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Resolving Medical Controversies

Itzhak Jacoby*

Ongoing Controversies

Several factors ensure that the number of unresolved controversies concerning medical technology will increase. First, there are insufficient resources to perform all the experiments that could resolve them solely on the basis of scientific evidence. Even if the safety and efficacy is found for an experimental population, controversy may arise regarding the generalizability of the results to populations that differ by age, sex, race or ethnic origin, severity of the condition or other attributes. Uncertainties always need to be resolved by practitioners in practice, and variations in the application of a technology are endless.

Consider, e.g., the recent trial on carotid endarterectomy (for removing atherosclerotic plaque from the major blood vessels in the neck leading to the brain). One scientifically sound clinical trial showed this procedure safe and effective in preventing strokes from severely occluded carotid arteries. A second trial was required to prove efficacy for persons with *partial* occlusions. Left to the discretion of surgeons, insurers and patients is the degree of occlusion that justifies surgery in patients of a certain age, sex and set of comorbidities. A confounding factor is that the procedure improves function and reduces mortality from stroke but seems to have no effect on reducing overall mortality.

When ultrasound became available and was shown to be safe, it was believed useful to screen all pregnancies. Experience has shown that little useful information is obtained in uneventful pregnancies. One controlled study suggests that ultrasound prenatal screening in low risk pregnancies is associated with worse-than-otherwise outcomes.¹

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¹ Bernard G. Ewigman et al., *The Effect of Prenatal Ultrasound Screening on Perinatal Outcome: RADIUS Study Group*, 329 N. Eng. J. Med. 821 (1993).

The Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (DHHS), mandated that a type of breast implant be removed from the market. Also, a class action later obtained a \$4 billion settlement in favor of women who had received the implants. Yet, a study at the Mayo Clinic found no relationship between the implants and disease.²

Support for prostate cancer screening using the prostate specific antigen test is equivocal. It produces a high rate of false positives that could instigate unnecessary and potentially harmful treatment.³ Also, the indication for treatment of this slowly-developing cancer is doubtful. Nevertheless, there is a great deal of public pressure to use this screening test as well as to treat prostate cancer aggressively, as promoted in subway placards featuring movie stars and congressmen.

The Need for Resolution

The pace of renewal and replacement of medical technologies has markedly increased. For emerging technologies, issues of efficacy, cost-effectiveness and safety must be resolved. For a strong healthcare delivery system, it is critical to do so as expeditiously as possible. This rarely occurs, however, for lack of an effective process. Existing processes are neither timely nor efficient — nor are their outcomes widely accepted. Medical practice guidelines, recently more systematically developed, have been found to have little utility. Thus, voluble policy debates rage, often pitting advocacy groups against health insurers, with people's health and billions of dollars at stake.

Ambiguity about appropriate use of a medical technology leads practitioners to differ in its use and insurance coverage to vary. Scientific uncertainty multiplies the likelihood that individuals adversely affected or denied coverage will litigate and burden courts with the need to decide whether care or coverage decisions are

² Sherine E. Gabriel et al., *Risk of Connective-Tissue Diseases and Other Disorders After Breast Implantation*, 330 N. Eng. J. Med. 1697 (1994); Marcia Angell, *Editorial: Do Breast Implants Cause Systemic Disease? Science in the Courtroom*, 330 N. Eng. J. Med. 24 (1994).

³ M. D. Krahn et al., *Screening for Prostate Cancer: A Decision Analytic View*, 272 J.A.M.A. 773 (1994).

appropriate.⁴ Not surprisingly, therefore, such cases are increasingly litigated.⁵ Yet, they are often very costly and have inconsistent, if not capricious, outcomes.

When a woman died after a claim for bone marrow transplantation to treat breast cancer was denied, the family sued. A court awarded \$89 million. Lack of evidence of efficacy did not protect Blue Cross/Blue Shield (BC/BS) from liability.⁶ Coverage has since become more widespread, e.g., it was recently extended to all federal government employees.⁷

Current Options

Litigation determines fault in a given case but does not resolve the core controversy. Civil trials do not ensure that scientific evidence is complete or comprehensible — much less balanced. Its apparent merit may be influenced by verbal skills of witnesses or attorneys. The judge or jury may not be able to assimilate the information. In short, while legal decisions banish uncertainty by fiat, conflict about further use or coverage of a technology will continue until uncertainty is otherwise removed, directly and indirectly raising healthcare costs for everyone by stimulating defensive medicine. Judicial shortcomings are matched by deficiencies in its scientific counterparts. Thus, the need to develop a process to resolve medical controversies is urgent — particularly one that combines the best of judicial and scientific principles.

More than 50 agencies and organizations resolve medical controversies, including the FDA and the Health Care Financing Administration (HCFA),⁸ the American Medical Association, the American College of Physicians' medical specialty societies and insurance companies all participate in healthcare technology assessment.

⁴ Gina Kolata, *Implants: Courts Dispose While Science Unfolds*, The New York Times, June 19, 1994, § 4, at 5.

⁵ Cheryl P. Weinstock, *Lawyers Debate the Insurability of Bone-Marrow Transplants*, The New York Times, Mar. 20, 1994, § 13LI, at 18.

⁶ Erik Eckholm, *\$89 Million Awarded Family Who Sued H.M.O.*, The New York Times, Dec. 30, 1993, at A1.

⁷ Rich Spencer and David Brown, *Federal Worker Health Program to Add Benefits*, Washington Post, Sept. 21, 1994, at A1.

⁸ A DHHS agency that makes decisions on Medicare coverage.

HCFA and BC/BS each exert important influence. Specialty societies also occasionally provide leadership. For example, the American College of Ophthalmology recently resolved a controversy by stating that drug store nonprescription reading glasses are adequate for people with otherwise uncomplicated visual needs.

Also, the Agency for Health Care Policy and Research, a relative newcomer in DHHS, administers a program to develop standards of medical practice. This program gathers evidence and develops practice guidelines. Although its approach is logical, guidelines are costly to develop. Also, a recent evaluation suggests that they may only be marginally useful.⁹ About two-thirds of the applications of technologies covered by guidelines were found to fall outside the stated policies. Yet, they were considered by the evaluators to be within the bounds of good medicine. Medical groups and others ask whether appropriate individuals prepare guidelines and whether it is reasonable to expect them to cover the array of indications and contraindications involved in care decisions. Such programs tend to neglect the most difficult and controversial applications, further diluting their usefulness.

The completeness of evidence presented to a panel depends upon the skills of presenters invited by the conference planning committee. As in litigation, nothing assures balance. As with other scientific conferences, there is little advance scrutiny of evidence and no procedure for cross-examination. Sometimes, evidence is insufficient to support a rational decision. Opportunity for public comment is generally limited; and, although attendees and others can submit views in writing, there is no assurance that their views will be considered. Ironically, consensus development does not require that a panel take a stand on difficult issues. Thus, conclusions are often weak.¹⁰

Reforming a Process Based on "Science Court" Principles

Emulated internationally, the process used by the National Institutes of Health (NIH), also within DHHS, is the most visible of its

⁹ U.S. Congress, Office of Technology Assessment, *Identifying Health Technologies that Work: Searching for Evidence* (1994).

¹⁰ Drummond Rennie, *Consensus Statements*, 304 N. Eng. J. Med. 65 (1981).

kind. Panel members respond to pre-posed questions to produce a consensus reflecting their assessment of evidence. Panelists obtain information through briefing materials provided by NIH staff and invited scientists. Attendees can make public statements, but the consensus document is developed in executive session. It is presented at a press conference on the morning of the third day.¹¹

Despite a logical construct, consensus conferences now have flaws. For example, NIH sponsors are themselves stakeholders. That topics are selected by NIH with little involvement of others tends to avoid issues on which the clinical community needs urgent guidance. Often, too, panels that are generally neutral include individuals with some stake in the technology being reviewed.

An effective process begins by selecting issues with strong policy implications. Joint sponsorship by the federal government and important healthcare players — the research community, providers, payers, and the public — will help ensure that potential topics are debated and that those selected involve a significant discrepancy between available knowledge and its practical application. Participation of all interested groups is also likely to result in impartiality of process custodians and to contribute to a broad sense of ownership of, and support for, conclusions.

The most important criterion for issue selection is a strong, albeit controversial, base of scientific evidence about the technology to support an empirical discussion of its merits. Data should come both from planned studies and “naturally occurring experiments” in day-to-day practice. Because of its complexity, data synthesis should be formalized, using the most up-to-date tools. Synthesis could employ meta-analytic or decision theoretic modeling. The consensus process at the heart of the conflict resolution should allow for thorough debate of issues, providing balance in the presentations of opposing viewpoints.

The “Science Court” model fulfills most of these criteria.¹² It offers broad stakeholder input, impartial sponsorship and adjudication,

¹¹ Fitzhugh Mullan & Itzhak Jacoby, *The Town Meeting for Technology: The Maturation of Consensus Conferences*, 254 J.A.M.A. 8 (1985).

¹² See, e.g., Itzhak Jacoby, *Consensus Development at NIH: What Went Wrong?* 4 Risk 133 (1993).

managed preparation and presentation of evidence, and thorough airing of facts via cross-examination. Case managers, who would translate opposing views of an issue into scientific facts, represent the critical feature most lacking in existing processes. Individuals or interest groups, carefully selected for expertise and constituency, would present their arguments to a referee or judge before allowing scrutiny by opposing case managers. Challenge of the other manager's statements would trigger mediation. The challenge resolution procedure would involve both oral and written presentations, in an effort to produce statements of the highest possible validity within time constraints. While some aspects of this process could vary, each case manager would definitely have the right to cross-examine the other.¹³

Selection of judges and referees would also involve consultation with appropriate scientific societies and organizations to assure unusual scientific capability and no obvious connection to the disputed issue. Also, case managers would examine proposed names for prejudice.

A new process for medical controversy resolution should address a broad range of issues, including safety, efficacy, cost and related economic concerns, quality of life, ethical and legal concerns. Statements issued as a result of the process should be subjected to extensive review to ensure that issues are adequately addressed and findings reasonably supported. The process and outcomes should be monitored over time and evaluated occasionally to identify means of improvement. Embracing all of the Science Court principles, a new approach should gain wide public acceptance, provide sound guidance for the practice of medicine and maintenance of public health, and eliminate the worst inefficiencies of the current system.



¹³ Task Force of the Presidential Advisory Group on Anticipated Advances in Science and Technology, *The Science Court Experiment: An Interim Report*, 193 Science 654 (1976).