Policies toward Medical Technology: The Case of Electronic Fetal Monitoring

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Abstract: Electronic fetal monitoring (EFM) is an example of a medical technology that has been widely accepted since its introduction in the mid-1960s. However, review of the literature does not provide convincing evidence of EFM efficacy, and four recent, controlled, clinical trials show little if any benefit in terms of preventing death or long-term disability of the baby. Public and private policies have largely acted to encourage use of EFM, and none have acted to slow or prevent its spread. This need for mechanisms to assure the timely evaluation of new medical technologies before they are accepted as a medical practice has led to a new medical devices program in the Food and Drug Administration, consensus development groups at the National Institutes of Health, and congressional legislation to establish a new National Center for Health Care Technology. (*Am J Public Health* 69:931-935, 1979.)

Electronic fetal monitoring (EFM) is a technology that was introduced into medical practice during the mid-1960s and was rapidly accepted into virtually every obstetric setting.[1-3] Many recently published articles recommend that all labors be monitored electronically.[1, 4-8]

EFM consists of three complementary techniques: external ultra-sound monitoring of the fetal heart rate and uterine contractions; internal fetal electrocardiogram (ECG) and uterine monitoring by passage of electrodes and catheter through the cervical os; and fetal scalp blood (FSB) sampling through the cervical os to determine fetal blood pH. Although this technology is now universally available, its use has stimulated increasing controversy.

The goal of EFM is to detect fetal distress during labor and delivery enabling intervention that will prevent perinatal morbidity and mortality. In particular, advocates believe the EFM detects stresses that cause brain damage and that rapid delivery will reduce the incidence of cerebral palsy and mental retardation. The only four randomized controlled clinical trials done since 1976 have demonstrated no effect on perinatal mortality and very limited evidence of benefit on perinatal morbidity.[9-12] An analysis of almost 600 published articles on EFM carried out by the authors concluded that "Review of the literature indicates little increased benefit from EFM compared to auscultation."[13] A special Task Force brought together by the National Institutes of Health in 1979 concluded: "Prospective and retrospective analyses show no apparent effect of EFM upon perinatal mortality and morbidity in low-risk patients."[14] With the recognition of significant risks and financial costs associated with EFM, a re-examination of its role is underway.[13, 14]

The purpose of this paper is to address public and private policy mechanisms that have encouraged the use of EFM. As a case study, the spread of EFM provides an instructive example of the deficiencies in present procedures for the evaluation and control of new medical technologies. Recent changes show some promise of ameliorating this situation.

Policies toward Medical Technology

The federal government has developed a series of formal programs relating to medical technology depending on its stage of development. The stages of development of a technology consist of basic and applied research, clinical trials to demonstrate efficacy and safety, diffusion, and widespread use. Programs have been developed to try to improve the process at each stage. Thus, the National Institutes of Health (NIH) support research, including some clinical trials; the Food and Drug Administration (FDA) requires companies to demonstrate efficacy and safety of drugs and medical devices before marketing; health planning agencies have some limited control over the diffusion of certain tech-

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nologies; Medicare and Medicaid provide reimbursement for the use of technologies determined to be medically necessary; and the Professional Standards Review Organizations (PSROs) review medical practice to assure appropriate use.

States have some analogous mechanisms, but we will not refer further to their independent involvement in this area. The private sector also has involvement at each stage of development, and, in some cases, implements formal policies similar to those of the federal government. Finally, each stage involves many complex interactions between the public and private sector. In what follows we concentrate on public programs but try to make observations on private policies where they are especially important.

Policies toward Development of EFM

NIH is the major government supporter of biomedical research and medical technology development with an annual budget exceeding $2 billion. In 1977, NIH funded about $2.5 million of research related to EFM.* Although much of this was basic research on fetal development and evaluation of fetal abnormalities, the University of Southern California, whose researchers include some of the major developers of EFM, has received almost $1 million in contracts for specific research on EFM during the period 1971 to 1975.*

Private firms have also invested in the development of EFM. In the United States, Corometrics, one of the major manufacturers of EFM equipment, has supported the research of one of the most active groups in the field. Research studies from that center at the University of Southern California show no acknowledgement that funding was received from Corometrics. This phenomenon of financial support to research by vested interest groups is common in medicine but is also one that introduces an element of bias that needs to be recognized.

Policies toward Evaluation of EFM

Until late 1978, there was no public agency which had a general statutory mandate to evaluate medical technologies. Partly as a result of this fact, many technologies had not been completely evaluated before they came into general use. This was the case with EFM.

In addition to its primary role in research and development, NIH is the main supporter of evaluations of technology. In 1975, NIH invested about $100 million in clinical trials, about 5 per cent of its total budget. An analysis of the NIH trials also shows that they are focused heavily on cancer therapy and that evaluations of diagnostic and preventive technologies are not common.[15] NIH grants tend to be awarded to those who have worked hard to develop a technology, yet these developmental researchers with a vested interest in the technology are certainly not the ideal ones to organize and carry out a rigorous evaluation. This situation was certainly the case with EFM, where the University of Southern California had received a large amount of financial support. On the other hand, NIH has not provided support for clinical trials to evaluate either EFM or FSB sampling.** Plans are presently being developed to fund a controlled clinical trial in high-risk patients.

Other federal agencies also fund clinical trials related to their missions. The controlled clinical trials of EFM in the United States were funded by the Maternal and Child Health Program of the Health Services Administration, Department of Health, Education, and Welfare, which has a direct interest in assuring the efficacy and safety of the services that it supplies.[9-10]

NIH has recognized the lack of well-validated information on many medical technologies. This led the Institutes to develop a "consensus" mechanism, in which experts are brought together to examine available evidence and clinical experience and to make recommendations on the use of specific technologies. Such a consensus group dealing with EFM, referred to in the introduction, released a draft report and held an open meeting on March, 6, 1979.[14] An important recommendation of the draft report was that auscultation is an acceptable method of monitoring the low-risk woman during labor and delivery. If followed by the obstetric profession, this recommendation would lead to considerably less EFM than is presently carried out. This consensus mechanism, still largely untested, could be a useful way of developing information for practitioners and the general public.

The Medical Devices Program, a new regulatory program of FDA, will assess EFM in the future. This program was established in the Medical Devices Amendments of 1976[16] and will eventually regulate all medical devices. Modeled after the Food and Drug Act that regulates drugs, the Amendments require the demonstration of "effectiveness" and safety before a device can be marketed. Using the FDA approach, companies wishing to market a medical device are required to present evidence, usually including the results of controlled clinical trials, showing effectiveness and safety before the device is approved for marketing. This law is still being implemented and FDA has not been given an adequate budget for carrying out the law.

Under the Medical Devices Amendments, all devices will be classified by special panels into one of three classes, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories are as follows: class I, general controls; class II, performance standards; and class III, premarket approval. Most devices presently on the market will be classified as class II, depending on the assumption that it will be possible to develop performance standards to assure safety and effectiveness. If existing information does not allow the development of performance standards, and general controls over manufacturing and so forth are not sufficient, class III is called for, and in such cases, the companies will be required to carry out studies that demonstrate safety and effectiveness.

*Data kindly provided by the National Institutes of Health

**D.S. Frederickson, personal communication.

The proposed classification of obstetric devices, developed primarily by a special panel of independent experts, was published in *The Federal Register* on April 3, 1979.[17] The fetal stethoscope is assigned to class I. The fetal blood sampler and a wide range of obstetric monitors were classified as class II. For example, ultrasonic monitors, fetal scalp spiral electrodes, intrauterine pressure monitors, and fetal heart rate (ECG) monitors are all put in class II. Three related technologies are put into class III: obstetric data analyzers, fetal electroencephalographic monitors, and fetal scalp clip electrodes; the first two of these technologies are apparently put into class III because they are considered experimental. The clip electrode has been in use for some years, but is generally considered to be less safe than the spiral electrode, and this decision will in effect remove it from the market until it can be shown to be as safe as the spiral electrode. The major concern with the obstetric data analyzer, which interprets fetal status during labor, is that its use can lead to misdiagnosis and a "course of action which could put the fetus or mother in unreasonable jeopardy," presumably from cesarean section. Other risks are noted for each technology. For example, the risks noted for the fetal scalp (spiral) electrode includes adverse tissue reaction, infection, trauma, and hemorrhage. These proposed regulations, as anticipated, focus on safety, and pay little attention to efficacy or effectiveness.[18]

Furthermore, FDA has generally used a definition of effectiveness that indicates that the drug or device must do what the manufacturer claims it will do. In the case of drugs, this has meant, for example, that drugs such as anticoagulants are evaluated for their ability to prevent coagulation, but are not examined for their ability to intervene in disease processes such as myocardial infarction. This implies that EFM devices will be evaluated on their ability, for example, to reliably record the fetal rate, but may not be evaluated on whether recording of the fetal heart rate makes any difference to the outcome of the infant. We should also point out that this discussion is speculative, since the law has not been fully implemented and no official performance standards for devices have yet been published. Since there are now more than 12,000 distinct types of medical devices, the restraints of limited manpower and budget will probably prevent full implementation of the law until well into the 1980s.[18]

In summary, EFM has not been rigorously evaluated in terms of its impact on morbidity and mortality. In the future, the Medical Devices Program may assure that some type of evaluation is done before widespread use of a device, but the dissemination and acceptance of EFM preceded passage of that law. Few evaluation studies were done with either private or public support. The fact that the Maternal and Child Health Program funded two clinical trials indicates that there may be value in providing funds to service programs to support evaluative studies.

Policies Regarding Health Planning for EFM

Problems of duplication of resources and rising medical care costs led to the passage of health planning legislation in 1974. Under the Health Planning and Resources Development Act of that year (P.L. 93-641), more than 50 state agencies and more than 200 local planning agencies were established. The health planning program has three main functions relating to medical technology: 1) development of National Guidelines for Health Planning; 2) certificate-of-need programs administered by the state agencies; and 3) appropriateness reviews of institutional services.

None of these programs has been applied to EFM. Certificate-of-need generally comes into effect if a capital investment exceeds $150,000. Unless the introduction of EFM involved major renovation in the hospital, it would fall well under this level.

Within an institution, a department of obstetrics generally can buy EFM equipment with funds from its operating budget, since the initial investment is a small one.

However, states do have the flexibility under the law to write their own requirements. We recently surveyed all state agencies to see if they do in fact review EFM services. One of the 35 respondents reviews EFM under certificate-of-need. One state reviews ultrasound monitoring only. The other 33 states indicate no activity concerning EFM.

In summary, neither public nor private policies constrain the purchase of electronic fetal monitors.

Policies toward Payment for EFM

If institutions providing EFM included it as part of their obstetric package, there would be no financial incentive to use EFM—there might even be a mild disincentive since EFM does have direct costs. On the other hand, if institutions do charge separately for EFM, there is an incentive to use the equipment to recoup the investment. The survey of health planning agencies mentioned above included a question about separate fees. A number of state agencies reported that separate fees for EFM are common. A survey of 563 institutions known to use EFM in 1975 revealed that 142 of the 344 respondents (46.3 per cent) charged a separate fee,[19] the most common fee being $25. Such a fee is an important incentive encouraging the use of EFM.

Third party payors, such as Blue Cross, generally reimburse institutions for their charges, depending on the specifics of the medical-care contract with the patient. Such reimbursement is generally available through insurance. The only major government program involved, the Medicaid program for the poor, generally follows the lead of Blue Cross and other major insurance programs. Thus, third party payment for EFM is probably readily available.

Policies toward Use of EFM

The only federal program that deals directly with use of technology is the PSRO program. Established in 1972 in the Social Security Amendments of that year, the PSRO program is a cost control and quality assurance program that reviews primarily hospital services delivered under the Medicare and Medicaid program.[20] The law requires that PSROs

use norms, criteria, and standards in evaluating medical services. Standards are developed typically by a consensus of physicians, based on typical patterns of practice in the area and on such regional or national information as may be available. However, PSRO is a peer review, physician-run program and standards have been largely local. As far as the central PSRO program knows, no PSROs have standards dealing with EFM.

Surveys have shown a high degree of support for EFM among practicing obstetricians. Given this support and the structure of the PSRO program, it is not likely that PSROs could be used to control the use of EFM.

Private policies have a profound impact on utilization. Many obstetricians and hospitals do EFM routinely, perhaps in some cases against the desires of the patient. Since obstetricians are convinced that EFM is efficacious, it seems to us that true informed consent is not being offered, because patients receive their information from a biased source.

Finally, malpractice is often the only recourse a patient has, and it is a powerful control over the medical profession. The malpractice dilemma is, in part, related to the defensive use of a technology like EFM without good evidence of benefit. The prudent obstetrician often sees no alternative but to monitor electronically. Nevertheless, the use of EFM reinforces the public misconception that a physician has the tools to adequately predict the effects of perinatal asphyxia to the degree that he or she be held legally accountable.[21] More than ten malpractice suits have been brought against institutions and physicians in cases where a newborn had died or been born mentally retarded and EFM had not been used. At least one suit has been brought against a physician for use of the EFM which allegedly caused a fatal infection of the mother. Resolution of the cases are likely to help institutionalize EFM even further.***

Discussion

The evidence indicates that EFM is of little if any proven benefit to low-risk patients than regular auscultation, and that EFM is a costly and dangerous procedure. Thus, its diffusion and routine use demonstrate a failure of public and private policies.

As is the case with many medical technologies, the public and private investment in the development of EFM has been considerable. It was not evaluated, however, before it was put into widespread use, and it still has not been adequately evaluated.

Both public and private policies have failed to ensure adequate evaluation of EFM and have not controlled its spread or use; yet, both sectors have readily provided reimbursement for its use. Thus, all policies, both public and private, have either been neutral or have encouraged the acceptance and use of EFM.

A new part of FDA, the Medical Devices Program, is implementing regulatory controls over EFM. However, these controls deal almost entirely with safety. Furthermore, given that FDA deals with efficacy from a very narrow perspective, little change can be expected from this program in EFM use in this country. NIH has implemented a program to develop and disseminate better information to providers and the public, the so-called "consensus mechanism." Although having considerable promise, the effects of this program are unknown.

Cases such as that of EFM have convinced the Congress that existing programs for evaluating medical technology are not adequate, and led to passage of legislation late in 1978 to establish a new National Center for Health Care Technology whose purpose is to carry out and fund studies of specific medical technologies.[22] The Center is presently being organized, and the Center has already indicated that EFM is a high priority for evaluative studies.

The strategy for change in use of technology embodied in these recent policy initiatives is one of information development and dissemination. Whether this will be effective in changing physician behavior remains to be seen.

***The authors have been made aware of these suits by communications from lawyers, physicians, and hospital administrators who have called or written for consultation.

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The University of Montreal, under the sponsorship of Health and Welfare Canada, the General Institute of Health Services of Canada, the Quebec Public Health Association and other scientific and professional associations is organizing an International Conference on Systems Science in Health Care in Montreal from July 14 to July 17, 1980. All those interested in the application in the health field of systems analysis, operational research, management sciences, cost-benefit and cost-effectiveness analyses are invited to participate in this conference, and to submit an abstract (of about 400 words) in French or in English to the Conference Chairman before December 31st, 1979. The applicants whose paper will be accepted will be advised in late February 1980. Texts received at the conference will be considered for publication in the Conference's Proceedings. Persons interested in organizing sessions on special subjects are asked to contact the Conference Chairman as soon as possible.

The objective of this Conference is to emphasize the application of the systems analysis approach in identifying and resolving problems encountered in the management of systems of recovery, maintenance, prevention and promotion of health. Contributions related to problems ranging from strategic choice-of objectives problems to tactical efficiency problems will be taken into consideration. Papers dealing with national and regional health systems will be considered, as well as those concerning the management of a particular institution or program. Theoretical propositions are welcome, but statements of successful practical applications will be favored.

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