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The Science of Making Better Decisions about Health: Cost-Effectiveness and Cost-Benefit Analysis

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Abstract

Despite spending far more on medical care, Americans live shorter lives than the citizens of other high-income countries. The situation has been getting worse for at least three decades. This paper describes the main scientific methods for guiding the allocation of resources to health – cost-effectiveness analysis (CEA) and cost-benefit analysis (CBA), sketches their methodological progress over the last several decades, and presents examples of how medical practice in other high-income countries, where people live longer, follows the priorities indicated by cost-effectiveness analysis. CEA and CBA support democratic decision-making processes, which have themselves benefited from scientific inquiry; these are touched on at the end of the paper.

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INTRODUCTION

Medical scientists are at work around the world producing new knowledge about health and disease, and new technologies to combat disease and improve health. They have had many successes: from the epidemiological investigations around London's Broad Street pump that confirmed cholera's transmission by water, to the identification of the agents of infectious diseases themselves – bacteria and viruses, to the development of vaccines, antibiotics, and other interventions that have brought so many diseases under control.

Those discoveries are not the end of the story nor the end of the need for good science. New knowledge and new technologies present human beings with choices. How those choices are made is as important to their ultimate effect on health as the knowledge and technologies themselves. And how those choices are made is as much in need of a scientific approach – an approach based on asking searching questions, seeking empirical evidence to address those questions, reasoning carefully about the evidence, and presenting the evidence and reasoning transparently so that others can understand, attempt to replicate, and agree or disagree with the conclusions.

Cost-effectiveness analysis and cost-benefit analysis are two important components of the science of decision making for health. Both have made great strides in recent decades not only in their scientific methods but also in their use for real-world decisions. I will describe them in this paper, sketch some of the methodological progress, and present examples to show how they have contributed to better health in high-income countries. They are not the only components of scientific decision making, and I will mention others, such as systematic reviews and meta-analysis, in the course of this paper. All these components support democratic decision-making processes, which have themselves benefited from scientific inquiry, and which I will touch on at the end of the paper.

THE DECISION CONTEXT: An International Perspective

It is well-known to this audience that the United States spends a much larger share of its national income on medical care than any other country, 18 cents of every dollar in 2011 (Table 1). This is 50% more than the next highest spender and almost double the amount spent by still other high-income countries.

By rights then, the U.S. should have the best health in the world, including the longest life expectancy. Instead U.S. life expectancy at birth is 1 to 4 years shorter than in the other high-income countries in Table 1. The deficit continues across the lifespan, with U.S. life expectancy at age 65 also less than that in most of the other countries and no better than equal to the rest. Figure 1 shows that the situation has only gotten worse in recent years, as U.S. life expectancy

has risen more slowly than that of other high-income countries. (The figure is for women. The IOM report contains a similar figure for men.)

The differences do not arise from medical science. All these countries have access to the same scientific evidence and the same medical technologies as the United States. The same medical equipment, medications, and surgical procedures are available to all. The science base in medicine is so international that all countries, including the U.S., routinely rely on randomized controlled trials and epidemiological studies conducted in the populations of other countries, not just their own. More than half the clinical trials registered on [clinicaltrials.gov](http://clinicaltrials.gov/ct2/search/map) are located outside the U.S. (<http://clinicaltrials.gov/ct2/search/map>). The Cochrane Collaboration, with branches around the world, bases its systematic reviews of what works in medicine on all the evidence, not just evidence for one, or a few, countries (<http://www.cochrane.org/cochrane-reviews>).

The central thesis of this paper is that differences in health across these countries arise in large part from differences in medical policy – in the way medical choices are made at the national level. To appreciate the difficulty of choosing well, consider the enormous range of possibilities facing decision makers. The medical sector alone offers many kinds of preventive care, acute care, chronic disease management, rehabilitative care, palliative care. Public health programs may fall in the medical sector or may cross sectors. An even wider range of activities outside of medicine is important for health and life expectancy: water and sewage systems; safe handling of food and related inspections of food imports, manufacturing plants, and restaurants; building codes and construction methods; safety regulation and safe manufacture of consumer products; safe design and maintenance of roads, bridges, train tracks, airports; regulation of environmental pollutants, and on and on.

How can decision makers select the best ways to improve health from this vast array? That is the question addressed by the science of decision making in health. It may not be coincidental that the countries that do better than the U.S. – longer life expectancies, despite spending less of their national income on medical care – have been quicker to use those methods to help set priorities. Their better health does not derive from better scientific knowledge, or better medical technologies, but from better choices.

The social sciences have studied how people make choices, how they can be misled or misconstrue choices, and how they can make choices that best serve their goals. Decision scientists have developed methods to help people make choices. The goal of these methods is to provide a formal process for evaluating decisions in order to help decision makers identify the best choices – the choices that serve their values and the values of those they represent – in situations where it is difficult for them to do so unaided.

Cost-effectiveness analysis, which grew out of operations research and then began to blend with cost-benefit analysis, is a central decision-support method used in the medical sector. I describe it next, sketch its scientific evolution, and provide examples showing how it aligns with decisions about medical care in the U.S., Canada, and the United Kingdom. Cost-effectiveness analysis is less useful for the wider range of choices that affect health, those outside the medical sector. So I next discuss cost-benefit analysis, which comes from economics, and provide examples of its use.

It is important to remember that every high-income country, including the U.S., provides medical services, and many other services crucial to good health, through systems that are largely financed by people other than those who receive the services or who make decisions about them. These decisions thus involve public goods, or what Nobelist Elinor Ostrom terms “social dilemmas”, and are often made by public groups of one sort or another (Ostrom 1998). That being the case, I conclude the paper by turning briefly to the processes of which cost-effectiveness and cost-benefit analysis are a part – the processes for making decisions about the social dilemmas of health in representative democracies. Because, as everyone agrees, cost-effectiveness and cost-benefit analysis are aids to decision making, not the entire decision making process, and the processes matter to the quality and validity of the decisions.

COST-EFFECTIVENESS ANALYSIS: A Guide to Better Decisions

Cost-effectiveness analysis (CEA) begins with the objective of maximizing health subject to a budget constraint. In other words, if \$3 trillion is available for medical care for the U.S. population (Centers for Medicare and Medicaid Services), CEA asks, what services should be purchased with that money to produce the best possible health for U.S. citizens?

The next step is conceptually simple. Evaluate the choices – the alternatives facing decision makers – in the terms established by the objective (health) and the constraint (costs). Make sure to include whatever is already being done, the status quo, among the alternatives. Based on the scientific evidence, estimate how much each alternative contributes to health and how much it costs. Then rank the alternatives in terms of their contributions to health, starting with the one that contributes the least, and compare them.

Table 2 presents a particularly straightforward CEA, published in 1993, of tetanus boosters for adults. The purpose of the analysis was to evaluate the U.S. Centers for Disease Control and Prevention’s recommendation that adults receive routine boosters at intervals of 10 years after the completion, at age 6, of a full schedule of childhood vaccinations. The analysis estimated the costs and years of life of three alternatives: no routine boosters after age 6; a single booster at age 65; and the recommended boosters every 10 years. All three alternatives included boosters for deep wound injuries. (The authors identified a single booster at 65 as worth considering based

on evidence that the rate of tetanus in the U.S., although low, rises sharply with age.) Projecting outcomes for a cohort of 3.6 million 6-year-olds over 80 years, they estimated that boosters at 65 would prevent about 300 cases of tetanus, compared with no routine adult boosters. Boosters every 10 years were estimated to prevent an additional 500 cases.

The alternatives are arranged in Table 2 in order of effectiveness, starting with no routine boosters, the least effective. If a more effective alternative costs less, the decision is easy. The less effective alternative can be eliminated from the choice set.

In this case, however, as commonly happens, greater effectiveness comes at higher cost, making the decision more difficult. So the next step is to compare alternatives two at a time, calculating a cost-effectiveness ratio to summarize the comparison. A cost-effectiveness ratio, often called an incremental cost-effectiveness ratio (ICER), is the difference in health between two alternatives, divided by the difference in their costs. For a single booster at age 65 compared with no routine boosters, the cost-effectiveness ratio is $(\$0.074 - \$0.060)/(19.464529 - 19.464526)$, which yields a cost-effectiveness ratio of \$4,500 for each year of life gained, in 1986 dollars. Scaled up to 2012 price levels, a single booster at 65 would cost an additional \$15,800 for every year of life gained, compared with no routine boosters after age 6. This is very reasonable compared with many interventions routinely offered in high-income countries.

The comparison between boosters every 10 years and a single booster at age 65 is strikingly different. Boosters every 10 years cost an additional \$281,700 in 1986 dollars for each year of life gained – almost \$1 million in 2012 dollars.

That comparison, health for dollars, is the central contribution of CEA. CEA does not ask how much an intervention costs per person – not very much as Table 2 shows. Nor does it ask how much the vaccine costs per dose; the study used a price of 43 cents per dose (and assumed no additional cost for administering it). Even today a single dose costs a dollar or two (U.S. Centers for Disease Control and Prevention). By these measures it would hardly seem worthwhile to take the trouble to evaluate such an inexpensive intervention.

CEA asks: How much does it cost to contribute to the objective – good health? What is the cost in relation to what we really care about, health? Cost per dose, or cost per person, is not the point, and looking at those numbers, without looking further, can be misleading. It turns out that boosters every 10 years are a very expensive way to get more health.

That information by itself, however, is not enough to rule out boosters every 10 years. The next question is: What else is out there? What else can be done to improve health and how does that compare with boosters every 10 years?

To illustrate that next step, Table 3 presents cost-effectiveness ratios for a larger set of choices. The first column shows the alternatives compared, the second column the cost-effectiveness ratio for that comparison from the original study. The third column adjusts the original ratios to 2012 dollars, so they can be compared across studies. The final column flips each cost-effectiveness ratio on its head to bring attention back to the goal, better health: it shows the number of additional healthy years that can be produced by that intervention, compared with its alternative, for an expenditure of \$1 million.

The final column shows that there are many possibilities for improving health that make better use of health resources. Aspirin for men at high risk of heart disease is cost saving, an easy choice. Smoking cessation programs are next most productive, bringing 161 years for each \$1 million; the number reflects the cost-effectiveness ratios of a mixture of programs with different approaches, weighted by enrollment. Aspirin for lower-risk men, total knee arthroplasty for people at low risk of perioperative complications, and tetanus boosters at 65 are also productive choices.

Clearly tetanus boosters every 10 years would not be at the top of the list. But neither would it automatically be rejected. The guideline for using cost-effectiveness analysis is to select the most productive choices first – the ones that contribute the most to health – and keep selecting as long as the resources hold out. If sufficient resources are available to provide all the interventions, all would be provided. If the resources are used up by interventions that provide more health, boosters every 10 years would not be provided.

Or *should* not be provided. The title of the table includes the economic term “opportunity cost”. The opportunity cost of a choice is the benefit lost because of that choice. Good decisions bring the most benefit – whatever was not chosen would have brought less. Table 3, last column, illustrates the concept. If boosters every 10 years are chosen and smoking cessation programs are not, each year gained from tetanus boosters has an opportunity cost of 161 years, the years lost because smoking cessation programs were not provided.

This may be a good point at which to make clear that cost-effectiveness analysis is designed to set priorities, given that health is the objective. It does not set the budget. That comes from elsewhere. To be more explicit, *cost-effectiveness analysis is not a tool for controlling costs*. It is a tool for making the best possible use of whatever health resources are available. By itself cost-effectiveness analysis will not reduce U.S. medical spending, nor even reduce its growth rate. It can help the U.S. allocate medical spending more effectively, to improve health and move closer to the life expectancies achieved by other high-income countries, but it will not control costs.

THE SCIENTIFIC EVOLUTION OF CEA

The purpose of CEA is comparison – comparison of alternative health interventions in order to identify those that make the most productive use of resources. To serve that purpose CEAs need to be comparable. And, as Table 3 suggests, they need to be comparable across a wide range of very different interventions aimed at very different health conditions. When they are not comparable, they can lead to poorer choices, not better ones. Much of the methodological development over the 40-50 years since CEA was first applied in health has gone to making CEAs comparable. I will briefly describe two central developments: the Quality-Adjusted Life-Year and the Reference Case.

The Quality-Adjusted Life-Year was developed because a comprehensive measure of health is needed that allows comparisons of interventions that deal with different diseases. Cases of disease, used in some early CEAs, could not serve the purpose; the implications for health of a case of diabetes are very different from those of a case of influenza. Lives saved was an improvement, but did not take into account that some measures save many more years of life than others. Years of life, used in the tetanus booster study, improved on lives saved by giving more credit to interventions that saved many years, but does not give credit for improvements in the quality of life – less pain, better function – that are important contributions of some interventions.

And so the quality-adjusted life-year (QALY) was created (Gold 1996, chapter 4). QALYs are years of life with each year weighted by the state of health, or quality, of that year. Quality is measured on a 0-1 scale – 0 for death, 1 for perfect health. Weights are elicited from a representative sample of people using various methods: standard gamble, time tradeoff, paired comparisons, or rating scales. Early QALY systems were the Quality of Well-Being (QWB) scale, the Health Utilities Index, and the EuroQoL (now the EQ-5D and EQ-5D-5L). Health utility measurement, as it is often called, continues to be an active field of research. QALYs are the measure of choice in high-income countries. (Led by the World Health Organization, low-income countries use DALYs, disability-adjusted life-years, which are similar in concept, but work from a different goal post. Using Japan's life expectancy as the goal, DALYs measure the number of disability-adjusted life-years lost in each country and evaluate health interventions in terms of how many of those DALYs can be "averted", that is, gained.)

QALYs address a crucial issue, but CEAs need to be comparable in other ways as well: health states included in QALYs, resources counted and their valuation, discount rate, methods for exploring uncertainty, how results are reported, and much more. I was fortunate enough to co-chair, with Milt Weinstein, one of the early efforts to address the issue of the broader comparability of CEAs. The US Public Health Service convened the first Panel on Cost-Effectiveness in Health and Medicine in 1993 and asked the panel to assess the state of the field and provide recommendations for the conduct of CEAs "in order to improve their quality and

encourage their comparability.” (Gold, Introduction, xvii). Michael McGinnis, Assistant Surgeon General (retired), explained: “The overarching goal for this work has been to move the field forward so that over the next decade, state and federal decision makers will have access to robust information with respect to the true cost per health effect gained for the continuum of health-related interventions – be they preventive, palliative, curative, or rehabilitative.” Thus, at the outset, the panel’s charge directed it to take a broad view and consider how CEA could inform decisions across the entire range of health interventions.

To meet that charge the panel’s recommendations defined a “reference case” analysis (Gold 1996; Russell 1996; Weinstein 1996; Siegel 1996). In the words of the panel “To promote comparability of CEAs ..., the panel proposes that studies include ... a reference case. The reference case is defined by a standard set of methods and assumptions. It includes a set of standard results: the reference case results. While an investigator might also present results based on different methods and assumptions to serve the other purposes of the analysis, the reference case serves as a point of comparison across studies. *It should be included whenever the CEA is intended to contribute to decisions about the broad allocation of health care resources.*” (Russell 1996:1173, italics added)

In the last 20-25 years cost-effectiveness analysis has become an integral part of decision making in many health agencies around the world and the reference case has been a powerful organizing principle – and a popular name for the resulting standards. Those agencies, like Australia’s Pharmaceutical Benefits Advisory Committee (PBAC), the Canadian Agency for Drugs and Technologies in Health (CADTH), and the United Kingdom’s National Institute for Health and Care Excellence (NICE) each have their own guidelines for economic evaluations, designed to promote comparability across the studies that inform their recommendations (PBAC 2008, CADTH 2006, NICE 2013). In addition, the World Health Organization (WHO) has guidelines for cost-effectiveness analysis (WHO 2003) and the Gates Foundation is engaged in developing its own reference case.

Since the first panel published its recommendations many strands of research have contributed to the improvement of CEA. They include better methods for systematic review and meta-analysis of the health and medical literature, which have contributed to better estimates of the parameters needed for CEAs. Groups like PRISMA (<http://www.prisma-statement.org/>) and the Cochrane Collaboration (<http://www.cochrane.org/cochrane-reviews>) have been particularly important as well as reports like the Institute of Medicine’s *Finding What Works in Health Care: Standards for Systematic Reviews* (<http://www.iom.edu/Reports/2011/Finding-What-Works-in-Health-Care-Standards-for-systematic-Reviews.aspx>). Advances in simulation modeling, another methodology fundamental to CEA, and standards for modeling, have also been important; I would mention NIH’s CISNET modeling network (<http://cisnet.cancer.gov/about/>) and the

recommendations of the 2012 ISPOR-SMDM Modeling Good Research Practices Task Force (Caro 2012).

HOW CEA RESULTS ALIGN WITH NATIONAL CHOICES

Let me now turn to examples that illustrate the differences in medical choices between the U.S. and two other English-speaking countries, Canada and the United Kingdom. Both Canada and the U.K. spend much less of their national income on medical care, yet have longer life expectancies at birth and at age 65 (Table 1). Both countries consider cost-effectiveness in setting medical policies, at the provincial level in Canada and the national level in the U.K., and have increasingly formalized the use of CEA in recent years. The U.K. created the National Institute for Health and Care Excellence (NICE) in 1999 to recommend services to be provided by the National Health Service (NHS). NICE includes an economic evaluation – a CEA – in every appraisal and has become a world leader in cost-effectiveness methods. (In support of my earlier point that CEA is not a cost-control mechanism, NICE was created at the same time that the Blair administration, as a matter of policy, increased spending on the NHS to bring health spending's share of national income up to the average for Europe.) CEA also plays a role in decisions made by Canada's provincial health plans. I will provide more detail in the section on process, which includes the process in Ontario, home to almost 40% of Canadians.

Tetanus boosters. Consider the recommendations for tetanus boosters in the U.S., Canada, and the U.K. The CEA presented earlier showed that a single booster at age 65 is good value, but that routine boosters every 10 years are an expensive way to produce better health.

All three countries recommend a series of doses before the age of 6 – 5 doses in the U.K., 6 in the U.S. and Canada – followed by a booster just before or during adolescence. For adults, both the U.S. and Canada recommend boosters every 10 years. The U.K. does not recommend routine adult boosters. The NHS site says: “After the full course of five injections, you should have lifelong immunity against tetanus. However, if you or your child has a deep wound, it's best to get medical advice.” It also recommends that anyone traveling to a country with “limited medical facilities” get a booster first if their last one was more than 10 years ago.

The national recommendations are in line with national spending. The U.K., which spends only 9.3% of its national income on medical care, recommends the most limited use of boosters, not even including one at age 65. Canada, at 11.2%, and the U.S., at 17.9%, recommend routine adult boosters every 10 years.

The tetanus vaccine has been available for 90 years and these recommendations were probably not influenced by an actual CEA in any country. The CEA mindset, however – how does this intervention contribute to better health – would be easy to apply informally. A few back-of-the-

envelope estimates of the number of cases prevented and the cost of repeated boosters would point to the same conclusion. A formal analysis is not always necessary. Long before NICE, the U.K. led in applying the CEA mindset to decisions about the National Health Service (Russell 1979).

Cervical cancer screening. In 1981 Eddy published a CEA that evaluated the cost-effectiveness of screening for cervical cancer at different frequencies. Similar results from a 1990 article are shown in Table 4, updated to 2012 dollars.

No one questions that screening for cervical cancer is effective, but the CEA showed that its cost-effectiveness depends strikingly on its frequency. In most cases cervical cancer is a slow-moving disease; few new cases are discovered with annual screening and the cost, in health, of not catching them immediately is small, while the cost, in resources, of screening so often is large. As screening grows more frequent, the cost of an additional year of life rises sharply: Screening every year instead of every two years costs, in 2012 dollars, almost \$4 million for each year of life gained.

In response to the earlier study the American Cancer Society (ACS) changed its recommendation for annual screening and recommended screening every three years. The reaction, subsequently repeated in response to other recommendations to limit screening, persuaded the society to go back to its original recommendation despite the CEA results. In 2002 ACS tried again, recommending at least 3 years between screenings for women with negative tests. Yet U.S. physicians continue to conduct more frequent screening (Lefevre 2013; Berkowitz 2013).

The U.K. and Canada, along with other high-income countries that achieve longer life expectancies while spending less on medical care, have long recommended screening at 3-5 year intervals. The NHS introduced screening in the 1980s: “Women aged between 25 and 49 are invited for testing every three years, and women aged between 50 and 64 are invited every five years.” (<http://www.nhs.uk/conditions/cervical-screening-test/pages/introduction.aspx>) The Canadian recommendation are to begin routine screening at age 25, screen women 25-69 every 3 years, and stop screening women 70 and older who have had 3 negative screens in the last 10 years (Canadian Preventive Services Task Force, <http://www.cmaj.ca/content/185/1/35.full>). These recommendations are based as much on the benefit/risk considerations as on cost-effectiveness. For example, the Canadian Preventive Services Task Force notes: “...the recommended 3-year interval balances the small incremental potential for benefit from shorter intervals against the greater potential for harm from increased testing and procedures with more frequent screening. Most countries outside North America use 3- or 5-year intervals.”

Table 5 underscores the point with results from a 2004 Commonwealth Fund survey of 5 countries, which shows that the U.S. screens more frequently than Canada, the U.K., Australia,

or New Zealand, for both cervical and breast cancer. All those countries spend less to achieve longer life expectancies. (New Zealand is not included in Table 1, but spends about 10% of national income on medical care and has a life expectancy of 81 years.)

COST-BENEFIT ANALYSIS: Looking for Health beyond Medical Care

For choices in the medical sector, a comprehensive measure of health like the QALY is sufficient to measure everything of value that is gained from an alternative, or almost everything. Choices that fall outside the medical sector may involve substantial benefits of other kinds in addition to better health. Good decisions require that everything of value be considered in making a choice. But how to aggregate the different benefits? Some form of aggregation, of summarizing benefits (and costs), makes it easier to compare alternatives and to give appropriate weight to each benefit. When benefits are not summarized decision makers, overwhelmed with information, may focus on one or two and lose sight of the rest.

Cost-benefit analysis (CBA) allows the aggregation of health and non-health benefits because it values benefits, as well as costs, in money terms. In the United States the Office of Management and Budget requires that a cost-benefit analysis be performed for all ‘economically significant’ regulations proposed by federal agencies (<http://www.reginfo.gov/public/jsp/Utilities/faq.jsp>).

Under this requirement many of the U.S. Environmental Protection Agency’s regulations, which involve substantial health as well as non-health benefits, are subject to CBA (Robinson 2007). In 2011, for example, EPA published a CBA of the 1990 Clean Air Act amendments, which compared their costs and benefits to those of the legislation in force when they were enacted, the 1970 Clean Air Act and 1977 amendments (US EPA, 2011). The analysis valued a variety of benefits: reductions in mortality and illness; improvements in visibility at recreational sites and in residential areas; benefits to commercial timber, agricultural crops, and recreational fishing; and reduced materials damage. The report noted that other potential, and even known, benefits had been identified but left unvalued (page 19): “... many beneficial outcomes involving human health or environmental improvement could not be expressed in terms of economic values because the scientific and economic studies to support such valuations remain inadequate or unavailable.”

Costs (public and private) and benefits were projected to rise over the three decades covered by the analysis, 1992-2020, with benefits consistently much greater than costs: by 2020 benefits were projected to reach almost \$2 trillion, compared with \$65 billion in costs (US EPA 2011, page 2 and Exhibit 1; 2006 dollars). Mortality benefits made up 90% of the monetized benefits (Exhibit 11). For those uncomfortable with valuing lives and health in money terms, the report included a rough cost-effectiveness ratio: the projected cost per life saved in 2020 was \$280,000 (page 21). If each premature death avoided means 5 more years of life, on average, that works

out to \$56,000 per year of life, or 18 years of life for \$1 million. The calculation ignores, of course, non-health benefits.

Table 6 details the projected health benefits, in natural units, for the two pollutants for which epidemiological evidence is strong and supports projections, fine particles and ozone. For other pollutants, such as carbon monoxide, estimates of the health benefits were not possible, e.g., because their effects could not be distinguished from those of other co-occurring pollutants.

This CBA served to confirm that a choice that had already been made was, and continued to be, beneficial: the benefits exceed the costs by a wide margin. It is more difficult to find evidence to show how CBA contributes earlier in the process, when choices are being considered but have not yet been made, because not all of the process is open to public view. As proponents of CEA and CBA often point out, the framework itself, and the experience of working with that framework, can shape the alternatives considered and the final choice in significant ways, leading participants to uncover new technological options, evidence for new health and non-health effects, better ways to value those effects, and new ideas for institutional arrangements to address a problem, in addition to testing their views of the costs and benefits of each option against careful estimates (Robinson 2011; Lisa Robinson, personal communication).

Nichols' history (1997) of an early CBA of regulations to reduce lead in gasoline shows how CBA can work prospectively to help identify promising alternatives and make decisions. Lead levels in gasoline had been substantially reduced by the early 1980s, in part because other environmental regulations required cars to be outfitted with catalytic converters, which fared better with unleaded gasoline. EPA was under no outside pressure to do more. But evidence suggested substantial benefit from reducing lead in gasoline still further. When a preliminary analysis supported the idea the agency proceeded with a full CBA and a regulatory proposal. Ultimately, the new regulation, to reduce lead in gasoline from 1.1 grams per leaded gallon to 0.1 grams, went into effect in 1985.

In Nichols' words the CBA "played a key role in shaping the rule". It showed, for example, that reducing lead to 0.1 per leaded gallon would yield substantial benefits at reasonable cost, but that a complete ban might cause problems for heavy agricultural machinery; so EPA considered, but did not propose, a ban. (Congress included a ban in the 1990 Clean Air Act Amendments). Although sensitivity analyses indicated that only under very unlikely circumstances might refineries fail to meet the schedule for reducing lead, analysts designed a lead banking program to make the transition still easier: refineries that reduced lead ahead of schedule could save the difference to use later or to sell to other refineries. As a third example, after the analysis began, EPA staff learned of new evidence that linked lead in gasoline to hypertension in adults.

The final CBA considered four very different kinds of benefit: (1) health benefits to children because less lead in gasoline would reduce the number who suffered physical and cognitive problems from elevated blood lead levels; (2) less damage to catalytic converters and thus better control of conventional pollutants; (3) lower expenditures on car maintenance because of less misfueling (use of leaded gas in cars designed for unleaded); and (4) fewer deaths and less morbidity due to less hypertension.

Valuing benefits in money terms allowed these different benefits to be aggregated and showed their importance relative to each other. The first three categories of benefit – children’s health, conventional pollutants, and car maintenance – were projected to be \$1,657 million in 1988, well above the projected additional refining costs of \$532 million (both 1983 dollars). The benefits from reducing hypertension were far larger: an additional \$5.4 billion, bringing total benefits to about \$7 billion. The agency’s legal counsel advised, however, that the hypertension benefits could not be used to support the legal case for regulation because the scientific evidence for the lead-hypertension link had not yet been peer reviewed. So the results were presented two ways – with and without the benefits from reducing hypertension. The hypertension benefits served to make the conclusion more robust: benefits exceeded costs.

It may be worth spending a little space to discuss the science behind the valuation of benefits in cost-benefit analysis. The social sciences, as I mentioned earlier, study how people make decisions and the circumstances under which they make the best decisions, those that bring them what they want. Different social sciences have chosen different natural laboratories for this study. Economists’ natural laboratory is the market. The theory with which they approach real-world markets is the theory of the competitive market. In competitive markets, well-informed buyers and sellers, none of them large enough to manipulate the market, exchange money for goods; the buyers receive all the benefit of the good, the sellers incur the full costs of producing the good.

When these conditions hold, and only when they hold, market prices represent, at one and the same time, how much people are willing to pay for one more unit of the good and how much it costs to produce one more unit of the good. Buyers’ willingness to pay reflects a tradeoff – to obtain this good the buyer had to forego other goods. They had to value it more highly than other goods. It is the tradeoff between this good and other goods that is the fundamental measure of value, with money as the common medium for measuring different tradeoffs; the money price of a good represents the amount of other goods given up. The willingness to give them up signals that the buyer values this good more than the other goods. On the supply side the cost of producing the good reflects the value of the goods that could not be produced, the opportunity cost of producing this good instead of others. In short, the competitive market system is a system for working through values and allocating resources to their mostly highly valued uses.

In the real world, of course, many markets fall well short of the requirements for competitive markets – certainly most of the markets that make up the medical sector do. So they don't produce the kinds of outcomes that accurately reflect people's valuations of goods and services. The purpose of CBA – the reason it was developed – is to evaluate the pros and cons of choices that arise in poorly functioning markets, or that occur outside of markets altogether, and, in tallying those pros and cons, to approximate the results that would come naturally from competitive markets: measures of benefits for each alternative that correctly represent the willingness to pay of those affected, their true valuation; and measures of cost for each alternative that correctly represent the costs of production, their true opportunity costs.

Fifty years ago economists valued lives and health for purposes of cost-benefit analysis at the present value of future earnings (Russell 2013). Several economists, including Drèze, Schelling, and Mishan argued that this was wrong (Jones-Lee 1985). They reasoned that life-saving should be valued at what the people affected would be willing to pay, the same principle that operates in the competitive market, and not by their discounted future earnings. By the 1980s the concept “that social decisions should, so far as possible, reflect the interests, preferences and attitudes to risk of those who are likely to be affected by the decisions” was accepted as a better way to think about valuing life-saving (Jones-Lee 1985).

Since then the basic principle in CBA has been that benefits should be valued as the people involved value them. Dollar valuations, like QALY weights, come from the people who will experience the benefits or from people like them. The methods used in the two CBAs I have described follow that principle: benefits are valued based on evidence from markets, or, if the good is not sold in markets, from related markets, evidence which reveals people's tradeoffs, their valuations. Lives saved, for example, are valued based on the tradeoffs revealed in labor markets, between wages and risk of death or injury on the job (Robinson 2007). The analysis of lead in gasoline was an early case of the use of this “value of a statistical life”.

The willingness-to-pay principle in CBA has been criticized for its link to people's incomes – people with more money can be “willing” to pay more than people with less money. In actual CBAs, this problem is at least somewhat attenuated by using average willingness to pay. CBA has also been criticized for ignoring the distributional consequences of decisions based on CBA, just as QALYs have been criticized for treating all QALYs as equal. Such criticisms are reasons why the process to which CEA and CBA contribute is important. I turn to that process now.

THE PROCESS of which CEA/CBA is a part

Everyone agrees that CEA and CBA are aids to decision making, not machines that produce decisions all by themselves without human intervention. A cost-effectiveness or cost-benefit analysis is one element in a larger decision-making process. That process is often spelled out in

legislation, agency guidelines, or the opening decisions of committees, and involves many of the elements we associate with good science and representative democracy.

The process is as important as the CEA or CBA. This section sketches some features of the process, or processes, to which CEA and CBA contribute. This is not my area of expertise, so it is not a comprehensive summary – only a few examples that point to the importance of process and to some common elements that, in many cases, we simply take for granted will be present.

Nichols' account of the lead in gasoline regulations contains numerous references to the process: the posting of a preliminary regulatory proposal and CBA, with a public comment period; the changes in the analysis and in the regulatory proposal as those involved learned more, sometimes from the public comments; the advice from legal counsel. Similarly, EPA's 2011 summary report on the 1990 Clean Air Act amendments makes frequent references to process. An example from the acknowledgements: "the full integrated report and this summary report were reviewed by the EPA Science Advisory Board's Advisory Council on Clean Air Compliance Analysis ... and its three technical subcommittees." The three technical subcommittees specialized in air quality modeling, health effects, and ecological effects.

In Canada, the Ontario Health Technology Advisory Committee (now Health Quality Ontario, <http://www.hqontario.ca/>), created in 2003 to advise the Ontario Ministry of Health and Long Term Care about nondrug technologies, has developed a multi-criteria decision framework to guide its deliberations. An article describing the framework states: "Designing a process that weighs scientific evidence appropriately, takes cost and values into consideration, and makes decisions fairly is not straightforward." (Johnson 2009) Only technologies approved by Health Canada, whose duties include safety and efficacy regulation of drugs and health products, are considered. Once the technology comes to Health Quality Ontario the committee considers four categories of criteria, detailed in the article, in making its recommendation: "(i) overall clinical benefit, (ii) consistency with societal and ethical values, (iii) value for money, and (iv) feasibility of adoption into the health system." Cost-effectiveness analysis, number 3, only one of the four categories.

In the U.K., the National Institute for Health and Care Excellence (NICE) is known for giving cost-effectiveness analysis a central role in making recommendations to the National Health Service. Yet the overview of the decision making process, the 93-page *Guide to the Methods of Technology Appraisal 2013*, spends at least as much time on the process of which CEA is a part as on guidelines for the CEA itself. Section 4 (7 pages), "Involvement and Participation," deals with the processes for ensuring that all points of view are represented, including patients, clinicians and manufacturers. Section 6 (10 pages), "The Appraisal of the Evidence and Structured Decision-making," discusses how an appraisal committee should be composed, what evidence it should consider, how it should seek and incorporate public comment, the social and

ethical values it is bound to take into account, the need for transparency in its deliberations, for clarity in explaining the reasons for its recommendations, and on and on. NICE explicitly states that “life-extending treatment at the end of life” may be evaluated differently from the general guidelines for cost-effectiveness, using a weighting of QALYs different from that for other technologies, so the process spells out the general approach and exceptions to that approach.

Any scientific, empirically based, method for evaluating choices requires projections of what will happen as a result of the choice. This is the contribution of CEAs and CBAs. And part of a good process is setting standards for those CEAs/CBAs: They are used to compare, so they must be comparable. I have mentioned some of the standards in the course of this paper. Here I want to point out that standards have been developed by every group that uses these decision-making tools. EPA, for example, explains that its *Guidelines for Preparing Economic Analyses* (2010) provide “(3) ...an overarching framework for economic analyses throughout the Agency and across EPA Program Offices; and (4) ensure that important subjects such as uncertainty, timing, and valuation of costs and benefits, are treated consistently in all economic analyses at EPA.” Standards for the analyses that inform decisions are part of defining the decision-making process.

The processes aided by CEA/CBA involve what Ostrom calls “social dilemmas” (Ostrom 1998). These are situations in which people need to act collectively to solve problems. She points out that behavioral experiments show that people act cooperatively much more often than would be predicted by theories based on pursuing individual self-interest. Further, “field research also shows that individuals systematically engage in collective action to provide local public goods or manage common-pool resources without an external authority to offer inducements or impose sanctions.” Whether we are hardwired to cooperate, or have learned to do so, there are many situations in which cooperation leads to better outcomes for everybody and human beings have the good sense to try to cooperate in those situations. Many of those decisions affect our health.

Ostrom reports two experimental findings that begin to explain how people arrive at cooperative solutions. First, talking face-to-face is important: “simple, cheap talk allows individuals an opportunity to make conditional promises to one another and potentially to build trust that others will reciprocate.” Notice, in this regard, the omnipresence of committees – committees that meet in person – in the decision making processes I have described. Second, people set up structures and rules that encourage cooperation and discourage refusal to cooperate, or, as Ostrom puts it, they “solve second-order social dilemmas that change the structure of the first-order dilemma.” ... “Most robust and long-lasting common-pool regimes involve clear mechanisms for monitoring rule conformance and graduated sanctions for enforcing compliance.” In this regard, notice the effort that goes into developing a process – who is represented on a committee, what evidence the committee is to consider, how the committee’s work is to be reviewed – as well as structures and regulations designed to enforce a decision once it is adopted, which I have not dealt with.

This is a story of people developing new techniques and new institutions to guide choices in social dilemma situations in medical care and public health. Social scientists who work with cost-effectiveness and cost-benefit analysis are contributing to that process. They might also fruitfully devote some of their scientific attention to the rest of the process. They could ask, What is this process that is aided by CEA/CBA? How well does it work? How could it be structured to work better? Some social scientists have been approaching the issue from the other side – the process rather than the CEA/CBA – and conversations among those working on the two sides might be useful. Ostrom has said: “...individuals temporarily caught in a social-dilemma structure are likely to invest resources to innovate and change the structure itself in order to improve joint outcomes.” CEA and CBA are part of changing the structure to improve the outcomes of decisions about health. What more can we do, as social scientists, to help?

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Table 1. Health Spending (as a percent of national income) and Life Expectancy at birth and at age 65, selected high income countries.

	Health \$	Life Expectancy		
	% of GDP, 2011	At birth, 2011	At 65, 2009	
			Men	Women
United States	17.9	79	17	20
Netherlands	12.0	81	17	21
France	11.6	82	18	23
Canada	11.2	81	18	21
Denmark	11.2	80	17	20
Germany	11.1	81	18	21
Switzerland	10.9	83	19	22
Greece	10.8	81	18	20
Austria	10.6	81	18	21
Belgium	10.6	80	18	21
Italy	9.5	82	18	22
Spain	9.4	82	18	22
Sweden	9.4	82	18	21
Japan	9.3	83	19	24
United Kingdom	9.3	81	18	21
Norway	9.1	81	18	21
Australia	9.0	82	19	22
Finland	8.9	80	17	22

Sources: % of GDP and life expectancy at birth from the World Bank, *World Development Indicators 2013*. Life expectancy at 65 from *Health at a Glance 2011: OECD Indicators*

Table 2. Cost-effectiveness analysis of adult tetanus boosters

	Per person		Discounted at 5%/year			ICER, 2012
	Undiscounted	Life	Cost*	Life	ICER*	
	Cost*	expectancy	Cost*	expectancy	ICER*	
No routine booster	\$0.832	68.315319	\$0.060	19.464526		
Booster at age 65	\$0.996	68.315417	\$0.074	19.464529	\$4,500	\$15,800
Booster every 10 yrs	\$4.135	68.315464	\$0.919	19.464532	\$281,700	\$986,100

* Incremental cost-effectiveness ratio, 1986 dollars, rounded to the nearest hundred. All three alternatives include a booster in the event of a deep wound.

Source: Balestra DJ, Littenberg B. *J Gen Intern Med.* 1993;8:405-412.

Table 3. Opportunity Costs: Healthy Years for \$1 million, selected interventions

	Cost per healthy year (original year \$)	Cost per healthy year (2012 \$)	Healthy years per \$1 million (2012 \$)
Tetanus boosters (<i>Balestra and Littenberg 1993</i> , and Table 2)			
Booster at age 65	4,527 (1986)	15,845	63
Booster every 10 years	281,748 (1986)	986,118	1
Total knee arthroplasty (TKA) for advanced knee osteoarthritis (<i>Losina 2009</i>)			
TKA, low risk of perioperative complications	9,700 (2006)	11,971	84
TKA, medium risk of complications	18,700 (2006)	23,077	43
TKA, high risk of complications	28,100 (2006)	34,678	29
Aspirin to prevent heart disease (<i>Pignone 2006</i>)			
men 45, 10-year risk 2.5%	9,800 (2003)	13,686	73
men 45, 10-year risk 5.0% or higher	cost-saving	cost-saving	cost-saving
Mammography for breast cancer (<i>Mandelblatt 2003</i>)			
women 50-79, screened every 2 years	25,021 (2002)	36,349	28
Screening for diabetes (<i>Hoerger 2004</i>)			
age 55/high blood pressure vs no screening	34,375 (1997)	60,794	16
all adults 55 vs adults w high blood pressure	360,966 (1997)	638,384	2
Screening once for HIV (<i>Paltiel 2006</i>)			
HIV prevalence = 1.0%	30,800 (2004)	41,209	24
HIV prevalence = 0.1%	60,700 (2004)	81,214	12
Diet/exercise to prevent diabetes (<i>Eddy 2005</i>)			
adults at high risk of diabetes	143,000 (2000)	227,495	4
adults with diabetes	35,400 (2000)	56,317	18
Smoking cessation (<i>Cromwell 1997</i>)			
15 programs weighted by % enrolled	3,294 (1995)	6,198	161

Table 4. Opportunity costs: Cervical cancer screening by screening interval

Screening intervals compared	Cost per year of life gained (2012 \$)	Life-years per \$1 million
every 3 years vs no screening	\$48,618	20.57
every 2 years vs every 3	\$1,534,582	0.65
annually vs every 2 years	\$3,890,556	0.26

Source: Eddy DM. Annals of Internal Medicine. 1990

Table 5. Clinical Preventive Care in Five Countries, 2004

	Australia	Canada	New Zealand	U.K.	U.S.
Pap test or cervical smear, women 25-64					
In past two years, %	68	70	69	58	85
Mammogram, women 50-64					
In past two years, %	71	71	77	63	84

Source: Schoen C, Osborn R, Huynh PT, Doty M, Davis K, Zapert K, Peugh J. Primary Care And Health System Performance: Adults' Experiences In Five Countries. Health Affairs. 2004 Web Exclusive: W4-487-W4-503.

Table 6. Health Effects of the 1990 Clean Air Act Amendments, numbers of cases, 2010 and 2020

Health Effect Reductions			
(PM2.5 & Ozone Only)	Pollutant(s)	Year 2010	Year 2020
PM2.5 Adult Mortality	PM	160,000	230,000
PM2.5 Infant Mortality	PM	230	280
Ozone Mortality	Ozone	4,300	7,100
Chronic Bronchitis	PM	54,000	75,000
Acute Bronchitis	PM	130,000	180,000
Acute Myocardial Infarction	PM	130,000	200,000
Asthma Exacerbation	PM	1,700,000	2,400,000
Hospital Admissions	PM, Ozone	86,000	135,000
Emergency Room Visits	PM, Ozone	86,000	120,000
Restricted Activity Days	PM, Ozone	84,000,000	110,000,000
School Loss Days	Ozone	3,200,000	5,400,000
<u>Lost Work Days</u>	<u>PM</u>	<u>13,000,000</u>	<u>17,000,000</u>

Source: US Environmental Protection Agency 2011. Exhibit 8. Differences in key health effects outcomes associated with fine particles (PM2.5) and ozone between the *With-CAAA* and *Without-CAAA* scenarios for the 2010 and 2020 study target years. (In number of cases avoided, rounded to 2 significant digits). The table shows the reductions in risk of various air pollution-related health effects achieved by 1990 Clean Air Act Amendment programs, with each risk change expressed as the equivalent number of incidences avoided across the exposed population.

Figure 1. Female life expectancy at birth, 1980-2005

Source: Institute of Medicine, *U.S. Health in International Perspective: Shorter Lives, Poorer Health* (2013), http://books.nap.edu/catalog.php?record_id=13497

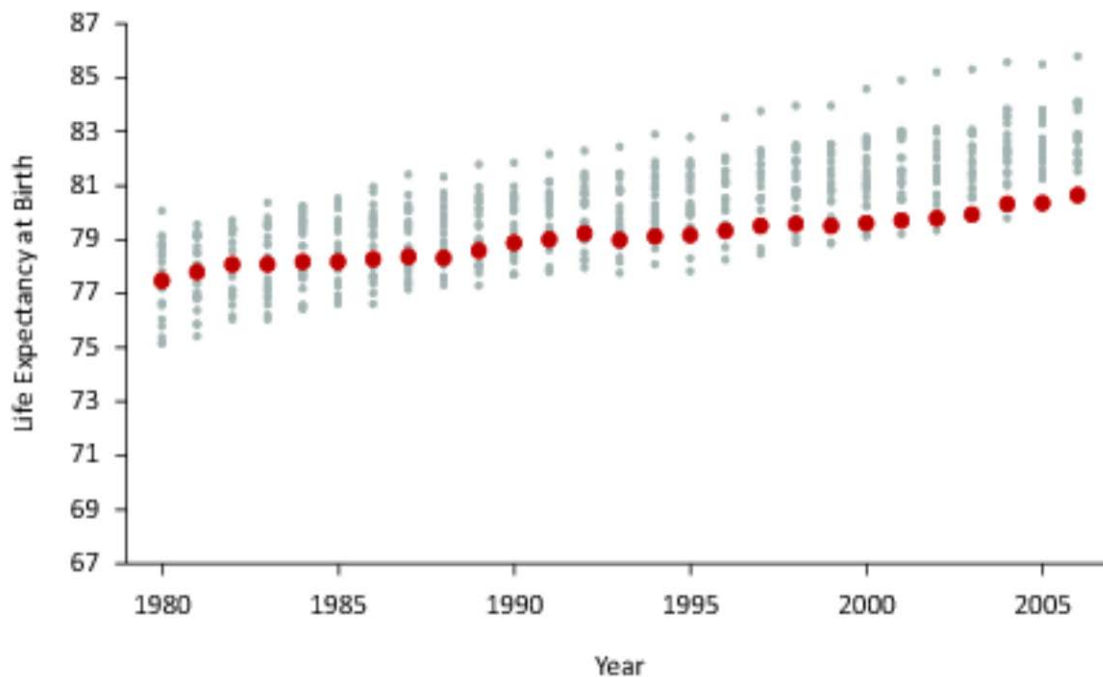


FIGURE 1-6 U.S. female life expectancy at birth relative to 21 other high-income countries, 1980-2006.

NOTES: Red circles depict newborn life expectancy in the United States. Grey circles depict life expectancy values for Australia, Austria, Belgium, Canada, Denmark, Finland, France, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom, and West Germany.

SOURCE: National Research Council (2011, Figure 1-4).