

FROM THE PRESIDENT ...

The Third World Congress of Environmental and Resource Economists held in July in Kyoto was a truly wonderful event. There were lots of great papers and insightful plenary speakers. Nobel Laureates Clive Granger and Joseph Stiglitz discussed deforestation in Brazil and the way forward on dealing with climate change issues. What is perhaps just as noteworthy is the attention that the World Congress received outside of normal academic circles. Prince Akishinomiya gave an inspired opening address to Congress participants while Yuriko Koike, the Japanese Minister of the Environment, participated in a panel on ways to reduce carbon emissions before she gave an enlightening and entertaining talk during the gala dinner. Japanese business and industry and government agencies filled a large room full of exhibits. Toyota even sent an economist who was very familiar with my work to help man their exhibit. It was all in all a very different sort of official reaction to the importance of what we do than what we typically experience. We are grateful to the U.S. Department of Agriculture, Economic Research Service, for their support of AERE's participation in the World Congress and I also want to express appreciation to Kenji Takeuchi, Kobe University, for his assistance with many logistical details.

Hopefully, the launch of AERE's new journal, the *Review of Environmental Economics and Policy (REEP)*, with its strong policy focus will help increase the visibility of the work we are all engaged in. Rob Stavins (Harvard), Carlo Cararro (Univ. of Venice) and Charlie Kolstad (UC Santa Barbara) have devoted a huge amount of effort to lining up an exciting set of papers and new features to help kick off the new journal. They will welcome your comments and feedback and most importantly your help in getting the journal into the regular circulation path of policymakers who call upon you for advice, as well as into the hands of students you have placed in government agencies, international organizations, consulting firms, and NGOs. Please notify your institution's library about the discount opportunity available for new orders placed by December 20th. (See details on page 5.)

The new AERE Fellows program was inaugurated at last year's AERE luncheon with the installation of

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New Recommendations For Valuing Health Outcomes

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Introduction

In 2003, the U.S. Office of Management and Budget (OMB) issued Circular A-4, which required Federal agencies to conduct cost-effectiveness analysis (CEA) of economically significant health and safety regulations, supplementing the long-standing requirements for benefit-cost analysis (BCA). In this guidance, OMB indicated its intent to ask the Institute of Medicine (IOM) to create an expert committee to provide recommendations for valuing health in regulatory CEAs. This committee was established in 2004 and its report was released in January 2006. The resulting recommendations are expected to significantly affect the practices followed by Federal agencies as well as by others interested in researching the cost-effectiveness of policy options.

The primary distinguishing characteristic of BCA is that it uses the same metric—dollars—to value both costs and benefits, so that they can be directly compared. In contrast, CEA involves using a non-monetary benefit measure (such as tons of pollution reduced or cases of illness averted) and then estimating the cost per unit of benefit or effect. For some observers, this distinction is the source of CEA's appeal: it avoids the need to explicitly assign dollar values to outcomes such as premature mortality and morbidity, a practice that has been an area of active controversy for many years. However, regardless of the type of analysis performed, the resulting regulatory decisions ultimately place a dollar value on the benefits by requiring the diversion of resources from other uses.

A key issue in regulatory CEA is how to develop an effectiveness measure that combines different types of benefits; e.g., various types of illnesses and injuries as well as premature mortality. Health economists have long used the quality-adjusted life year (QALY) for this purpose when assessing medical interventions and health programs. This metric involves first ranking the health-related quality of life (HRQL) impacts of a condition on a scale anchored at zero and one, where zero is equivalent to death and one is equivalent to perfect or optimal health. The resulting estimate is then multiplied by the duration of the impacts to determine the QALYs associated with the condition. For example, if a condition lasts for one year, and HRQL with the

condition is 0.8 (a decrement of 0.2 from the perfect health value of 1.0), then the condition is valued at 0.8 QALYs ($0.8 * 1$ year).

While these assessments are sometimes referred to as cost-utility analyses, QALYs are a measure of utility only under certain very restrictive assumptions. The QALY is best described as a practical approach for comparing preferences across different health states, rather than as a utility measure.

The remainder of this essay briefly summarizes the IOM Committee's recommendations and discusses key implications for selected Federal agencies. More information on the Committee's investigations is available at www.iom.edu/CMS/3809/19739.aspx as well as in its 2006 report, *Valuing Health for Regulatory Cost-Effectiveness Analysis*.
Committee Recommendations

Based on its investigations, the IOM Committee's major conclusions include the following.

- CEA, like BCA, offers a useful tool for the development and assessment of regulatory interventions to promote human health and safety...
- As in the case of BCA, the results of CEA...are not by themselves sufficient for informed regulatory decisions...
- Although it is feasible to apply CEA to regulatory interventions today, additional data and methodological improvements would enhance the quality and usefulness of such analyses.
- Greater consistency in the reporting of assumptions, data elements, and analytic methods and in presenting the resulting estimates...would increase the transparency and comparability of the results and lead to better informed policy decisions.
- Comparisons of cost-effectiveness ratios for diverse interventions can be misleading if they do not include information that highlights differences in methods, unmeasured effects, and distributional impacts across interventions. (IOM 2006, p. 10)

The Committee's report includes 12 recommendations. First, the Committee recommends the use of the QALY as the integrative effectiveness measure for regulatory analysis, based largely on practical considerations including its widespread use, flexibility and ease of application. The Committee's review of alternative measures, such as the disability adjusted life year (DALY), the healthy year equivalent (HYE), and saved young life equivalent (SAVE) suggests that they are less feasible, have been used less extensively, and/or have not been adequately evaluated.

Furthermore, the Committee states that QALY estimates "should be based, to the greatest possible extent, on research that considers the risk characteristics addressed and the population affected by the regulatory intervention" (IOM 2006, p. 161). When it is not possible to conduct new primary research on the preferences of those affected, the Committee indicates that agencies should use generic indices with values derived from the general population. These indices, such as the Euro-QOL (EQ)-5D, provide values for individual health state attributes (such as limited mobility or problems with pain) that then can be combined to provide weighted values for different illnesses or injuries. In cases where such generic indices are used, the Committee notes that the attributes of the illness or injury "should be based on information obtained from people who are familiar with the conditions, such as patients" (IOM 2006, p. 162). This approach distinguishes between the value of the health state (which should be based on the preferences of those affected by the costs and benefits of the regulation) and the description of the HRQL impacts (which should be provided by those who have experienced the condition). In Chapter 3 of the report, the Committee provides more detailed guidance on different approaches for developing these measures, including the use of expert judgment, benefit transfer techniques, and population survey data. Simplified examples of these approaches are provided in three case studies, which address specific air pollution, food safety, and traffic safety rules.

The Committee also developed several recommendations for constructing and reporting cost-effectiveness ratios. Its second recommendation notes that "[r]egulatory analyses should report four measures of cost-effectiveness: [c]ompliance cost per death averted"... "[c]ompliance cost per life year gained"... "[a] health-benefits-only ratio using the net change in QALYs as the outcome measure"... and "[a] comprehensive ratio using QALYs as the outcome measure and incorporating the value of other benefits as offsets to compliance costs" (IOM 2006, p. 167). The

Committee felt that it was important to report these ratios because each provides different types of information and "no single formulation will be ideal in all circumstances" (IOM 2006, p. 168).

Furthermore, in its third recommendation, the Committee indicates that the "[t]he life year and QALY estimates used in regulatory analyses should reflect actual population health as closely as possible, comparing the predicted HRQL and life expectancy of the affected population in the absence of the intervention (i.e., the regulatory baseline) to the predicted post-intervention HRQL and health-adjusted life expectancy." While this recommendation is consistent with other recent discussions of best practices (most importantly, Gold et al. 1996), many existing studies compare HRQL with the condition to perfect or optimal health (i.e., a value of 1.0). This latter approach will usually overstate the QALY gains associated with an intervention because few individuals will be in perfect health in the absence of the condition of concern. The degree of overstatement will be larger for older individuals since HRQL generally declines with age. For example, research using the EQ-5D indicates that average population health declines from roughly 0.9 to 0.7 when compared for U.S. individuals aged 20 to 29 and 80 to 89 (Hanmer et al. 2006).

The fourth recommendation notes that "[i]ncremental cost-effectiveness ratios are generally the most useful summary measure for comparing different regulatory interventions" (IOM 2006, p. 175). Reporting incremental ratios allows analysts and decision-makers to review whether the increase in cost is commensurate with the additional units of benefits, addressing some of the interpretation problems that may otherwise result from reliance on ratios. In regulatory analyses, these ratios are reported along with the BCA results (i.e., net benefits, or benefits minus costs), which provide additional information on the comparative impacts of different options.

Recommendation 5 builds on the second recommendation regarding the reporting of several different ratios. It notes that, "[i]n addition to reporting effects in the aggregate, regulatory analyses should report QALY impacts separately for each health endpoint. Impacts should also be reported in terms of single-dimension measures such as avoided cases of disease and cause-specific mortality" (IOM 2006, p. 175). Recommendation 6 indicates that "[t]he reporting of all CEA results should be accompanied by information on related uncertainties and on nonquantified effects (IOM 2006, p. 177). Both of these

recommendations again reflect the Committee's desire to ensure that decision-makers receive a rich array of information on the potential impacts of different policy options.

The seventh recommendation comments on a practice that is relatively common in regulatory analysis; the use of monetized QALY estimates to value nonfatal morbidity impacts in BCAs. The Committee strongly discourages this practice while recognizing that agencies may need to rely on it until estimates of willingness to pay become available for a wider range of health impacts. The Committee's objections stem from the fact that the value of statistical life year (VSLY) estimates used in such monetization reflect a different methodological and theoretical foundation which is not entirely compatible with QALY measurement.

The Committee also considers the other types of information needed for regulatory decision-making. In recommendation 8, it notes that "[t]he regulatory decision-making process should explicitly address and incorporate the distributional, ethical, and other implications of a proposed intervention along with the quantified results of BCA and CEA" (IOM 2006, p. 181). In recommendation 9, it indicates that "policy makers and program administrators should work to ensure the substantive involvement of a broad range of individuals and groups at all stages of policy development for regulating risks" (IOM 2006, p. 184). Both recommendations reflect the Committee's interest in ensuring that decision-makers consider factors other than quantifiable measures of economic efficiency.

Finally, the Committee identified several priorities for further research. Recommendations 10, 11, and 12 note that these priorities should include "improving the data used to assess the health risks," collecting additional HRQL data through population surveys routinely administered by the Department of Health and Human Services and other agencies, and developing "an integrated research agenda to improve the quality, applicability, and breadth of HRQL measures for use in regulatory CEA" (IOM 2006, pp. 185-187).

Implications for Agency Analyses

The Committee commissioned a report on current Federal agency practices (Robinson 2004), which covers those agencies most likely to be significantly affected by the Committee's recommendations. This report reviews the practices of agencies that finalized economically significant rules with quantified health or safety impacts between January 2000 and June 2004 and/or that were in

the process of developing such rules. These agencies include: (1) the Environmental Protection Agency (EPA); (2) the Food and Drug Administration (FDA); (3) the Food Safety and Inspection Service (FSIS); (4) the Occupational Safety And Health Administration (OSHA); (5) the National Highway Traffic Safety Administration (NHTSA); (6) the Federal Motor Carrier Safety Administration (FMCSA); and, (7) the Consumer Product Safety Commission (CPSC).

Most of these agencies had developed methods for estimating the QALY gains attributable to their regulations before the IOM report was completed. Some agencies have a long-standing tradition of using monetized QALYs in their BCAs. Other agencies had begun to develop approaches in response to the CEA requirements in Circular A-4, which became effective for analyses of proposed rules in January 2004 and for final rules in January 2005; before the Committee completed its deliberations.

The practices of three of these agencies (EPA, FDA, and NHTSA) are briefly summarized below as examples of the range of practices in place when the IOM Committee conducted its deliberations. The remaining agencies either tended to follow similar practices or were uncertain of their plans for implementing the new CEA requirements. These practices have continued to evolve due to the IOM recommendations and other factors.

EPA is responsible for a substantial share of all economically significant rules subject to the OMB requirements, and has developed a pilot approach for CEA that treats premature mortality differently than morbidity (Hubbell 2006, USEPA 2005). Years gained due to averted premature mortality are assigned an HRQL value of 1.0, which is equivalent to assuming that those life years would be lived in perfect health. In contrast, for morbidity, EPA compares HRQL with the condition to likely HRQL in the absence of the condition, assuming that the affected individuals would otherwise be in normal or typical health for their age (i.e., values of less than 1.0). Using a perfect health comparison for premature mortality leads to higher estimates of the associated QALY gains than would an approach that used the same type of average health comparison applied in assessing morbidity impacts.

EPA treats premature mortality differently than morbidity to address concerns about equity (particularly across younger and older populations), reflecting related requirements in OMB Circular A-4. The OMB requirements in turn reflect the significant public outcry that resulted when EPA presented sensitivity analyses

based on research suggesting that older individuals may be willing to pay less for averting mortality risks than would younger individuals (a.k.a. the “senior discount”). As noted earlier, the Committee recommends that the basic estimates of QALY gains reflect the actual expected change in health status and that analysts highlight these sorts of equity concerns through separate discussion, possibly accompanied by alternative quantified results.

While EPA was just beginning to experiment with the use of QALY estimates as OMB was in the process of developing Circular A-4, many other agencies have been using these types of estimates for many years. Historically, EPA has relied on estimates of willingness to pay to value health outcomes in its regulatory BCAs, or on cost of illness estimates when willingness to pay values were not available. In contrast, FDA and others use QALY measures to estimate willingness to pay (see, for example, USFDA 1998).

FDA either transfers HRQL estimates from the available literature or uses expert judgment to apply a generic HRQL index, then multiplies these values by the expected duration of the effect to estimate the QALY gains attributable to its regulations. For its BCAs, FDA then uses VSLY estimates to calculate monetized QALYs. For example, if the value of a statistical life year was \$200,000, and averting a health effect resulted in a QALY gain of 0.2, this gain would be valued at \$40,000 ($\$200,000 * 0.2$). FDA then adds medical costs to these monetized QALY estimates to estimate the total value of averting the cases of illness. Complying with OMB’s new CEA requirements has been relatively straightforward for FDA, who now uses the same approaches to estimate QALY gains in both types of analysis.

NHTSA has also used monetized QALYs in its regulatory analyses for many years, but the details of its approach differ significantly from the approach used by FDA. NHTSA has traditionally calculated equivalent lives saved (ELS) by comparing monetized QALY gains and expenditures associated with nonfatal injuries to the values for fatal injuries (USDOT 2002). The QALY component of this analysis is based on the Injury Impairment Index originally developed by Hirsch et al. and adapted by Miller et al. (1991, 1995). This index differs from those used more widely in the health economics literature in how the domains are defined and in the approach used to weight different health states.

NHTSA and FDA, as well as EPA, are affected by the Committee’s recommendation that estimates of

QALY gains be based on comparisons to expected post-regulatory health (rather than to perfect health) to the maximum extent possible. Implementing this change is relatively straightforward, since it generally involves simply substituting available estimates of average population health for the perfect health values previously used. This change may be more complicated when a regulation disproportionately affects individuals with pre-existing health conditions or other characteristics that affect post-regulatory health status. As noted earlier, the Committee recommends that issues of equity be addressed separately in the presentation of the results rather than incorporated into “base case” QALY estimates, recognizing that agencies may also want to present alternative estimates adjusted for equity concerns.

A greater challenge is posed by the Committee’s recommendation that QALYs not be assigned monetary values. Both FDA and NHTSA use monetized QALYs in their BCAs because of the scarcity of well-conducted willingness to pay studies that address the health effects of concern. Developing a larger catalog of willingness to pay values will require a long-term research agenda with increased resources for these types of studies.

The Committee’s report also will affect the detailed implementation of the approaches used by the agencies to estimate the QALY gains associated with regulations, since it includes suggested practices for benefits transfer and expert elicitation as well as specific recommendations for developing and reporting these values.

Conclusions

If accepted by OMB and the agencies, the Committee’s recommendations will lead to changes in current practices. Some of these changes are relatively straightforward, such as altering the assumptions regarding “without condition” or post-regulatory HRQL. Other changes would require the investment of additional resources over an extended time frame, particularly to develop estimates of willingness to pay that do not rely on the monetization of QALY measures as well as fund the types of QALY-related research included in the Committee recommendations.

In February 2006, IOM and Resources for the Future hosted a conference for Federal agency staff to discuss these recommendations. In addition to the issues noted above, agency staff expressed concern about the number of ratios that would need to be calculated and reported. They viewed these requirements as both a workload

problem and a communication issue, given the need to avoid overwhelming senior level decision-makers and stakeholders with information that can be difficult to interpret. While the Committee reasoned that which ratios are most meaningful will vary depending on the nature of the regulation, determining how to best communicate the implications of the results may be difficult.

Another area potentially in need of further exploration is how to best address uncertainty. OMB Circular A-4 includes significantly expanded discussion of, and requirements for, uncertainty analysis. The complexities of regulatory analysis, along with the need to address uncertainties in both the BCA and CEA components of such analyses, will present a number of challenges for the regulatory agencies that are not addressed in detail in the IOM report.

Overall, the Committee's report is intended to provide a useful guide to the current state of QALY measurement and its application to regulatory analysis. It provides a practical approach for conducting regulatory CEA, while at the same time noting its limitations and suggesting the types of supplementary information needed. However, the report's recommendations pose challenges as well, pointing out the need for additional research and for analysts to determine how to best communicate the conclusions that busy decision-makers should draw from a range of different measures.

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