hygienic practice, there remains a risk of infection from the use of contaminated ink. People who get tattoos must be made aware of this risk and should seek medical attention if lesions consisting of red papules or a diffuse macular rash develop at the tattoo site. Consumers should patronize artists who use sanitary tattooing practices and who can confirm that their inks have undergone a process that eliminates harmful microbial contaminants.

In light of the recent tattoo ink–related outbreaks of nontuberculous mycobacterial infection, the FDA is committed to pursuing educational and outreach efforts to health care providers, public health officials, consumers, and the tattoo industry. Our messages seek to raise awareness, improve diagnosis, and encourage adverse-event reporting, with the intent of preventing future infections. The FDA encourages health care providers, public health officials, consumers, and tattoo artists to use MedWatch to report to the FDA any tattoo-related infections and any other adverse events related to tattooing.[3] The agency will continue to collaborate with other public health partners in investigating reported adverse events, identifying root causes, and taking the actions necessary to prevent future illnesses.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From the Food and Drug Administration, Center for Food Safety and Applied Nutrition, College Park, MD.

This article was published on August 22, 2012, at NEJM.org.

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DOI: 10.1056/NEJMp1206063

There Is More to Life Than Death

Pamela Hartzband, M.D., and Jerome Groopman, M.D.

Physicians and patients alike crave certainty. We all want to know that we're making the best decisions about our health. But how do we know what's best? The value of screening tests such as mammograms, prostate-specific antigen (PSA) measurements, colonoscopies, electrocardiograms, and routine physical examinations has recently been called into question. Expert groups have made sweeping recommendations regarding such testing that will significantly affect medical practice.

Numbers and formulas convey a sense of certainty and seem to provide a scientific and rational basis for making medical decisions. Classic medical decision analysis, widely used by expert groups, is based on the work of Daniel Bernoulli, an 18th-century mathematician who devised a formula to determine the "best" choice.[1] When an outcome is uncertain and the choice involves risk, this "best" choice is the option with the "highest expected utility." To find that number, you multiply the probability of a given outcome by the utility, or impact, of that outcome: (probability of outcome) × (utility of outcome) = expected utility. In economics, the probability of a future outcome might refer to the likelihood of selling a certain number of products. The utility is generally calculated in monetary terms — the effect on the bottom line. This formula has been imported into medicine, where decisions invariably involve risk and uncertainty. In clinical decision analysis, the outcome that is generally measured is death. This outcome fits neatly into the Bernoulli formula. Death is readily determined, easily quantified, concrete.

For example, the U.S. Preventive Services Task Force (USPSTF) based its recent recommendation against routine PSA screening largely on the U.S. Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial that showed no difference in mortality between a PSA-screened group and a control group. This expert panel concluded that the harm from treatment of prostate cancer that was diagnosed through PSA testing outweighed any benefit. The chairperson presented the result of the panel's analysis

with certainty: "It's obvious," a "no-brainer."[2] The PLCO study has been criticized for methodologic deficiencies, including the prescreening of 40% of study subjects before enrollment and greater than 50% "contamination" of the control group due to nonprotocol PSA testing. Furthermore, epidemiologic data show a 40% decrease in the number of deaths due to prostate cancer since the advent of PSA testing in the United States, with no other proven explanation.

But what of outcomes other than death? Epidemiologic data show a 75% decrease in the number of men presenting with advanced prostate cancer since the introduction of PSA screening. And in the European Randomized Study of Screening for Prostate Cancer (ERSPC), the incidence of locally advanced and metastatic cancer was 40% higher in the control group than in the PSA-screened group.[3]

How do we balance the possibility of a later life with advanced prostate cancer marked by bone pain, pathologic fractures, and urinary obstruction against the more immediate symptoms of incontinence and impotence that often follow surgical or radiation treatment of early-stage prostate cancer? Is it possible to put numbers on the "utility" or impact of these conditions on a man's life?

Similarly, the USPSTF concluded that the absolute benefit from routine mammograms in women 40 to 49 years of age was insufficient to offset the harm, including false positive results leading to anxiety and unnecessary biopsies. A statistician on the panel also used the term "no-brainer" when interviewed by the *New York Times* about this conclusion. But mammography increases the likelihood of identifying breast cancers that are small enough to be treated with conservative therapy such as lumpectomy and reduces the need for mastectomy and chemotherapy.

So for a woman in her 40s, how do you balance the anxiety and discomfort associated with undergoing a biopsy for a false positive mammogram against the possible need for more extensive surgery, radiation, or chemotherapy for a larger cancer detected later in life? Again, how can we quantify the "utility" or impact of these conditions on a woman's life?

Classic decision analysis has adopted several methods for doing just that. One method is the time tradeoff, in which a healthy person is asked how many years of life he or she would be willing to give up in order to reverse a medical condition and return to health. Another method is the standard gamble (derived from game theory), in which the person is asked to imagine that there is a magic pill that can prevent or reverse a certain medical condition but that also carries the risk of causing instant death. What odds between perfect health and instant death would you be willing to take? Notably, death is the primary end point in both these methods.

But these calculations are profoundly flawed. They require people to imagine themselves in a health state that they haven't experienced. Even we, as physicians who have cared for many patients with a particular condition, find it difficult to accurately imagine what our lives would be like if we were living with that condition ourselves. This inability to forecast the future is attributable to what cognitive psychologists term the "focusing illusion." People cannot anticipate the global impact of a specific future change in their lives. Rather, they tend to focus on one aspect of the change and disproportionately weigh its effect on their lives.

For example, with regard to the treatment of prostate cancer, no man can predict what incontinence or impotence might mean for him. That's partly because impotence and incontinence vary in severity and may wax and wane. But people also have a remarkable capacity to adapt to such changes. Indeed, when quality of life is assessed by patients themselves, there is no difference in assessments between men with prostate cancer who underwent prostatectomy and those who chose active surveillance. There is often a profound disconnect between the way healthy people view medical conditions and the way patients with these conditions view themselves.

Daniel Kahneman, the cognitive psychologist and Nobel laureate, in addressing a meeting of medical decision analysts, likened efforts to quantify the experience of illness using these methods to the attempts of 19th-century physicists to measure the viscosity of the ether, which of course did not exist.[1] Yet these methods, though flawed, are widely used. In Britain, the National Institute for Health and Clinical Excellence (NICE) asks healthy British citizens to use such methods to assess what their lives would be like were they to become sick. NICE then uses the information to set priorities about screening tests and treatments for the National Health Service. In the United States, in the wake of health care reform, the same methods are being pro-

posed as ways to calculate the cost-effectiveness of various treatments and decide what is worth paying for. For example, an expert committee of the American College of Physicians recently issued a position paper based on the use of the time-tradeoff method for calculating quality-adjusted life-years (QALYs) and recommended a price of $65,000 per QALY as the cutoff for reimbursement.[4]

Paul Slovic, a leading researcher of risk, has pointed out that "when experts judge risk, their responses correlate highly with technical estimates of annual fatalities." He adds, however, that risk means much more to most people than simply numbers of deaths. "Their conceptualization of risk is much richer than that of the experts and reflects legitimate concerns that are typically omitted from expert risk assessments."[5]

Basing decisions on the outcome of death ignores vital dimensions of life that are not easily quantified. There are real complexities and uncertainties that we all, patients and physicians alike, confront in weighing risk and benefit. Wrestling with these uncertainties requires nuanced and individualized judgment. It is neither ignorant nor irrational to question the wisdom of expert recommendations that are sweeping and generic. There is more to life than death.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From Beth Israel Deaconess Medical Center and Harvard Medical School — both in Boston.

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DOI: 10.1056/NEJMp1207052