Consensus Development in Biomedicine: The Liver Transplant Controversy

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DEMOCRATIC SOCIETY IS SUPPOSED TO ENCOURAGE, even protect and institutionalize, a diversity of opinion. In a post-industrial democracy, where the production of knowledge is so vital to the national interest, we ought to expect such diversity in all areas of science. Indeed, the 1980s have witnessed not only diversity, but strong dispute, particularly in all aspects of biomedicine. Major social protest—full-blown controversies—have occurred on topics ranging from Laetrile (Markle and Petersen 1980) to recombinant DNA (Krimsky 1982). Controversy may revolve around esoteric scientific claims (Studer and Chubin 1980) or broad-based social values (see Nelkin 1984).

While some scholars assert that controversies may be an aid in technology assessment (Rip 1987), most policy makers find them politically disruptive. Thus, various proposals and efforts, both formal and informal, have been made to resolve controversy. One such proposal was the "science court," in which disputes were to be formally adjudicated according to the rules and procedures of jurisprudence. Another effort, which has been actually implemented, is the Consensus Development (CD) program, sponsored by the National Institutes of Health (NIH). Here, a jury of experts address a predetermined set of questions, weigh

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conflicting evidence, and render a recommendation to the scientific community.

In this article we argue that the CD program acts as a mechanism to contain rather than to resolve controversy, and, therefore, functions as a mechanism of social control: to confer upon scientific uncertainty the imprimatur of official agreement, authority, and policy. The conferences, rather than being sites of negotiation and conflict resolution, are formal and predictable. After a theoretical exegesis and a brief description of the CD process, we focus on the 36th CD conference, the case of liver transplantation (LT). We analyze the events leading to the conference and suggest their importance in agenda setting and, ultimately, in determining the outcome—or consensus statement—of the conference. We conclude with some observations on the public performance of democracy, which has all the trappings of theatre but the unmistakable mark of backstage politics.

The Politics of Science

It is now generally recognized that medical knowledge and practice are products—and inseparable ones—of their culture. Rather than viewing facts and values as sharply distinct categories, it is instructive to view medical knowledge as contingent on particular social, political, and economic arrangements. As Freidson (1975) has concluded, the accepted boundaries of medicine at any time are not given, but rather are the contingent outcome of negotiation between various social forces. Thus, medicine becomes more than a body of instrumental knowledge; rather it serves as a:

> set of categories that we use to filter and construct our existence . . . a form of language which does not simply reflect some pre-existing external reality, but instead creates its own object of analysis (Wright and Treacher 1982, 6–7).

In American society, the institution of medicine has a powerful influence on, and is in turn influenced by, the polity, economy, and culture. In certifying certain knowledge and practice as correct or fallacious, medicine exerts powerful social control. Though developed as a concept in the sociological study of deviance, social control—

defined as the mechanism and processes by which society ensures that its members behave in expected and approved ways—is applicable to medicine. Officials ranging from federal regulators to journal editors, or, in this case, NIH staff and CD panelists, routinely make decisions which favor certain vested interests at the expense of others, and thus directly shape the behavior of a wide variety of actors.

From this perspective, the analyst's task is to demystify medicine, or more specifically CD conferences, and to show how questions of medical knowledge and practice are actually adjudicated. We understand that politics, in its broadest sense, is a normal part of any decision-making process. To the scientific actors in our dispute, the term "politics" is a pejorative, denoting a possible loss of control to hostile interests. Yet, knowingly or not, scientists routinely use their expertise and instrumental knowledge in ways to change the distribution of professional advantage and disadvantage. Our use of the term "politics" is naturalistic and analytic. Politics made explicit is science better understood. The point is not to separate science from politics, which is impossible, but to separate science from backstage politics, which conceals or clouds understanding.

Consensus Development

On October 4, 1978, the NIH officially established the Office for Medical Applications of Research (OMAR) to administer CD conferences. The purpose of these conferences, according to Donald H. Fredrickson (1978), then director of the NIH, was "to hasten resolution of scientific issues," especially those with "important social dimensions." CDs were to "lay out the state of the art—what it is we know and do not know from data scientifically derived." To achieve this goal, conferences were to have specific guidelines or "imperatives," including (1) a focus on specific questions that were "susceptible to solution," (2) a format that allowed for "broad and open participation," (3) a "careful balancing" of the views of participants, and (4) the provision of a "clear record of deliberation." This view was reinforced by two other OMAR officials who claimed that the purpose of CD conferences was "to seek consensus on the difficult questions and controversial issues surrounding a technology" (Perry and Kalberer 1980, 169).

The Consensus Development process has been described in detail

by the University of Michigan's Institute for Social Research which published an evaluation of OMAR in 1982 (Wortman, Vinokur, and Sechrest 1982). According to Wortman and his associates, OMAR staff often compare CD conferences to a judicial process in the courtroom: The conference questions constitute the charge, the speakers' presentations and audience comments provide the evidence, and the panel, as a jury, weighs the evidence and reaches a verdict in the form of a consensus statement. Departing from the courtroom model, the OMAR charge urges the panel to be active in questioning speakers about their presentations. The panel is told that the consensus statement should be based on and reflect only the evidence that is presented in the public sessions of the conference (Wortman, Vinokur, and Sechrest 1982, 97).

By 1986 there had been more than forty CD conferences. Their range has been broad: from life or death (coronary artery bypass surgery) to the annoying (travellers' diarrhea), from evaluation of a technique (tomographic scanning of the brain), to diagnosis (the Pap smear), and to treatment (chemotherapy of breast cancer). Yet, from the program's inception, the selection of topics for CDs has been problematic. According to Wortman, Vinokur, and Sechrest (1982, 30) several criteria play a role in determining a topic's suitability for CD. Most important is the adequacy of the scientific knowledge base. Other criteria mentioned by NIH staff include adequate public interest, unresolved questions concerning "efficacy, technical, logistical, or cost factors." Requests from other government agencies, such as the Health Care Financing Administration (HCFA), might also stimulate a conference. Finally, political interests or pressures may advance a particular subject for CD consideration.

In the early days, CD programs were often controversial. As time passed, however, OMAR shied away from controversy, avoiding social, economic, legal, and ethical issues involved in the evaluation of a technology. For example, medical economics was to be avoided, according to a former director of OMAR, because it "is not an exact science . . . and is fraught with all kinds of opinion" (quoted in Wortman, Vinokur, and Sechrest 1982, 78). Indeed, CDs are now seen as vehicles not to resolve controversy, but to aid technology transfer:

> This unique program is an attempt to reproduce in microcosm, at one time, in one place, the process of knowledge evaluation, transfer,

> and transformation, that ordinarily occurs within the context of the entire biomedical system and its contingent systems. . . . OMAR is intended to be the "facilitator" that will permit basic and, in particular, clinical research to be transferred more rapidly into health care practice (Asch and Lowe 1984, 377).

OMAR is responsible not only for topic selection, but for the development of CD questions and selection of the jury of experts. The questions presented to a CD conference clearly define the issues to be assessed. In the Wortman, Vinokur, and Sechrest analysis of CD conferences from 1980 through 1982, "technical" issues overwhelmingly predominated. Indeed, only 5 of 84 questions addressed any social issue (one question addressed an ethical issue, one a legal issue, and three an economic issue). One OMAR staff member objected to any question that did not "deal with science," and stated succinctly that NIH "doesn't have political science here" (Wortman, Vinokur, and Sechrest 1982, 77).

Selection of a panel chair, panelists, and speakers is crucial. No federal employee is allowed to chair a panel. In OMAR's view, a panel chair needs impeccable credentials and specialty knowledge, but should not have any publicly stated views with respect to the CD questions. This view of the chair as expert but impartial seems problematic to us. According to Wortman and his associates, other panel members tended to be from elite institutions: Harvard, Johns Hopkins, and the Mayo Medical School were each represented at more than one-half of the conferences. The Wortman, Vinokur, and Sechrest analysis also showed an ambivalence toward nonmedical (lawyers, ethicists, etc.) professionals. Although nonmedical specialists were represented on seven of the twelve (1980–1982) conference panels, five of these seven panels never addressed such questions. Wortman and his associates found little diversity in speakers invited to present evidence to CD panels. Allied health professionals were included in two, and consumers in one, of 18 conferences. An economist participated in the Pap smear CD, and a health care policy analyst testified at the endoscopy and febrile seizure CD. Even so there was no discussion of social issues in either of these consensus statements. On the other hand, although economic issues were addressed in the thrombolytic therapy consensus statement, there were no social scientists on either the panel or the speakers list.

Liver Transplantation

We now examine in detail the 36th CD Conference, the case of liver transplantation, held on the NIH campus, June 20-23, 1983. After placing the controversy in an historical context, we consider the negotiation process which led to a CD; finally, we assess the conference itself.

Historical Context

The first effort to replace a human liver was made at the University of Colorado on March 1, 1963, by Dr. Thomas E. Starzl. That patient did not survive the day. In the next three attempts by Starzl, the longest survival was 22 days (Starzl, Marchioco, and Von Kaulla 1963). In September 1963 and January 1964, other unsuccessful attempts were made in Boston and Paris. These failures led to a moratorium on clinical trials until October 1966. After several more failures, on July 23, 1967, the first extended survival of a human recipient was achieved. The patient, a 1-1/2-year-old girl, lived for more than 13 months before dying from hepato cellular carcinoma, which had been the original diagnosis (Starzl, Groth, and Brettschneider 1968).

From 1963 through 1979, 170 patients were treated by Starzl and his team, an average case load of less than one dozen per year. These patients had a one-year survival rate of 32 percent and, as of 1983, 18.8 percent were still alive. Six patients have lived more than 10 years (Starzl et al. 1982). It is now clear that the initial difficulties in transplantation were caused not only by primitive technique, but also by the generally wretched condition of the patients. As Starzl's team has become more experienced, it has performed transplants on healthier (albeit needy) patients.

Beginning in 1980, a powerful new immuno-suppressant, cyclosporine A, was used in all liver transplantation procedures. Of the 40 liver transplants with cyclosporine A performed in 1980 and 1981, the one-year survival rate shot up to 70 percent with a projected two-year survival of 60 percent. With such improved survival, adjuvant treatment with cyclosporine A has become standard practice. Yet, cyclosporine introduced some new problems and issues into the liver transplant equation. Cyclosporine is always used with corticosteroids,

and both must be used throughout the patient's life. Though most of the literature on adverse effects of cyclosporine comes from experience with kidney transplants, where it is also routinely used, this literature is generally seen as relevant to all transplant sites. In 20 to 40 percent of all cases, cyclosporine is nephrotoxic; less often it is hepatotoxic. Other frequent adverse effects seen in clinical trials include nausea and vomiting (Rapaport 1984). In two epidemiological studies, transplant patients had a 49 (Hoover and Fraumeni 1973) and 28 (Kinlen et al. 1979) times increased risk of non-Hodgkins lymphoma, with most occurrences in the first year. An increased risk of Kaposi's sarcoma has also led to worry about AIDS (Sell, Folks, and Kwon-Chung 1983). Even so, in 1983 cyclosporine was approved for use in kidney, liver, and heart transplants. Yet to date, the therapy, which costs some $6,000 per year, is not covered by extended Medicare (Walsh 1984). Ironically, it is this issue and not the hepatic procedure itself, which triggered the Health Care Finance Administration's interest in the liver transplantation CD conference.

These problems notwithstanding, liver transplantation, according to the *British Medical Journal* (1981), "had come of age." The *British Medical Journal* editorial began with this fateful sentence: "Fortunately, liver transplantation has failed to arouse the sort of sensational publicity that has been focused on heart grafting."

All of this quickly changed. Starzl has called 1982 "the breakout year" (Starzl et al. 1982). For 19 years, he had performed virtually all liver transplants in the United States. Beginning on January 1, 1982, "organ harvest teams," trained the preceding year, "assumed responsibility for 100% of the procurement procedures" and 40 percent of the recipient operations were performed by "young faculty members or fellows" (Starzl et al. 1982) at the University of Pittsburgh, where Starzl had relocated in 1981. Indeed, organs for transplantation in Pittsburgh were obtained from all over the country. To meet this objective, several Pittsburgh corporations have donated their private jet airplanes (Starzl et al. 1982).

In 1982 Starzl's team alone performed 80 liver transplants; in 1983 they performed more than 100 such operations, each of which took more than 18 hours. These procedures, performed now at various medical centers around the United States, began to attract tremendous media attention. Headline newspaper and feature television stories showed the desperate pleadings of parents—and, in one case, of President

Reagan—for suitable livers that would save children dying of liver diseases. These features depicted Starzl not only as a brilliant surgeon, but as a man who loves to play with his own children, but whose time is spent saving the lives of other children.

Reflecting on the history of liver transplantation, Starzl sees something approaching nobility in the early failures of his colleagues: "The fact that they had the personal qualities to be able to accept defeat or victory with equal grace was fortunate since failure was the dominant theme with all such efforts until recent times" (Starzl et al. 1982, 614). Of his own later successes he not immodestly concludes: "The history of medicine is that what was inconceivable yesterday and barely achievable today often becomes routine tomorrow" (Starzl et al. 1982, 634).

Until the early 1980s almost all liver transplants were performed in two centers: at Colorado and then Pittsburgh, by Starzl, and at Addenbrook's Hospital in Cambridge and Kings College Hospital in London, by Dr. R. Calne. There are significant differences, particularly regarding patient populations, between the two centers. The English group has selected older adults; the American group, especially in recent years, has focused on children and infants. In England most transplants are performed on patients with primary hepatic malignancies and cirrhosis; in the United States most patients have congenital diseases of the liver.

Why and how differences in these patient populations developed is beyond the scope of this study. Yet, the implications of these differences are clear. It is far easier to mobilize social, political, and financial forces to save a young child than it is to save an elderly person. It is to the mobilization of forces in the United States that we now turn.

Negotiating the LT Conference

The officials we interviewed at the National Institute of Arthritis, Diabetes, Digestive, and Kidney Diseases (NIADDK) were opposed to sponsoring the CD conference. They told us that such a conference was premature given the paucity of clinical data. At worst they feared a media circus where entrepreneurial surgeons and emotional parents would argue for the routinization of what many felt was an experimental procedure.

Congressional pressure and extensive media coverage, in addition

to Surgeon General Charles Everett Koop's efforts forced NIADDK officials to consider a conference. Koop's role in this story seems to fit Howard Becker's (1963) definition of "moral entrepreneur." Koop is known not only as a brilliant pediatric surgeon, but as a vigorous polemicist against abortion and feminism. When President Reagan nominated him in 1981 for surgeon general, there was substantial opposition to his appointment. Citing his lack of experience for the job, the *New York Times* called him "Dr. Unqualified" in three separate editorials, and the American Public Health Association opposed the nomination, an action it had never before taken in its 109-year history. Koop's approach to liver transplantation was characterized by a blend of strong belief and scientific certainty.

OMAR officials viewed the CD conference on liver transplants as having "political," not scientific, roots. As NIH's John Kalberer (personal communication 1983) told us: "It's being held because it's a political request," which he identified as "TV and newspapers and the emotions of these children. NIH people, if they had their druthers, would not have a conference in this area." Richard Crout (personal communication 1983), then OMAR associate director, was more specific: "The topic was picked basically by HCFA [Health Care Finance Administration] facing the decision on whether to reimburse [insurance companies for covering the costs of the operation] back in 1980 . . ." Thus did both officials fear that NIH would lose control of liver transplantation procedures.

In early 1980 Charles Lowe, then acting associate director of OMAR, requested that the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMMD) supply him with an objective summary of the current state of the art of liver transplantation. This was intended to clarify "Medicare issues assigned to NIAMMD" in relation to liver transplants. Liver transplants are extremely expensive and, as with any experimental procedure, are not covered by Medicare benefits. If such transplants were to be judged as part of standard, accepted medical practice—as routine therapy—then Medicare would be forced to reevaluate its payment policies. On April 7, 1980, NIAMMD staff responded to Lowe's request, providing a state-of-the-art assessment, and concluding that "despite recent improvements . . . hepatic transplantation is still largely an experimental procedure with relatively unpredictable outcome in individual cases" (G. Hirschman, personal communication to C. Lowe, 1980).

Late in 1981 a meeting was held with Surgeon General Koop, Dr.

Starzl, and representatives of the American Liver Foundation. Also invited, but absent, was Congressman Jim Courter (New Jersey), member of the Armed Service and Postal Committees. In a letter to the surgeon general, Representative Courter (December 21, 1981) stated that:

> . . . recent developments with Cyclosporine A have greatly enhanced the success of liver transplantation as a rehabilitative technique. Consequently I believe the new evidence demonstrates a need for the government to consider reevaluating its classification of liver transplantation as an "experimental" surgical procedure.

Courter then expressed support for "expanded grant support for clinical programs like that under Dr. Starzl's direction at the University of Pittsburgh Medical School." Courter concluded with the "understanding that you [the surgeon general] are planning to present the Secretary [of the Department of Health and Human Services (DHHS)] with a policy memorandum on the issue of liver transplantation vis-à-vis government support within the next three months."

The surgeon general's memo to Edward N. Brandt, assistant secretary of DHHS, dated 3 February 1982, is most interesting. In a section entitled "Projections for the Future," Koop identified—and then dismissed—a pivotal ethical issue. He claimed that some 20,000 to 25,000 deaths per year are due to various types of liver disease. Yet, because most of these are patients with alcoholic cirrhosis they would not be "bonafide candidates for liver transplantation." Indeed "performing liver transplantation even on a reformed alcoholic" would open up a "Pandora's box."

Instead, Koop maintained that the operation should be limited to children, among whom some 200 to 500 are born annually with biliary atresia. Based on such ethics and logic, Koop made two recommendations:

1. Find a way to fund the University of Pittsburgh Health Center's transplantation unit as they gear up to train other teams.
2. Declare liver transplantation . . . to be no longer an experimental procedure but one which should be paid for as a service by Medicaid up to the age of six years.

Events now began to accelerate. On 17 February 1982, Brandt sent Koop's letter to Charles Lowe at OMAR and asked him (for the first

time) to consider a consensus conference on liver *and renal transplants*. Such a conference should, in Brandt's words, consider three issues:

1. The scientific basis for transplantation and the clinical problems presently encountered.
2. The supply of organs for transplantation and methods to achieve an increase.
3. Training programs necessary to enhance transplantation.

Note that Brandt, by using terms such as "increase," "enhance," etc., was implicitly endorsing the techniques, a priori the proposed conference. Note also that the issues which were to dominate the CD conference were already defined.

On 26 February, Lester Salans, acting director of NIADDK (note name change, and attendant reorganization from NIAMMD), in a letter to the acting director of NIH, set out the institute position: They were, and would continue to be, opposed to a CD conference as envisioned by the surgeon general. In general, scientists at NIADDK felt that such a conference would be premature because ". . . the total experience with liver transplantation utilizing Cyclosporin A is not yet extensive enough to draw meaningful conclusions concerning wide, clinical application." This theme of prematurity was echoed not only throughout NIADDK, but in OMAR as well. As John Kalberer, former associate director of OMAR, told us in 1983: "It's turning out that [Starzl's] success rates aren't all that great and there are a number of infection problems that are very complicating."

Salans's 26 February memo then addressed the surgeon general's two recommendations. Of the first, that the NIH fund Starzl to train other teams, Salans was cleverly (even devilishly) legalistic. If, indeed, liver transplantation has moved beyond experiment to clinical practice (Koop's claim which Salans did not share), then NIH cannot help "since NIH is responsible for training for research, rather than clinical specialty training." Salans then declined Koop's second request by declaring that liver transplantation is still an experimental procedure.

Salans then addressed Brandt's request for a CD conference, calling it a "good one." However, Salans suggested a "state-of-the-art" conference/workshop rather than a CD conference because the latter implied "that the technology to be discussed has matured to the point where it is no longer experimental but ready for routine and wide scale

application . . . clearly not the case with liver transplantation." He also advocated separating liver from kidney transplantation, given state-of-the-art differences in these two procedures.

Finally, Salans declared the institute to be fully behind Starzl and his broadened efforts: ". . . should Dr. Starzl require additional research support, a supplemental funding application by him and his institution is in order." On 26 March 1982, Thomas E. Malone, acting director of NIH, endorsed all of Salans's positions, again declaring that "whereas the NIH has responsibility for training scientists in research methodology, it has no mandate for the surgical training that would be required in transplantation manipulation."

The issue of finances, never far off-stage, now reappeared and soon commanded stage center. On March 24 the acting director of the Office of Health Research, Statistics, and Technology (of the Public Health Service) met with Drs. Malone and Lowe to discuss the surgeon general's 3 February memo. Three possible outcomes of a CD conference were envisioned: that liver transplantation would (1) still be considered experimental, (2) no longer be considered experimental only in the "hands of certain experts," (3) become accepted practice for certain indications. In the first outcome NIH would not, of course, recommend a change in Medicare policy as they would for the third outcome. The second outcome would be problematic, and in such a case "interesting, legal and administrative challenges [to Medicaid] would arise" (H. Margulies, personal communication to T. Malone, 30 March 1982).

On 2 April 1982, Robert A. Streimer, acting director, Office of Coverage Policy, Bureau of Program Policy, HCFA, wrote: "As agreed at the February meeting of the HCFA's Physicians' Panel, we are submitting to [the Public Health Service], for a reassessment, the question of the safety and efficacy of liver transplantation. . . ." The motivation for the February meeting, according to Streimer, was "congressional interest on the issue" and the surgeon general's memo.

On that same day the politicians were heard from again. Congressman Wayne Gresham (California), member of the Public Works and Post Office Committees, and Representative Courter, wrote letters to Richard Schweiker, Secretary of Health and Human Services. After expressing concern over "the suffering of so many children," Gresham asked that transplantation procedures be reclassified from experiment to therapy so that patients might receive federal benefits. In his reply of 27 April

to Gresham and Courter, Schweiker promised that an expert scientific panel would convene on 8 June to plan for a CD or a state-of-the-art conference. Such a conference might make possible a determination of whether liver transplants are experimental or therapeutic.

Harold Roth, associate director for Digestive Diseases and Nutrition, NIADDK, was put in charge of the 8 June meeting. A shy, reticent man, Roth was (and remained) opposed to a CD conference. He not only believed that such a conference was premature, but that it might inappropriately be captured by political interests—that is, interests hostile to the NIH. Nevertheless he chaired the 8 June meeting with the surgeon general, NIADDK and OMAR staff, plus six United States M.D.s, 1 Ph.D. (a biostatistician), and the principal surgeons, Starzl (an M.D. and Ph.D.) and R. Calne from Great Britain. As Arthur Caplan (personal communication 1984) has noted: "Inviting transplant surgeons to 'assess' transplant procedures is [like asking] foxes to guard the hen house!"

The group was charged to work fast. According to Salans's directive, the group would decide that morning whether "adequate data exists to decide on the safety and efficacy of liver transplantation using Cyclosporin A. If the answer was YES, then a consensus conference would be planned. If the answer was NO, then a research conference would be planned." In either event, the afternoon would be devoted to planning a conference. That morning, not surprisingly, the panel voted unanimously that a CD conference was appropriate.

Even if data were not current, the panel concluded that they could be collated in time for a CD conference. In fact, the CD conference later served as an excuse to get, for the first time, good data. As Richard Crout (personal communication 1983), who replaced Dr. Lowe and was associate director of OMAR at the time of the CD conference, told us: "Dissemination is not the issue. It's to smoke out the surgeons—to make them move from the anecdotal in the newspaper to a presentation before peers of their data."

Seven questions, relating to issues such as the quality of data, expectations of surgical success, and additional needed research, were identified. Not included in this list were ethical concerns such as patient selection or economic issues such as cost effectiveness.

As directed, Roth now began a series of preliminary meetings to construct a CD process. On 20 August he met with Dr. Rudi Schmid, future chair of the CD panel, to draft a schedule of presentations and

a list of CD panelists. It was suggested that the panel include not only hepatologists and other physicians, but also a "lay person interested in liver diseases" (Thelma Thiel, to be nominated by the American Liver Foundation), a "parent of a child with liver disease" (to be nominated by the Children's Liver Foundation), an ethicist (Albert A. Johnson), and an expert in technology assessment (Harvey Fineberg). A planning committee, composed of Roth, Schmit, three physicians, and OMAR and NIADDK, was to meet on November 1, in Chicago, to continue planning.

On 27 April 1983, Koop and Brandt testified before Congressman Albert Gore's Investigations and Oversight Subcommittee, Committee on Science and Technology. Through his subcommittee, Gore had long been active in science, particularly biomedical, policy. Throughout the hearing Gore criticized federally funded health programs for withholding reimbursement for liver transplants. "I don't think the word 'experimental' can be fairly used to describe a procedure that has a 75–80% success rate. The real issue is how quickly the bureaucracy represented at the table can adjust to change of circumstance."

Barely two weeks before the CD conference came Koop's coup: The Surgeon General's Workshop on Solid Organ Procurement for Transplantation—Educating the Physician and the Public. For three days in Winchester, Virginia, optimistic and hopeful presentations about organ, particularly liver, transplants were heard. The timing and media coverage of this workshop were a perfect prelude to the CD conference.

And so a three-year process, the debate and planning which led to a liver transplantation CD, was about to climax. Some thought this process too long; others found it reasonable and orderly. Some blamed NIH for foot-dragging; others put the blame, if any, elsewhere. Even at OMAR we got two different versions of this story. John Kalberer (personal communication 1983) told us:

> Once the outside community, which looked like the big enemy, embraced the process in varying degrees (the surgeons march to their own drummer—that's what makes them surgeons), the internal group here at NIH was the most jaundiced group. They were the most resistant in every way possible and looked upon our office, OMAR, as being terribly regulatory and dictatorial.

But Richard Crout (personal communication 1983) had a distinctly different view:

> The delay in the decision was not created by HEW. The delay was created by Starzl and Gore who, seeing a conference coming, wanting to influence its outcome, start a political movement in which complaining about delay becomes one of the complaints.

The Conference

The Consensus Development conference was held on June 20-23, 1983, on the Bethesda campus of the National Institutes of Health. The conference was highly planned and tightly scheduled. For two days the panel heard evidence from invited speakers—internists and pediatricians on the first day, surgeons on the second day. On the second evening the panel retired, and 36 hours later issued its draft consensus statement—first for conference participants and then for a press conference.

The panel was chaired by Rudi Schmid, Dean of the University of California, San Francisco, School of Medicine. Schmid received his M.D. from Zurich and was a member of several medical faculties, including the University of Chicago and Harvard. He is a specialist in liver physiology and pathophysiology. The conference agenda, according to Schmid's interpretation, was first to examine the natural history of the disease and then to discuss the results of the transplants. He urged presenters to avoid the "subjective" elements, especially anecdotes, and to "be objective." He reminded the panel of the tight schedule and invited them to ask questions immediately after each speaker's presentation; the audience was directed to limit their unscheduled questions to two minutes per presentation.

The panel consisted of a dozen members, in addition to the chair. Nine were M.D.s (two of whom were from Harvard); the dominant specialities were hepatology, pediatrics, and surgery. One M.D. was identified as a "family practitioner/medical ethicist" (who said not a word during the two days of public sessions), and one layperson was identified as a "public representative" (Executive Director, Volunteer Trustees of Not for Profit Hospitals, Washington, DC). The two Ph.D.'s on the panel were listed as a "biostatistician" and an "immunologist."

The Physicians' Sessions

Two sessions were devoted to "Natural History and Conventional Therapy of Liver Diseases." What emerged as central to the physicians, and especially to the French pediatrician Daniel Alagille, was the quality-of-life issue. Longevity alone cannot be the criterion if the patient is bedridden, unable to work, and in the case of children, deprived of anything resembling a normal life. How then, does one define the "success" of liver transplantation? Are one-year survival rates significant? Alagille argued they are not; five years should be adopted as the milestone. However, Alagille was the only one to raise such issues. Equal time was devoted to cirrhosis resulting from alcohol—three million cases per year—and to Wilson's disease, a rare condition. The biostatistician on the panel said he "shivered" when surgeons stated: "You have a feel for the patient who will live only a year."

The Surgeons' Sessions

The second day of the conference brought presentations from the four liver transplantation centers: United States (Pittsburgh), England, West Germany, and the Netherlands. In outlining his experience with liver transplantation, Starzl called the procedure "a service, not human experimentation." He said that patient selection is the key; in contrast to patients in Britain, half of whom are 18 or older, Starzl operated on young children, even infants, exclusively. Before and after pictures of his patient-recipients were on display in the lobby outside the conference auditorium. A few patients plus their families were in the audience, the invited guests of Dr. Starzl.

The British surgeon Williams outlined the demography of the donor problem in Europe. He claimed that there are no pediatric donors in England and that intravenous cyclosporin A has led to instability in survival rates, although it curtailed rejection of the transplanted organ. The German surgeon Pichlmayr reported that liver transplantation began at Hannover in 1972. Out of 91 operations involving 87 patients, only 15 were children. Organ procurement is the chief obstacle to transplantation for children, even though the operation is preferable to chemotherapy which extends life on an average only 3 to 4 months. U.S. Surgeon General Koop mentioned (for the first time at the conference) the concept of "presumed consent" as an

alternative to the ineffective "uniform donor card" system (see Caplan 1983). He also cited Gallup poll results showing that 75 percent of the American public favors transplants.

During a brief audience discussion, a lay member of a Pittsburgh hospital institutional review board (IRB)—not the one assigned to the University of Pittsburgh where Starzl operates—called for a discussion of the "psycho-social" considerations surrounding the decision to perform transplants in young children. She argued that transplantation should not be a surgical decision and read an excerpt from a statement drafted by her IRB, implying that the spirit of "informed consent" is violated in such cases. This unscheduled appearance, by a dissenter no less, ruffled the conference organizers. Upon exiting the auditorium she was confronted by Crout and an OMAR staff member. They questioned her credentials and the status of her statement. They insisted that she clarify (1) her position on the IRB, and (2) admit that the source of her excerpt was a draft document not yet approved by the IRB. Chairman Schmid called on her at the outset of the final afternoon session. She complied with Crout's request but did not retract the statement. Later, she told us, "I am in hot water over the statement," but would not talk further.

Forum

The concluding session of the conference was called "Forum: Transplantation vs. Conventional Therapy." The most controversial presentation (in a conference that had studiously avoided controversy) was a "biomedical technology assessment" of liver transplantation by Harvey Fineberg, now Dean of the Harvard School of Public Health. His analysis was based on a Massachusetts task force report on transplantation (Fineberg 1983)—a task force he chaired. Fineberg made explicit every issue that was purged from the conference agenda as "nonscientific." He began by asserting that clinical performance and cost are both part of scientific merit, that most of the fundamental questions in liver transplantation are value judgments. He then asked: How do liver transplantations and conventional therapy compare—by disease and stage of disease—in terms of patients' longevity, quality of life, and cost (across medical centers)? He proposed a randomized clinical trial design, in which "aims of equity and evaluation converge," to answer the questions. Some panelists reacted very negatively to his

proposal. They challenged technology assessment with such questions as: What is it, a "quasi-science"? Does it have a literature? Who does it? They also summarily dismissed clinical trials as "unethical."

In his concluding statement, Starzl claimed that at Pittsburgh all transplants are done on "pre-terminal" patients, those sicker than liver transplantations done elsewhere. His patients are all desperate; all avenues have been exhausted; they will die without a new liver; transplantation is a last resort. In a mild dissent British physician Sheila Sherlock clearly favored nonsurgical therapy. But Sherlock lauded the marshalling of resources, including public opinion, that Starzl and his team have done, and endorsed the transplantation approach as nonexperimental. She recognized its momentum and demonstrable success at saving a few lives. Her concluding testimony was that liver transplantation in the United States is a fait accompli.

The Consensus Statement

After a day in executive session to prepare the draft consensus statement, the panel announced its findings and recommendations. "Liver transplantation," they wrote, "is a promising alternative to current therapy in the management of the late phase of several forms of serious liver disease." They then stated that "the survival and complication rates of patients who have undergone liver transplantation are the major criteria for judging efficacy. . . . Selecting an appropriate stage for a given illness for liver transplantation is a complex issue." It was now admitted that the panel's data collection and scope had been incomplete. "The requirements for conducting a liver transplantation program by a sponsoring institution are formidable. . . . Additional information permitting cost-benefit analysis should be secured. . . . Critically important information is either unavailable or so incomplete as to defy meaningful interpretation."

The "conclusion" read as follows:

> Liver transplantation is a therapeutic modality for end-stage liver disease that deserves broader application. However, in order for liver transplantation to gain its full therapeutic potential, the indications for and results of the procedure must be the object of comprehensive, coordinated, and ongoing evaluation in the years

ahead. This can best be achieved by expansion of this technology to a limited number of centers. . . .

Impact of the Conference

The CD conference was covered widely not only in the mass media, but in the scientific literature as well. In the *Annals of Internal Medicine*, an article written (most amazingly) by Starzl and his team stated its conclusion in its title, "Liver Transplantation Comes of Age" (Van Thiel, Schade, and Starzl 1983). The *Journal of The American Medical Association*, which has an agreement with OMAR to publish all CD statements, reproduced the CD conference summary. They clearly endorsed the technique, though they cautioned that extensive liver transplantation will lead to several problems in blood-banking, a subject not even raised at the CD. In *Lancet* Sheila Sherlock (1983, 779) supported liver transplantation, as she had at the conference, but pointed out that: "The cost of a liver transplant is about $70,000. This must be weighed against the outlay on a patient with end-stage liver disease being treated with conventional methods." Actually, the total first-year costs of a liver transplantation are $230,000 to $280,000 so Sherlock's point needs to be amplified, as Evans (1983) maintained in a letter to *Lancet*. Yet, even this cost, he argued, could be met by building ten fewer MX missiles.

Discussion

The CD panel bestowed a qualified endorsement upon the procedure. Acknowledging both uncertainty and ignorance, it attached the imprimatur of the NIH to the delivery of a technology which affects relatively few patients, but galvanizes much public opinion. It also signaled that hospitals should indeed concentrate human and fiscal resources if they wish to participate in this unfolding life-and-death scenario, without assurance that any subvention from the federal government is forthcoming.

In some ways, the consensus statement reflects the misgivings that we heard both prior to and during the conference. Yet, the outcome

of the proceeding was a foregone conclusion. There had been virtually no unplanned inputs and the consensus statement contained few surprises. Indeed, we found that the preconference process, with its negotiations and compromises on the questions to be adjudicated, speakers to be invited, and the composition of the consensus panel, to be far more intriguing than the conference itself.

The CD conference, like the concepts of peer review and science court on which it was predicated (Kantrowitz 1976; Kalberer 1985), is designed around an inadequate model of science. It assumes that a strict separation of factual from value issues is possible, and further, that objective evidence compels experts to converge on the "correct" decision. Yet, acceptance of this simple fact-value distinction leads to a host of problems. "Is the emphasis to be placed on consensus or development?" asked one participant from the 1984 cholesterol and heart disease CD:

> The former is a contrived situation, and unlikely to be achieved with much solidarity within the short time set aside for such a meeting. . . . [A] well-orchestrated so-called consensus conference between doctors and the public with the implicit intention of exerting psychological and political pressure should not be permitted too loud a voice . . . and be recognized as special pleading and evaluated as such (Oliver 1985, 1088–89).

Rather than consensus this critic would emphasize development: a conference to work out ways in which ideas on "how complex scientific, professional, ethical, social, and economic issues" (Oliver 1985, 1088) might be addressed. OMAR's response to this stinging criticism, which maintained that CD panels are strictly "neutral" and that "only scientific issues are considered at our CDs" (Jacoby and Rose 1985, 205), again asserted a rather unrealistic, naive model of science.

Thus, the liver transplant conference restricted the relevant issues to those defined as "technical" in content. Questions of cost (Who pays for the procedure?), equity (How are recipients chosen?), and ethics (Can recipients' post-transplant "quality of life" be weighed against no life at all?) were excluded from the conference agenda. This is ironic in that they formed the rationale for the conference. If liver transplantation was deemed an experimental procedure by the consensus panel, then third-party payment was unlikely. However, if it was classified as a therapy with all the trappings of success, i.e.,

impressive survival rates and enhanced quality of life, then a government subsidy for the procedure would be warranted. This emerged as the pivotal issue, yet was barely addressed at the conference. The result was that these issues became *implicitly* important, shaping the consensus statement in ways unrecognized, or at least not admitted, by the participants themselves.

How the liver transplant conference assumed a confirmatory role is a study in the political nature of science policy. In his introduction at the conference, Richard Crout, then associate director of OMAR, reviewed the charge to the panel, observing that this is a special kind of scientific meeting because the panel listens to and examines the issues in public, a process which leads to exchange between the panel and the expert speakers (witnesses invited to present "testimony"). He compared this process to a "town meeting." Yet, town meetings are hardly objective forums in which all citizens participate, weigh arguments, and freely decide. Rather, such meetings are often controlled by special interests, which not only set agendas, but also control the access and distribution of crucial information.

Thus, CD conferences may, in fact, resemble town meetings, but not in the way Crout suggested. Rather, as a former director of OMAR has stated, they are "conducted as a public hearing, with predetermined choreography" (Asch and Lowe 1984, 377). Consensus questions, in the words of the same writers, "act as boundary-setting devices to ensure that the message transmitted does not exceed the charge and the expertise of NIH" (Asch and Lowe 1984, 379). Indeed, the conference serves as an apparatus of social control:

> Representation . . . hinges on an implicit understanding that, in exchange for involvement in the NIH Consensus Process, special interest organizations in the biomedical arena will refrain from conducting a duplicate or parallel exercise that has the potential for creating a competing or even contradictory "message," thus confusing the recipient of the NIH message (Asch and Lowe 1984, 381).

Thus, it is clear that the CD program aims not so much to resolve the legitimate ambiguities of science, but rather to authorize a political settlement of scientific differences. This unfortunate conclusion is due, in part, to the site of the CD program. NIH is in the paradoxical position of having both a mandate to advance research and at the

same time being asked to make a self-assessment of whether one of its highly touted activities is worthwhile.

Transplant "therapy" will be done. The outstanding questions in the United States case now to be resolved are the gap between the demand for, and the supply of, organs from cadavers, the morality of "presumed consent," and the suitability of "abortises" as donors (Caplan 1987). Who gets and who pays are the recalcitrant issues that must frame future discussions.

For us, however, our study raises troubling questions about resolving technical controversies in general, and the NIH consensus program in particular. Science is political and so there is nothing wrong with political solutions to scientific problems. But when backstage politics predetermines the public agenda rather than explores its alternatives, then it is time for a second opinion.

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