of the U.S. Department of Labor, the Occupational Safety and Health Administration (OSHA) ensures safe working conditions by regulating and enforcing workplace health and safety standards. As of the drafting of this report, neither OSHA nor the U.S. Department of Labor has agency-specific guidance that addresses the valuation of health risks in economic analysis. Historically, OSHA used cost of illness to value the benefits of reducing injury risk (LaTourrette and Mendeloff, 2008). However, in a 2004 rulemaking on Occupational Exposure to Hexavalent Chromium, OSHA acknowledged the limitations of the cost of illness approach and the importance of capturing individual willingness to pay (OSHA, 2004). In the regulatory impact analysis for this rule, OSHA valued nonfatal lung cancers at 58.3 percent of the value of a fatal cancer based on the approach used in the EPA's Stage 2 Disinfectants and Disinfection Byproducts Rule (EPA, 2005). As previously discussed, this value is based on the 1996 study by Magat et al. that valued a case of nonfatal lymphoma.

[14] The Abbreviated Injury Scale is an anatomically based severity scoring system that classifies and ranks injuries by severity on a six-point scale (AAAM, 2019). While the Abbreviated Injury Scale is used to classify individual injuries, the Maximum Abbreviated Injury Scale (MAIS) is used to classify a crash by the most severe injury suffered by a person in that crash.

Recent Regulatory Impact Analysis

The NRC staff identified two more recent final rules as having monetized the benefits associated with decreased cancer risks: the Final Rule for Occupational Exposure to Respirable Crystalline Silica (OSHA, 2016a) and the Final Rule for Occupational Exposure to Beryllium (OSHA, 2016b). The review of the final economic analysis for each of these rules showed that the approach to valuing nonfatal diseases was the same: OSHA provided low and high estimates for valuation, citing the significant variation in the severity of symptoms among individuals for both silica- and beryllium-related diseases. For a low estimate, OSHA used values of $64,000 in 2012 dollars and $67,000 in 2015 dollars for silica and beryllium morbidity, respectively, based on estimates of the value of statistical injury derived from an analysis of hedonic wage studies (Viscusi and Aldy, 2003). For the high estimate, OSHA used the previously cited estimate of willingness to pay to avoid nonfatal lymphoma as a fraction of the VSL (Magat et al., 1996).

OSHA benchmarked these high and low values against several other valuation techniques that monetized various forms of lung disease. The EPA estimated a cost of $460,000 in 2008 dollars for a case of chronic bronchitis (EPA, 2008). A report prepared for OSHA estimated the costs of silicosis by combining the costs of five categories: medical costs, wage work loss, household production loss, administrative costs of claims processing, and quality of life impacts (Miller, 2005). This report estimated the total costs of silicosis at $335,000 when inflated to 2012 dollars. Based on these benchmarks, OSHA concluded that the value of silicosis and chronic beryllium disease likely fell within the high and low values estimated. OSHA did not choose to select any single value as a mid-range or best estimate for the noncancer illnesses. Notably, OSHA used these estimates to describe the value of nonfatal illnesses, as well as the morbidity preceding mortality (OSHA, 2016a).

U.S. Department of Agriculture

The USDA is responsible for developing and executing Federal laws related to a broad range of activities such as farming, forestry, and food production. Within the USDA, the Economic Research Service (ERS) serves as the principal social science research agency, conducting and communicating socioeconomic research for public policy decisionmaking and to inform the public about emerging issues in agriculture, food, and the environment (USDA, 2019a). The ERS publishes and maintains information on the costs of foodborne illnesses for 15 major pathogens that account for over 95 percent of the foodborne-related illnesses, hospitalizations, and deaths each year in the United States (USDA, 2019b). These cost estimates incorporate medical costs due to inpatient and outpatient care, lost wages, and an individual's willingness to pay to reduce mortality risks resulting from foodborne illness.

In estimating the economic costs associated with a foodborne illness, disease outcome trees delineating the potential outcomes and their likelihood are developed for the various pathogens. Health outcomes may be defined by whether a patient was hospitalized or treated without hospitalization, whether illness becomes chronic, and whether illness leads to death (USDA, 2019c). Human capital costs are estimated for the hospitalized and non-hospitalized outcomes, and willingness to pay (through the VSL) is applied to mortality risks. These cost estimates do not monetize the willingness to pay to avoid pain and suffering associated with nonfatal illness risks, and the USDA asserts that this results in a "conservative approximation" of individual's overall willingness to pay to avoid foodborne illness.

The ERS methodology for estimating these costs is described in "Making Sense of Recent Cost-of-Foodborne-Illness Estimates" (Hoffman and Anekwe, 2013). To estimate the costs of medical treatments, the average length and costs of hospital stays are taken from the Nationwide Inpatient Sample database[15] using International Classification of Disease codes to identify pathogen diagnosis. The opportunity costs associated with lost work days were estimated based on a daily wage rate. Hoffman and Anekwe (2013) discuss issues surrounding the estimation of disutility costs, including sparsity of disease-specific willingness to pay estimates and controversy surrounding the practice of monetizing QALYs. Ultimately, the ERS chose not to monetize the disutility associated with nonfatal illness outcomes.

INTERNATIONAL PRACTICES

Organisation for Economic Cooperation and Development

One practical approach to valuing morbidity impacts in a benefits analysis is to assume that the morbidity costs are a near constant fraction of the total health impact. The OECD has, in recent studies, marked up the mortality costs by 10 percent to account for morbidity costs (OECD, 2014). This practice originally was based on the results of two studies: the European Union's 2012 cost-benefit analysis for the Thematic Strategy on Air Pollution, which demonstrates that mortality costs account for 91 percent of the total health costs when using mean VSL to value mortality costs; and a 2010 study conducted by the EPA on the benefits of the Clean Air Act Amendments, which attributed 93 percent of the total health benefits to mortality reductions (OECD, 2014). A study done in conjunction with the World Health Organization (WHO) analyzing the economic impact of air pollution in Europe reaffirmed this stance (WHO and OECD, 2015):

> For the present, it seems preferable to choose an indicative estimate for the additional cost of morbidity from the most comprehensive recent studies available. Quantitatively, however, this is not necessarily a serious limitation when estimating the economic cost of the [burden of disease] of air pollution, because mortality dominates over morbidity.

This study cited two evaluations: the first, conducted by the EPA on the 1990 Clean Air Act Amendments (EPA, 2011), indicated that mortality costs accounted for 92.4 percent of the total health effects costs,[16] and the second, conducted by the European Union supporting the Clean Air Policy Package (Holland, 2014), estimated the mortality costs to account for 91.9 percent of the total health impact. It is important to note that all these studies looked at health effects due to air pollution, which have a particular set of health endpoints. A 10-percent value may not be appropriate for all possible health outcomes.

United Kingdom

In the United Kingdom, Her Majesty's Treasury oversees the development and execution of the government's public finance and economic policy. The treasury produces guidance for the appraisal of government projects and policy proposals in a document known as "The Green

[15] The Nationwide Inpatient Sample is the largest publicly available database of regional and national estimates of inpatient utilization, access, charges, quality, and outcomes of hospitalizations (Agency for Healthcare Research and Quality, 2020).

[16] This value is extracted from the central estimate for 2020 for fine particulate matter, in which the sum of particulate matter mortality and ozone mortality as a percent of health effects is 92.4 percent (Table 7-2 in EPA, 2011).

Book" (Her Majesty's Treasury, 2018). The Green Book notes that willingness to pay should be the starting point for valuing either prevented fatalities or prevented nonfatal casualties. It also states that, in general, for valuing nonmarket benefits and costs, revealed preference methods are preferred, followed by stated preference methods. In its annex on nonmarket valuation, the Green Book outlines some approaches to the valuation of risks to life and health. This guidance focuses on the use of QALYs to value health impacts that affect life expectancy or quality of life, designating this value to be £60,000 ($94,000) per QALY in 2009 prices. A Department of Health guide published as a supplement to The Green Book describes the basis for this QALY value (Department of Health, 2010). This guide was issued to address the special problems that can arise when identifying and weighing the effects on health and health services of policies, programs, and projects.

The estimate of the value of a QALY draws on work by the United Kingdom Department for Transport (DfT) to estimate the value of a prevented fatality in a road traffic accident using a stated preference technique for willingness to pay. The average age of people killed in motor vehicle traffic accidents is about 40 years for men and 49 years for women, resulting in remaining life expectancies of 45.2 years and 39.1 years, respectively, using cohort life expectancies for 2009. These future life years can be quality-adjusted using average United Kingdom values for HRQL, derived from surveys of self-reported health status for respondents of different ages. After discounting at 1.5 percent, the QALY expectancy at age 40 for men and age 49 for women is 23.8 and 27.6, respectively. On this basis, the weighted average QALY loss for deaths from road accidents is estimated as 26.7 QALYs. Dividing the DfT's value of a prevented fatality of £1,637,420 ($2,564,252) by 26.7 QALYs, the result is £61,327 ($96,039) per QALY. This value is rounded to a single significant digit to reflect the uncertainty surrounding this estimate.

The United Kingdom's HSE is a government agency responsible for the regulation of workplace health and safety. The agency covers a wide range of activities, such as producing research and statistics to support regulations and reviewing and enforcing regulations. In 2007, the HSE issued "Human Costs of a Nuclear Accident: Final Report," which was commissioned[17] to peer review the approaches used to value health effects arising from exposure of the public to radiation (HSE, 2007). This report was undertaken to support the development of the COCO-2 Model for the Assessment of Economic Impact of Nuclear Accidents.[18] During development of the COCO-2 model, the HSE noted that the different government departments in the United Kingdom used varying approaches to value health effects (HSE, 2007). For morbidity valuation, the HSE recommends using monetized QALY losses for the purposes of the COCO-2 model, citing simplicity and a lack of direct elicitations.

SUMMARY

When valuing nonfatal illnesses and morbidity effects, organizations acknowledge that using estimates of individual willingness to pay is the theoretically preferred approach. Despite this, many agencies use proxy measures because primary willingness to pay estimates for the health impacts of concern are either unavailable or inadequate. The EPA and OSHA continue to use benefits transfer of willingness to pay estimates where feasible; however, other Federal agencies, such as the FDA and the National Highway Traffic Safety Administration, have used monetized QALYs in recent cost-benefit analyses. In addition, the consideration of the medical

[17] The work was commissioned through National Economic Research Associates Economic Consulting.

[18] COCO-2 is a model for assessing the potential economic costs likely to arise off site following an accident at a nuclear reactor.

resource and human capital costs due to illness varies by agency. While some agencies add the cost of illness to the willingness to pay or monetized QALY estimates, others discuss the merits of doing so qualitatively. Internationally, the OECD uses a simple markup of the mortality benefits based on previous analyses, while the United Kingdom promotes the use of monetized QALYs in the absence of primary willingness to pay studies.

CONCLUSION

This report provides an overview of the current state of practice in the monetary valuation of nonfatal health risks for application in the cost-benefit analysis of government regulations. This review found significant variation across agency practice in the approach to valuing nonfatal health risks. For those agencies that have recently monetized nonfatal cancer risks, the staff identified two methods as having been applied to cancer morbidity: (1) willingness to pay using benefits transfer of a stated preference study and (2) monetized QALY changes.

OMB Circular A-4 allows for proxy methods to be used when "data are not available to support monetization." Many Federal agencies include similar language in their agency-specific guidance documents—that while willingness to pay estimates are preferred, proxy measures may be used in the absence of "suitable" or "reasonable quality" estimates.

The willingness to pay approach is widely accepted as the preferred method for valuing the benefits of government regulation and for valuing changes in health risks (OMB, 2003). Government agencies use one primary study to estimate the willingness to pay value for nonfatal cancer. Because of the lack of data on willingness to pay for different cancer types, it is difficult to apply this valuation technique generally. In contrast, adopting a monetized QALY approach allows analysts to value cancer types individually for many distinct forms of cancer and their various stages.

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