~~11504~~

BY THE COMPTROLLER GENERAL 110438

Report To The Congress

OF THE UNITED STATES

Evaluating Benefits And Risks Of Obstetric Practices--More Coordinated Federal And Private Efforts Needed

The Federal Government, through the Department of Health, Education, and Welfare, has a number of responsibilities relating to U S obstetric practices, including

--ensuring the safety and effectiveness of drugs and medical devices,

--funding medical research and Professional Standards Review Organizations,

--educating the public on health care, and

--paying for deliveries under some federally funded programs

HEW needs to better coordinate these responsibilities, better educate the public on the benefits and risks of various childbirth practices, and do more to help minimize incorrect use of obstetric practices

~~907080~~
110438

HRD-79 85
SEPTEMBER 24, 1979

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D C 20548

B-164031(5)

To the President of the Senate and the
Speaker of the House of Representatives

This report discusses the need for the Department of Health, Education, and Welfare to better organize its activities relating to medical practices used during childbirth and to increase its efforts, in concert with the private medical community, in evaluating these practices and informing and educating the public about their benefits and risks. The Department's responsibilities and activities relating to obstetric practices include promoting research; regulating drugs and medical devices; developing medical care quality standards and evaluating the quality of medical care; providing health education, information, and promotion; and providing or paying for obstetric care.

Our review was made because of the intense controversy over the benefits and risks of various obstetric practices, increasing congressional concern over the cost and quality of medical care, and the fact that obstetric practices affect more than 6 million women and infants annually.

Copies of this report are being sent to the Director, Office of Management and Budget, and the Secretary of Health, Education, and Welfare.

Elmer B. Staats
Comptroller General
of the United States

COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

EVALUATING BENEFITS AND RISKS OF OBSTETRIC PRACTICES--MORE COORDINATED FEDERAL AND PRIVATE EFFORTS NEEDED

D I G E S T

Representatives from the medical community say that obstetric practices in the United States have contributed to a declining fetal and infant mortality rate. However, critics cite hazards associated with some of the practices or point to differences between these practices in the United States and in some other countries.

Particularly controversial practices include elective induction of labor, the use of medication to relieve labor pain, the preventive use of forceps, routine electronic fetal monitoring, and the increasing use of cesarean sections. A GAO review of these practices showed that in many cases information is inconclusive about their benefits and risks. The review also showed a lack of controlled and long-term studies on the effects on a child of the use of some procedures. (See pp. 8 and 9.)

The Federal Government, through the Department of Health, Education, and Welfare (HEW), attempts to ensure the safety and efficacy of drugs and medical devices, funds medical research and Professional Standards Review Organizations which evaluate medical practices, educates the public on health care, and pays for deliveries under some federally funded programs. (See pp. 5 and 13.)

Several HEW agencies have responsibilities for or interests in obstetric procedures, but no one organization has responsibility for pulling the diverse efforts and interests together into a planned, coordinated approach. The Food and Drug Administration regulates some aspects of the use of drugs and medical devices in obstetrics. Several other HEW agencies sponsor research or administer

health education, information, and promotion activities. Professional Standards Review Organizations are responsible for establishing criteria and standards for and evaluating the necessity, quality, and appropriateness of medical care. (See pp. 13 to 27.)

GAO's review showed that HEW has taken some actions regarding obstetric practices, for instance, on the safety and efficacy of some drugs used in obstetrics. In 1978, HEW's drug advisory committee recommended that labels of drugs used for induction contain a warning stating that the benefit versus risk ratio for elective induction of labor has not been defined. It recommended that two drugs used for induction of labor be removed from the market. In March 1979, an HEW advisory committee discussed the use of drugs to relieve pain during childbirth. Although HEW has a system for collecting information on adverse drug reactions, it has no system for periodically reviewing marketed drugs. Its efforts are concentrated on the licensing of new drugs. Its review of medical devices under a 1976 act is still being put into effect. (See pp. 14 to 19.)

HEW has also had limited involvement in other areas. It has sponsored some research on obstetric practices, but most of these have been short term and not part of an overall plan. In March 1979, HEW sponsored a conference to discuss the benefits and risks of electronic fetal monitoring and other topics. Except for evaluations of the use of cesarean sections, Professional Standards Review Organizations have done few medical care evaluations on obstetric practices. (See pp. 20 to 27.)

RECOMMENDATION TO THE CONGRESS

GAO recommends that the Congress consider the problems identified in this report relating to regulation of selected drugs used during labor and delivery in deciding

whether or how to strengthen the Food and Drug Administration's authority on procedures for regulating drugs. (See p. 36.)

RECOMMENDATIONS TO THE SECRETARY OF HEW

GAO recommends that the Secretary of HEW designate the newly created National Center for Health Care Technology or some other organization to oversee, coordinate, and promote departmental activities relating to obstetric practices. Specific activities should include:

--Convening a panel of representatives from Federal agencies and medical and consumer organizations with interests or responsibilities involving obstetric practices to develop a plan for reviewing obstetric practices.

--Evaluating, consistent with this plan, existing research to give the public an assessment of what is known and unknown about the benefits and risks of various U.S. obstetric practices.

--Setting priorities for and coordinating HEW's research efforts on various obstetric practices and developing a plan to obtain needed data, including long-term effects on the child. (See pp. 36 and 37.)

--Determining how to help minimize incorrect use of obstetric procedures through Professional Standards Review Organizations.

--Emphasizing health education, information, and promotion activities on obstetric practices for health care providers and the public.

COMMENTS BY HEW AND MEDICAL PROFESSIONAL ORGANIZATIONS

GAO received written comments on a draft of this report from HEW and informal comments

from the American College of Obstetricians and Gynecologists, the American College of Nurse-Midwives, and two representatives of the American Academy of Pediatrics. These comments and GAO's evaluation of them are summarized in chapters 4 and 5 of this report. HEW's comments are included as appendix III of this report.

HEW agreed with most of GAO's recommendations and identified several actions it had taken or planned to take to help resolve the controversy surrounding obstetric practices. The American College of Obstetricians and Gynecologists said that it is willing to work with HEW in this area.

Representatives from the American Academy of Pediatrics agreed that more research on the benefits and risks of obstetric practices is needed, and believed that the benefits of various obstetric practices need to be given more consideration. The American College of Nurse-Midwives believes that more emphasis needs to be given to educating couples on childbirth.

Contents

ABBREVIATIONS

ACOG	American College of Obstetricians and Gynecologists
CPHA	Commission on Professional and Hospital Activities
FDA	Food and Drug Administration
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare
MCE	medical care evaluation
NICHD	National Institute of Child Health and Human Development
NIH	National Institutes of Health
NINCDS	National Institute of Neurological and Communicative Disorders and Stroke
OTA	Office of Technology Assessment
PSRO	Professional Standards Review Organization

CHAPTER 1

INTRODUCTION

Methods used in childbirth to facilitate labor and delivery have become a controversial issue in the United States. Many have questioned the necessity, benefits, or safety of some of the procedures. Critics cite hazards which are associated with some of these obstetric practices or point to differences in use of particular practices within the United States or between the United States and other countries. Some of these countries have lower infant mortality rates than the United States, which some say indicates a need to reexamine the childbirth methods used here. Representatives from the medical community, on the other hand, say that U.S. obstetric practices have contributed to the declining U.S. perinatal (fetal and infant) mortality rate. They claim that the benefits derived from using these practices exceed any risks associated with them.

How babies are delivered is an important national concern. Each year more than 3 million deliveries occur in the United States. Obstetric practices used during these births may improve the chances for mother and baby to come through the birth process healthy. But on the other hand, these same practices may contribute to perinatal mortality, birth injury, or permanent injury to the child, and may contribute to injury to the mother.

In 1977 delivering babies ranked as the highest diagnostic category for all discharges for females from non-Federal, short-stay hospitals in the United States. In fact, in 1977, about one in every six women discharged from U.S. non-Federal hospitals had been admitted to give birth. According to American Hospital Association data published in 1976, about 4,620 of approximately 7,070 U.S. hospitals offer obstetric services. The distribution of births in these hospitals in 1976 was as follows:

Number of births	Number of hospitals
1-99	850
100-199	690
200-299	510
300-2,999	2,480
3,000 and over	90
Total	4,620

In April 1978, the Senate Subcommittee on Health and Scientific Research held hearings on the implications of various obstetric practices on the health of mothers and children. Several witnesses questioned their safety for the child. They also questioned elective use of certain of these obstetric practices. After these hearings, we met with Subcommittee staff members and agreed to look into some of the issues concerning selected obstetric practices and Federal agency involvement.

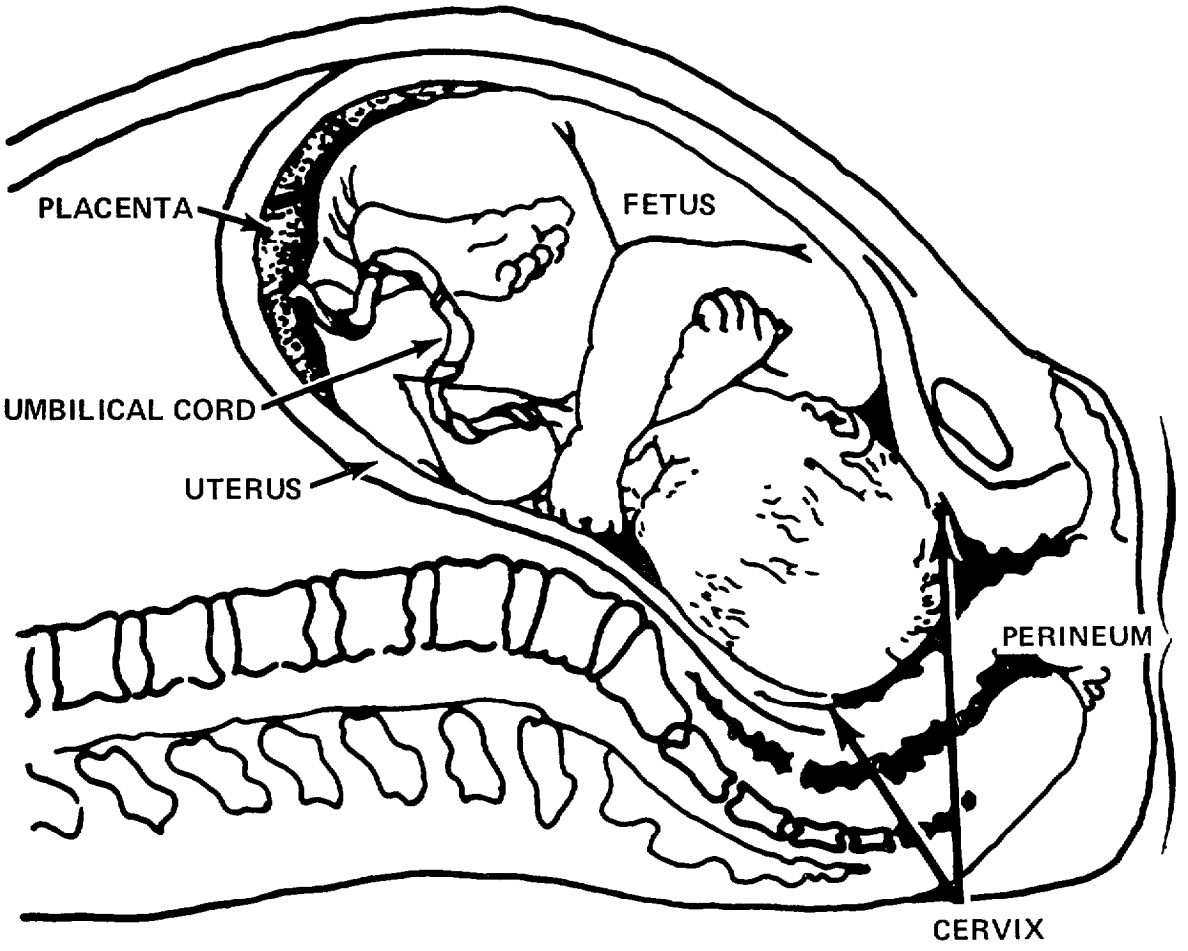
THE BIRTH PROCESS

Labor is the process by which the fetus passes from its intrauterine environment to the outside world. Unless the baby is delivered by cesarean section, three stages of labor occur: dilation, delivery of the baby, and delivery of the placenta.

The first, "stage of dilation," begins with the onset of regular uterine contractions and ends with the complete dilation of the cervix (the lower end or neck of the uterus). The main goal during this stage is the shortening, thinning, softening, and opening (dilation) of the cervix. The average length of the first stage of labor is about 12 hours in a first labor and about 7 hours in subsequent labors. However, marked, individual variations occur in the length of the first stage.

The second, "stage of expulsion or delivery," begins with the complete dilation of the cervix and ends with the birth of the baby. The goal of this stage is the descent of the fetus through the vaginal canal and the infant's eventual delivery. The length of this stage generally depends on the amount of resistance the infant must overcome, but can also be affected by other factors, such as inadequate uterine contractions. For a woman who has already had a child and is now pregnant with a baby which is small, the second stage may be only momentary. However, in a first labor or in a subsequent labor when the baby is large, the mother may have to exert much voluntary effort (bearing down) to advance the baby through the birth canal. The second stage of labor is considered prolonged but not abnormal if it lasts more than 1 hour. The textbook, "Williams Obstetrics," states that the median length of the second stage is 50 minutes in the first and 20 minutes in subsequent labors but notes that its length can vary widely. In the United States, obstetricians believe that the second stage should generally not exceed 2 hours because of potential danger to the baby or mother.

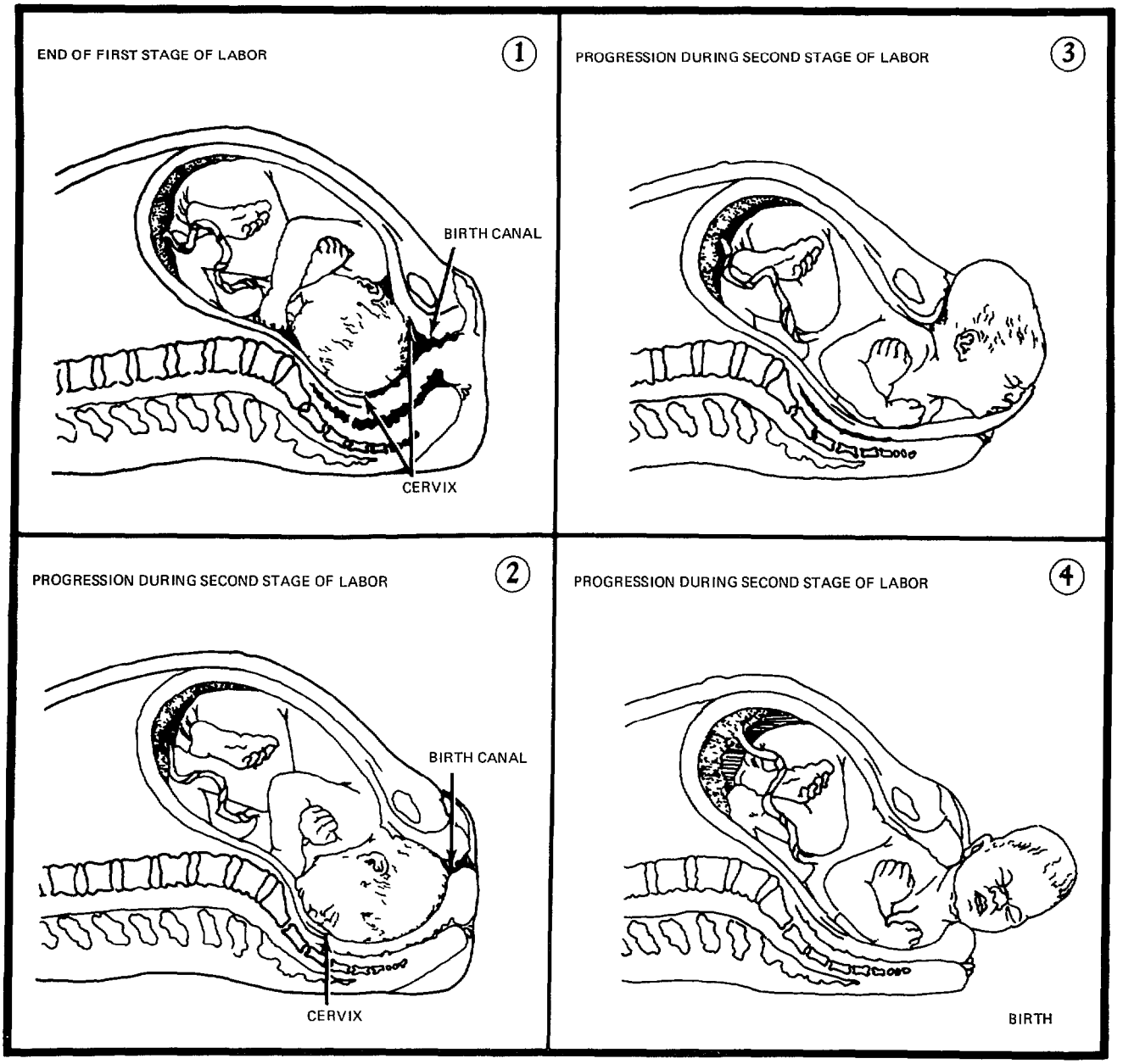
The third stage of labor, "the placental stage," begins when the delivery of the baby is complete and ends with the delivery of the placenta. The goal of this stage is the separation and expulsion of the placenta (a spongy structure that grows on the wall of the uterus during pregnancy and through which the fetus is nourished; also called afterbirth).



TRANSVERSE SECTION TAKEN LATERALLY THROUGH THE PELVIC REGION OF MOTHER IN LABOR PRIOR TO DELIVERY

SOURCE ADVENTURE TO MOTHERHOOD J ALLAN OFFEN M D

PROGRESSION OF FETUS DURING LABOR



SOURCE ADVENTURE TO MOTHERHOOD J ALLAN OFFEN M D

OBSTETRIC PRACTICES USED IN THE BIRTH PROCESS

Some obstetric practices are used routinely; some only when complications develop. Still others are used both routinely and for complications. We focused on five of them: induction of labor, use of drugs for relief of labor pain, instrument delivery (forceps or vacuum extraction), electronic fetal monitoring, and cesarean section. Each practice is discussed separately in our staff study, "A Review of Research Literature and Federal Involvement Relating to Selected Obstetric Practices" (HRD-79-85A).

FEDERAL AGENCY INVOLVEMENT IN OBSTETRIC PRACTICES

Federal agencies are involved in the area of obstetric practices in several ways, including regulating obstetric drugs and devices, funding research, and evaluating medical practices. The Food and Drug Administration (FDA) of the Department of Health, Education, and Welfare (HEW) is responsible for reviewing obstetric drugs and devices for safety and efficacy. HEW also funds research on obstetric practices, primarily through its National Institutes of Health (NIH), although several other agencies are also involved. Professional Standards Review Organizations (PSROs), which are funded by HEW, evaluate health care practices, including those used in obstetrics. In November 1978, a National Center for Health Care Technology was established to conduct and support research, demonstrations, evaluations, and statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the United States.

The Federal Government also pays for many deliveries through such programs as Medicaid, Maternal and Child Health, the Civilian Health and Medical Program of the Uniformed Services, and the Federal Employees Health Benefits program. The Department of Defense also provides obstetric services in many military hospitals. In fiscal year 1977, the Department of Defense paid nearly $67 million for physician and in-hospital care for about 53,900 deliveries under its Civilian Health and Medical Program. Also in 1977, Medicaid and the Maternal and Child Health programs were the expected source of payment for 182,761, or nearly 15 percent, of 1.2 million deliveries reported by 1,558 hospitals for which expected payment data were reported by the Commission on Professional and Hospital Activities (CPHA),

a private-nonprofit organization that collects, analyzes, and disseminates health care information.

PROFESSIONAL INVOLVEMENT IN OBSTETRIC PRACTICES

The American College of Obstetricians and Gynecologists (ACOG) is a professional organization for obstetricians. ACOG issues general standards for obstetric care and periodically publishes technical bulletins and statements on areas of interest to its members. ACOG was also involved in a 1967 National Survey of Obstetric Practice funded by HEW. (See p. 21.)

ACOG's publications touch on a variety of obstetric topics. Its standards for obstetric-gynecologic services for intrapartum care give recommendations for hospital admission policies and procedures for dealing with labor and delivery. The technical bulletins describe currently acceptable clinical techniques. They do not, however, represent ACOG's official policy or recommendations and do not exclude other acceptable methods of handling similar problems. Concerning the five obstetric practices we reviewed, ACOG has issued technical bulletins on fetal monitoring, obstetric analgesia and anesthesia, and induction of labor. ACOG has also issued a statement on use of medications during labor and delivery, urging physicians' caution until the long-term effects of these medications are known.

SCOPE OF REVIEW

We reviewed over 1,000 U. S. and foreign research articles on selected obstetric practices identified through the National Library of Medicine's computer based Medical Literature Analysis and Retrieval System and a review of bibliographies of articles we obtained primarily from the National Library of Medicine. We assessed the scope and depth of the research done in terms of such factors as the number of patients studied, the time period involved, the use of control groups, and the procedures evaluated, and we summarized the conclusions reached. We made no attempt to make a clinical evaluation of the articles we reviewed, nor did we attempt to evaluate pre-publication review and approval requirements of various journals.

We also contacted headquarters officials of the following HEW agencies and offices about their involvement in obstetric practices:

--Food and Drug Administration
  Bureau of Drugs
  Bureau of Medical Devices
  Bureau of Radiological Health

--Health Care Financing Administration
  Health Standards Quality Bureau

--Health Resources Administration
  National Center for Health Statistics

--Health Services Administration
  Bureau of Community Health Services
    Office of Maternal and Child Health

--National Institutes of Health
  National Institute of Child Health and Human Development
  National Institute of Neurological and Communicative Disorders and Stroke

--Office of the Secretary
  Office of the Assistant Secretary for Planning and Evaluation

We also met with officials of the Office of Technology Assessment (OTA) and received information from PSROs on evaluations of obstetric practices.

In addition, we obtained information from CPHA on hospital occurrence in 1977 of the five obstetric practices we reviewed. CPHA has a data base of about 2,200 hospitals (about 1,900 in the United States and about 300 in Canada and Puerto Rico). These hospitals discharge about 17 million patients a year and account for about 42 percent of the short-term discharges in the United States and 28 percent in Canada. For 1977, CPHA received data on 1.3 million deliveries in the United States.

A copy of the bibliography of articles we reviewed and a summary of research articles dealing with effects on the infant for the five obstetric practices we reviewed can be obtained from the

Human Resources Division
U.S. General Accounting Office
Room 130
12420 Parklawn Drive
Rockville, Maryland 20857

CHAPTER 2

RESEARCH LITERATURE INCONCLUSIVE

The research literature we reviewed was inconclusive in determining the benefits versus risks of certain obstetric practices used during labor and delivery. Consumer representatives and some medical professionals are concerned about the increasing elective and preventive use of these practices and about the rising cesarean section rate. The practices they are questioning include:

--Elective induction of labor--that is, beginning labor artificially for the convenience of either the patient or the physician.

--Use of medication for pain relief during labor and delivery in doses and ways which may be harmful to the fetus/child.

--Use of forceps (an instrument which can help deliver the fetus from the vagina) and the preference of some European countries for the vacuum extractor (also used to facilitate vaginal delivery).

--Routine use of electronic fetal monitoring.

--A doubled cesarean section rate in the United States between 1971 and 1976.

Generally, the research literature did not address the effects of these practices on the child beyond the first day of life. Also, most of the research was retrospective, dealt solely with one hospital's experience with a particular practice, and did not have matching control groups. In commenting on a draft of this report, ACOG noted that the general absence of adequate control groups is a major problem with all of these research studies.

Some research studies did offer conclusions about the benefits of these procedures. For instance, some said the procedures actually harmed the infant. Others cited incorrect use of the procedure as the cause of harm to the fetus/child. Still others indicated that use of one practice may lead to use of another which may harm the infant. On the other hand, some researchers strongly advocate using these obstetric practices.

The research literature seems to confirm that such practices as those listed above have a place in obstetrics. However, the literature does not resolve the question of how often or whether to use the practices electively, preventively, or routinely.

A detailed description of our research literature review of the five obstetric practices mentioned above can be found in our staff study, "A Review of Research Literature and Federal Involvement Relating to Selected Obstetric Practices" (HRD-79-85A).

EXTENT OF USE OF SELECTED OBSTETRIC PRACTICES

National data on the extent of use of the reviewed obstetric practices are not gathered routinely except for cesarean sections. Also, we were not able to obtain large-scale data on elective use of induction, preventive use of forceps, routine use of fetal monitoring, or use of external methods of electronic fetal monitoring. However, data we obtained from CPHA on 1.3 million reported deliveries for 1977 showed variation in using these procedures particularly by region of the country.

	All United States	North-eastern	North Central	Southern	Western
	(percent)				
Induction	11.8	13.7	13.6	8.8	10.3
Use of anesthesia	80.8	75.3	81.1	80.6	86.7
Forceps	25.6	24.2	23.9	31.7	22.2
Vacuum extraction	.3	.3	.2	.1	.8
Intrauterine procedures (note a)					
--for cesarean sections	8.6	8.2	9.4	6.4	10.4
--for total deliveries	10.4	10.6	10.8	7.9	13.0
Cesarean sections	13.4	15.0	12.4	13.3	13.8

a/Primarily internal fetal monitoring.

CPHA also supplied information on these deliveries by type of hospital (teaching versus nonteaching), hospital bed size, and payment source. Charts derived from these data are in appendix II, showing data and percentages. The data showed the percentage of use of these procedures tends to be:

--Higher in teaching than nonteaching hospitals, with the biggest variance occurring in the use of intrauterine fetal procedures, which were used during (1) 11.6 percent of cesarean deliveries in teaching hospitals versus 6.5 percent in nonteaching hospitals and (2) 16.4 percent of total deliveries in teaching hospitals versus 7.0 percent in nonteaching hospitals.

--Greater for larger hospitals with the biggest difference being in intrauterine procedures for total deliveries which ranged from 6.2 percent for hospitals with 1 to 199 beds to 14.8 percent for hospitals with 400 or more beds.

--Less for deliveries paid for by Medicaid and title V (the Maternal and Child Health program) than from other sources except for intrauterine fetal procedures, with the largest difference being 72.6 percent use of anesthesia under Medicaid and title V versus 82.1 percent for other payment sources.

SCOPE OF STUDIES GENERALLY LIMITED TO THE FIRST DAY OF INFANT'S LIFE

In general, the studies we reviewed looked only at the effects on the infant right after birth. However, a few studies did go beyond this period and concluded that adverse effects may not be immediately detectable.

The largest study providing data beyond the first day of birth is the Collaborative Perinatal Project (see p. 23). Data from the project have been used in other studies, including those on the effects of medications and forceps.

Other long-term studies were limited. One was reported by Niswander et al. in 1966 concerning elective induction of labor. Also, a limited number of studies of forceps and vacuum extraction followed up on children for more than 1 year after birth.

SOME STUDIES CITED EFFECTS ON INFANT FROM CERTAIN OBSTETRIC PRACTICES

Research studies we examined listed a number of harmful effects as the result of certain obstetric practices. Some authors even cited induction of labor, cesarean section, drugs used to relieve labor pain, forceps, and electronic fetal monitoring as a cause of infant death. However, the percentages of such reported deaths were not high. Another effect cited was prematurity due to an incorrectly timed cesarean section or induction of labor. Obstetric drugs were connected with behavioral alterations in the infant, infant depression, and slowing of fetal heart rate. Scalp abscesses and other head wounds were sometimes found to result from electronic fetal monitoring. Head injuries were also cited as resulting from delivery by forceps or vacuum extraction.

However, not all studies associated these practices with harm to the infant. Some said that they had no effect or that selected practices were beneficial.

CHANCE OF INCORRECT USE OF A PROCEDURE

Cases of incorrect use of a procedure causing harm to the infant have occasionally been cited in the literature. For example, excessive amounts of drugs used to relieve the mother's labor pain or for induction of labor can harm the infant. Also, several deaths have been attributed to accidently injecting the fetus with a pain relieving drug. In addition, incorrect use of forceps, vacuum extraction, or scalp electrodes used for fetal monitoring can cause infant head injuries.

QUESTIONS ABOUT WHEN TO USE A PROCEDURE

Our literature review confirmed that obstetric procedures can facilitate delivery and can help decrease infant mortality and morbidity. However, sometimes a proposed procedure may be risky or its need questionable. As a result, some questions are raised about the need for using these obstetric practices in such cases. For example:

--Is induction of labor justifiable as an elective procedure for the convenience of either the patient or physician? One of FDA's drug advisory committees recently concluded that the benefit-to-risk ratio for elective induction of labor has not been defined.

FDA, therefore, is requiring manufacturers of drugs used in induction to add a warning to their drug labels. However, FDA is not requiring that physicians warn their patients about these drugs.

--What is the proper balance between pain relief for the mother and possible danger to the fetus from medications used in labor and delivery? Heavy doses of these medications may provide greater relief to the mother but also have a greater harmful effect on the fetus.

--Is preventive use of forceps a justifiable obstetric practice?

--Is routine electronic fetal monitoring justifiable?

--Does the marked increase in cesarean sections indicate an increasing need for these operations, and are appropriate steps being taken to see that scheduled cesarean sections are not done too soon?

CHAPTER 3

THE FEDERAL GOVERNMENT SHOULD DO MORE TO HELP RESOLVE THE CONTROVERSY OVER OBSTETRIC PRACTICES

In view of its various responsibilities affecting obstetric practices--including those used in labor and delivery--the Federal Government through HEW should do more to (1) evaluate these practices, (2) help resolve some of the controversy surrounding them, and (3) better inform and educate the public on their benefits and risks. The responsibilities in question include those for ensuring the safety and efficacy of drugs and medical devices and funding medical research. In addition, local PSROs could do more to establish medical care standards and criteria and encourage hospitals to perform additional medical care evaluations (MCEs) in the area of obstetric practices.

Our review showed that current Federal efforts in these areas of responsibility are limited or lacking. Specific problems include:

--FDA's regulation of drugs depends on when the drugs entered the market, and FDA's adverse drug reaction reporting system does not supply enough information on long-term effects and adverse reactions to the drugs. FDA's regulation of medical devices is relatively new and not yet fully implemented.

--Federal funding of research on the obstetric practices we reviewed has been fragmented and lacks overall direction.

--PSRO MCEs of obstetric practices have been infrequent because, according to HEW, PSROs and hospitals have given higher priority to the medical and surgical areas which involve larger numbers of patients.

--HEW has given little emphasis to educating and informing the public on risks and benefits of obstetric procedures.

In 1978, the Congress established a National Center for Health Care Technology in HEW. However, at the time of our

review it was too early to evaluate the work of the new center, although it appears to have the potential for helping resolve some of the controversy over obstetric practices

PROBLEMS WITH FDA's REGULATION OF DRUGS AND MEDICAL DEVICES

FDA is responsible for regulating drugs and medical devices under the Food, Drug, and Cosmetic Act of 1938, as amended. One of FDA's major responsibilities is to approve new drugs before marketing. FDA's approval process for new drugs is based on animal studies and clinical studies on a limited number of humans. FDA does not have the opportunity to observe long-term effects until drugs are marketed and used extensively. Also, FDA does not require regular reviews of marketed drugs, and its present system for monitoring marketed drugs does not ensure that it knows about all adverse reactions. Thus, there is no assurance that action will be promptly taken when needed to remove drugs from the market or add label warnings. FDA requires label warnings for physicians on possible adverse effects of drugs. We believe that more information on benefits and risks should be given to patients during the prenatal care period. The major legislation on FDA's regulation of medical devices is the Medical Device Amendments of 1976. However, at the time of our review FDA was still in the process of implementing its programs under these amendments. FDA is not responsible for regulating medical procedures.

Legislative background for regulating drugs and medical devices

Under the Food, Drug, and Cosmetic Act, as amended, FDA is charged with ensuring that human and animal drugs and medical devices are safe, effective, and properly labeled. The provisions of the act for "new drugs" require that the manufacturer of such drugs submit evidence to FDA demonstrating their safety and efficacy before placing them on the market. The new drug application is the process for submitting this evidence. Before 1938, no such requirement existed.

The Kefauver-Harris Amendment of 1962 strengthened the 1938 act by requiring submission of substantial evidence of a drug's effectiveness before marketing. Thus, drugs entering the market between 1938 and 1962 had only to prove safety but not effectiveness, and those marketed before 1938 were

exempt from FDA regulation altogether (under a "grandfather clause") as long as they retained the same composition and labeling.

In response to the 1962 amendments, FDA has been conducting a retrospective evaluation of the effectiveness of drugs put on the market between 1938 and 1962. This Drug Efficacy Study Implementation program is still going on. Panels of experts are reviewing effectiveness data supplied by the manufacturer and are classifying drugs in one of four effectiveness categories. Those classified ineffective are to be removed from the market.

The Congress further modified the act by the Medical Device Amendments of 1976. Under these amendments, FDA became responsible for assuring the public that devices are safe and effective when used properly.

FDA's Bureau of Drugs and Bureau of Medical Devices carry out these functions. FDA also has drug advisory committees to assist the Commissioner of Food and Drugs and the Director of the Bureau of Drugs in reviewing new drug applications. Upon request from FDA they review the use of particular drugs. The Anesthesiology Advisory Committee reviews those used in anesthesiology and related areas, and the Fertility and Maternal Health Drugs Advisory Committee reviews other obstetric drugs, such as those used in induction of labor.

No testing of long-term effects on the child

When evaluating a new drug for approval, FDA does not require testing for the potential long-term effects on the infant or child because it is considered impractical to do so. The testing which does occur considers only very short-term effects on the infant. Thus, there is no assurance that these drugs do not have a long-term or postponed adverse effect on the child.

Before it approves any drug for marketing, FDA requires three separate phases of clinical tests of the drug in humans. The number involved in these tests, however, is limited. These usually are:

--Phase I: first human testing; generally limited to 20 to 50 people.

--Phase II: generally about 100 to 200 people.

--Phase III: may include several thousand people.

However, FDA's guidelines only require a check of the newborn at birth for such things as Apgar score 1/ and time to sustained respiration.

No periodic reviews of drugs already on the market

FDA does not periodically review drugs once they are on the market. However, negative effects of drugs may appear after their widespead use. Nevertheless, FDA's advisory committees mentioned above have made few reviews of the effect on the fetus/infant of drugs used during labor and delivery. We could find only one such review by the Anesthesiology Committee between 1967 and 1978. In 1977 and 1978 the Fertility and Maternal Health Drugs Advisory Committee reviewed all drugs used for induction of labor. In 1978, the Committee recommended that a warning label be added to the labels of drugs used for induction of labor, stating that the benefit versus risk ratio for elective induction has not been defined. It also recommended that two drugs used for induction of labor be removed from the market. However, many other drugs used in obstetrics have not been looked at. In March 1979, an FDA advisory committee discussed obstetric pain killers and appointed a subcommittee to look into the matter further.

Adverse reaction reports incomplete

Based on the research literature we reviewed, FDA's current adverse drug reaction system does not contain complete data on all such reactions found. For instance, the research articles we reviewed showed over 20 times more occurrences of one particular fetal effect than did the FDA information for the same time period. FDA's explanation for the incomplete data included not putting research literature reports in its computer system and physicians' reluctance to report adverse drug reactions due to fear of malpractice suits.

1/Apgar score is a measure of the physical condition of a newborn infant. A more detailed definition is contained on p. 42.

Informing physicians and the public of adverse drug reactions is a responsibility for FDA under the Food, Drug, and Cosmetic Act, as amended. As noted, in some cases adverse reactions to new drugs, or frequent occurrence of such reactions, only come out after widespread use of the drug rather than through clinical tests. As a result, FDA must continuously acquire and evaluate current and cumulative data about adverse reactions to keep its information up to date.

To gather information on adverse drug reactions and to assist in drug regulation, FDA created an adverse drug reaction reporting system in 1960. This system was to alert FDA to severe drug reactions and to identify a trend if a drug continued to be associated with the same reaction. FDA obtains adverse reaction information from various sources, including drug manufacturers, hospitals, and physicians. Nevertheless, sometimes physicians are reluctant to report adverse reactions. For example, physicians are reluctant to file reports since malpractice attorneys often use these data in preparing their cases. Therefore, voluntarily submitting such data might not be in their best interests. Another possible factor is that different physicians usually care for the mother and infant. Therefore, the physician caring for the infant may not associate delayed reactions with drugs used during labor and delivery.

We found a notable discrepancy between data collected by FDA's adverse reaction reporting system and that shown in the literature we reviewed. All data were for about the same period. An FDA list gave data, starting with the fall of 1969 until October 1978, on adverse reactions to drugs used in the third trimester of pregnancy and/or labor and delivery. The report showed 136 reports of adverse reactions to 25 drugs used in obstetrics. The most commonly reported reactions were apnea (transient stopping of breathing, 12 times), bradycardia (slowed heartbeat, 10 times), stillbirth (9 times), respiratory distress (7 times), death (6 times), nervousness (6 times), and neonatal jaundice (4 times). However, based on our review of U.S. research literature for 1970 to 1978, this list appears quite incomplete. For example, the literature reported over 200 cases of fetal bradycardia (mainly after paracervical block) as compared with 10 shown by the FDA system.

An FDA official told us that FDA does not attempt to review research literature and insert adverse reactions reported in the literature in its computer file of adverse reactions, but just includes data for which adverse reaction

reports were submitted to FDA. In our report, "Assessment of the Food and Drug Administration's Handling of Reports on Adverse Reactions From the Use of Drugs" (B-164031(2), Mar. 7, 1974), we concluded that FDA's adverse drug reaction reporting system had not achieved its purpose of being a means of collecting available information on drug reactions. We recommended that FDA centralize within the monitoring unit all information on adverse drug reactions located throughout FDA, including information from medical literature. Although FDA generally agreed with our recommendation, our current work showed that it had not yet done this.

Drug labeling directed at the physician only

Warnings on the labels of obstetric drugs are for the physician, who may not pass them on to the patient. Currently, patients are dependent on their doctors to heed these warnings and to use the drugs properly. However, FDA is considering a way of also getting information about these drugs to patients. It seems to us that it would be preferable for HEW to encourage and assist health care providers to give prospective mothers information on childbirth practices during the prenatal period.

The primary reason for prescription drug labeling is to give the doctor enough information to use the drug safely and effectively in treating patients. The labels may also carry warnings, including possible adverse reactions and contraindications (situations in which the drug should not be used). FDA does not require labeling or package inserts for patients containing such information. Also, physicians are not required to tell their patients about the contents of labeling. In addition, FDA has no way to insure that physicians heed warnings on drug labels or even heed listed contraindications. In its April 7, 1975, Federal Register notice proposing prescription drug labeling regulations, FDA stated "* * * the labeling is not intended either to preclude the physician's use of his best judgment in the interest of the patient or to impose liability if he does not follow the package insert."

An FDA official told us that although labeling currently is intended for the physician administering the drug, FDA is considering requiring patient package inserts that would tell the patient about potential risks and benefits of drugs. In relation to this, FDA sponsored a conference on language for patient package inserts in December 1978.

Legislation has been proposed (such as S.1045 and S.1075) which would enhance FDA's authority to regulate drugs. The proposed legislation contains provisions relating to several aspects of FDA's activities, including drug approval procedures, patient education, and post-marketing surveillance. As of July 1979, the Congress was still considering various proposals.

Medical device safety classifications still being put into effect

FDA is in the process of classifying medical devices according to their safety and effectiveness. Through its Bureau of Medical Devices, FDA must assure the public that medical devices are safe and effective.

The Medical Device Amendments of 1976 to the Food, Drug, and Cosmetic Act of 1938 require FDA to classify all medical devices into one of three categories. The following class names refer to the amount of control FDA will exercise over each particular class:

--Class I, General Controls. Devices for which existing controls are enough to assure safety and effectiveness or when insufficient information exists to determine controls are sufficient and the device is not life-sustaining or life-supporting and does not present a potential unreasonable risk of illness or injury.

--Class II, Performance Standards. Devices for which controls are not enough to assure safety and effectiveness, but for which enough information exists to establish a performance standard to give this assurance. Performance standards may relate to the construction, components, ingredients, and properties of medical devices.

--Class III, Premarket Approval. Devices for which not enough information exists to assure that general controls and performance standards will provide reasonable assurance of safety and effectiveness. The devices are either life-sustaining or life-supporting, or they present a potential unreasonable risk of illness or injury.

Obstetric devices remain to be classified under this system. At the time of our review, FDA was planning to classify fetal monitors, forceps, and vacuum extractors as Class II devices. As a result of this classification, FDA would need to adopt performance standards for these devices.

FEDERAL RESEARCH FUNDING FRAGMENTED AND LACKING DIRECTION

Many Federal agencies, especially within HEW, sponsor research on obstetric practices. However, this research is generally not coordinated as part of an overall plan. In addition, the scope of these studies was generally short term, and most did not consider effects on the fetus/child. One large prospective study had Federal sponsorship. This was the Collaborative Perinatal Project which began in the late 1950s and included over 50,000 pregnancies. (See pp. 23 to 25.) Researchers are still analyzing its data which followed up on the children to age 7.

Scope of research limited

Most federally funded research on obstetric practices, other than the Collaborative Perinatal Project, is directed at short-term rather than long-term effects and deals with a small number of patients. FDA funded one other project which was to examine the long-term effects of drugs used to relieve labor pain on the infant/child, but it was canceled before completion because FDA was unhappy with the contractor's progress. Also, many of the studies we reviewed dealt with less than 100 patients. Most of the studies we reviewed which were federally funded were very narrow in scope. For example, a study might review one specific drug administered by one specific route of administration.

Agencies funding research do not coordinate their efforts

Although many Federal agencies fund obstetric research, they do not coordinate their efforts. For the most part, agencies acted independently and had no overall action plan or list of priorities. During our review, we concentrated on HEW research efforts. They generally lacked an overall direction or goal. Most of the research we reviewed was funded by NIH. The two NIH institutes most active in obstetric research are the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) and the National Institute of Child Health and Human Development (NICHD). Other HEW components involved in research are the Office of Maternal and Child Health within the Health Services Administration and the Office of the Assistant Secretary for Planning and Evaluation. This list also includes FDA to a limited extent. Finally, some research has been done by agencies outside HEW, including OTA. No formal

mechanism existed to coordinate the research activities of the various agencies.

A major function of NIH is to conduct and support research into the causes, diagnosis, prevention, and cure of human diseases and on the processes of human growth and development. NINCDS has this research responsibility for neurological, sensory, communicative, and muscle disorders. As part of this function, NINCDS sponsored a massive, multidisciplinary, prospective research effort known as the Collaborative Perinatal Project. (See pp. 23 to 25.) NICHD conducts and supports biomedical and behavioral research on child health, maternal health, and problems of human development, especially retardation. Within NICHD, the Center for Research for Mothers and Children generally directs its research on humans at a specific topic such as sudden infant death syndrome or high-risk pregnancies. Also, NICHD funded some research studies on drugs and on fetal monitoring.

Due to both the inherent limitations in clinical trials and the need for improved methods of disseminating research information, NIH initiated a process for developing a consensus among representative experts regarding the proper role of a given medical technology. This process is called "technical consensus development." At the time of our review, NIH had not held any consensus development conferences on the five obstetric practices we looked at except fetal monitoring. In March 1979, a consensus development conference on antenatal diagnosis was held which addressed fetal monitoring, predictors of fetal maturity, and other topics.

The Office for Maternal and Child Health within the Health Services Administration supports research aimed at improving the health of mothers and children. For example, concerning infant and perinatal mortality and morbidity, the research focuses on such topics as the effects and outcome of designating certain regional hospitals for high-risk maternal and infant care; the relationships between perinatal and infant mortality and morbidity and gestational age and birth weight; and the redefining of the essential components of prenatal care. Regarding obstetric practices, the Office of Maternal and Child Health has funded a project on the increased incidence of cesarean section in California and two studies on fetal monitoring in high-risk pregnancies.

The Office of Maternal and Child Health also supported a national survey of obstetric practices and associated services in hospitals in the United States done by ACOG. In this survey a comprehensive questionnaire was sent to every known

hospital in the United States maintaining a maternity service. The response rate was 73 percent, and the 3,883 hospitals completing the questionnaires reported 2,795,601 births--approximately 80 percent of the hospital births occurring in the United States in 1967. The questionnaire included questions on pregnancy outcome, induction of labor, cesarean sections, use of anesthesia, physical facilities, hospital staff, laboratory facilities, and care of the newborn.

HEW's Office of the Assistant Secretary for Planning and Evaluation may also fund research on obstetric practices. This office hired a consultant to study the increasing cesarean section rate.

Although FDA's primary involvement in obstetric practices is in regulating drugs and devices to ensure their safety and efficacy, FDA also sponsors research. However, FDA's involvement in research on the obstetric practices we looked at has been almost nonexistent. FDA did sponsor one study to find ways of assessing the effects of selected drugs used to relieve labor pain on infants and young children. The study was to cover the first few years of a child's life but was canceled before completion.

FDA's Bureau of Radiological Health plans and conducts research to determine health effects of radiation exposure. As of September 1978, the Bureau had been involved in some research concerning the use of ultrasound during pregnancy. However, it did not focus on ultrasound use for fetal monitoring during labor and delivery.

Also, HEW's National Center for Health Statistics performed a National Natality Survey in 1972. This survey involved an 0.2-percent sample of the 2,818,000 legitimate, live, hospital births occurring in the United States in 1972 linked with a mail followup survey of the mothers, physicians, and hospitals associated with those births. In the survey, five types of delivery (spontaneous, forceps, cesarean section, breech, and other) were examined according to a wide variety of social and demographic, maternal health, infant health, and health insurance characteristics.

In addition to HEW, other Federal agencies are involved in obstetric research. A number of the research studies we reviewed were done at military hospitals by military doctors. Also, other work has been done by OTA.

OTA has done some research on fetal monitoring. The basic function of OTA is to assess for congressional committees the beneficial and adverse effects of technologies,

together with analyses of alternative technologies. In September 1978, OTA published a report entitled "Assessing the Efficacy and Safety of Medical Technologies." This was done in response to a request by the Senate Committee on Labor and Human Resources

> "* * * to examine current Federal policies and current medical practices to determine whether a reasonable amount of justification should be provided before costly new medical technologies and procedures are put into general use."

The report examines the importance and the current status of information on efficacy and safety of medical technologies as well as ways of generating that information. One of the 17 case studies in this report was on electronic fetal monitoring. In April 1979, HEW's National Center for Health Services Research published a report on a literature review of the costs and benefits of electronic fetal monitoring.

Collaborative project still incomplete

The NINCDS Collaborative Perinatal Project, begun in the 1950s, is still incomplete. Researchers are continuing to analyze the data from this project. Some have criticized the project because (1) patients were not selected for obstetric practices randomly, (2) patients were treated in many different institutions by physicians of varying competence and training and in hospitals with different philosophies of obstetric care, (3) the control group used may not have been appropriate for assessing obstetric practices, and (4) obstetric practices have changed considerably since the time of data collection. Nevertheless, several researchers have used the project's data as a basis for their own studies.

The Collaborative Perinatal Project is a prospective cohort study which seeks leads to the causes of cerebral palsy, mental retardation, learning disorders, congenital malformations, minimal brain dysfunction, convulsive disorders, and communicative disorders through studies which relate the events, conditions, and abnormalities of pregnancy, labor and delivery, and early neonatal life to the neurological and mental status of the children of these pregnancies as the children grow and develop. Through 1978, project costs were about $125 million.

The project was designed to record and observe the obstetric progress of pregnant women and to follow up on

development of their offspring to age 7. According to HEW, children with cerebral palsy were the study cases, and those children without cerebral palsy were the control group. Researchers did not attempt to influence any medical decisions in the course of pregnancy, labor, or delivery. The project studied 55,908 pregnancies between 1959 and 1965. The study sample was about half black and half white and was not intended as a statistical sample of the United States.

Deliveries occurred between 1959 and 1966 at 14 hospitals affiliated with 12 universities throughout the United States. According to HEW, either all or a randomly selected group of women seeking care at each of these hospitals were enrolled in the project. The children studied in the project were examined during their first year and again in their third and fourth years. At 7 years of age children received extensive testing, including a pediatric-neurological examination, a battery of psychological tests (including an I.Q. determination), and visual testing. In June 1974 an assessment of speech, language, and hearing development completed the followup on the children. As of June 1976, the basic data file on the project was complete.

In March 1978, NINCDS contracted for another study using data generated by the Collaborative Perinatal Project. This comprehensive study will look at effects on the offspring of labor and delivery. This study, currently funded at $127,000 annually, is scheduled for completion in March 1982. One objective of the study is to determine the

> "* * * relationships between the various types of maternal anesthesia-analgesia and development of the child; specifically to examine in detail the time-dose relationships and drugs used in combination during the course of labor and delivery in relation to long-term neurological outcome in the child."

However, the data to be used are for births occurring between 1959 and 1966. ACOG questions the current usefulness of the project data because obstetric practices have changed considerably since the 1959-66 period and because it believes the Collaborative Perinatal Project's methodology was not appropriate for assessing obstetric practices.

LITTLE EVALUATION OF OBSTETRIC PRACTICES BY PSROs

Since their creation, PSROs appear to have done little to evaluate the obstetric practices we reviewed, other than cesarean section. PSROs were established by the 1972 amendments to the Social Security Act to assure the necessity, appropriateness, and quality of health services under the Medicare, Medicaid, and Maternal and Child Health programs. A major part of this congressional mandate is the performance of MCEs by PSROs to review care or medical management practices to assess the quality or use of health services. But so far, in the area of practices used during labor and delivery, few MCEs have been done; the largest effort has been in evaluating cesarean sections.

Under the PSRO program, HEW's Health Care Financing Administration contracts with nonprofit organizations of local physicians to develop and implement a health care review system. Part of this system is the retrospective MCE study in short-stay general hospitals. Either PSROs, or hospitals under authority from them, select topics for review, develop criteria, review medical records, identify problems, and see that corrective actions are taken. HEW encourages PSROs and hospitals to conduct MCEs on all patients rather than just Medicaid, Medicare, or Maternal and Child Health patients to obtain a better analysis of practice patterns.

However, because (1) PSROs have done so few MCEs on obstetric practices, (2) the scope of evaluations varied so much in those choosing to evaluate cesarean sections, and (3) information is not readily available on the criteria used or quality of evaluations, no conclusive data are available on the safety or necessity of these procedures (from MCEs). Although PSROs could help provide some of the answers to questions raised by critics of these procedures or researchers, PSROs have generally not given much emphasis to this area. According to HEW, most topics selected for MCEs have centered on more frequent medical/surgical admissions. Although HEW has not issued guidance to PSROs for evaluating obstetric procedures, some efforts are beginning toward developing criteria for cesarean sections.

Statistics on obstetric MCEs

From 1975 to 1977 cesarean section and normal delivery accounted for 3.8 percent of the total MCEs reported by 97 PSROs. In terms of topic frequency for this period,

cesarean section was 7th and normal delivery was 14th. In August 1978, HEW provided us with a computer list of MCEs done in the areas of normal delivery and cesarean section. According to this list, 68 PSROs reported 391 MCEs on obstetrics--234 on cesarean section and 157 on other deliveries. Of these 68 PSROs, 16 reported only 1 MCE on deliveries and 9 reported more than 10. Nine PSROs accounted for 191, or 49 percent, of all MCEs on obstetrics. Excluding cesarean sections, 43 of the 68 PSROs reported none or one MCE on obstetrics.

MCE abstracts submitted to HEW by PSROs generally contained insufficient information to determine specific study objectives or findings. According to HEW, this is partly because some of the information is protected by guidelines governing the confidentiality of patients and practitioners. We sent questionnaires to the 9 PSROs reporting more than 10 MCEs on obstetrics to obtain additional information on the scope and findings of their evaluations. Replies from seven of the nine are summarized below.

Cesarean section

Study objectives in this area varied considerably. Forty-one studies addressed the necessity of or reasons for a cesarean section, and for 38 studies, objectives were not documented or given. Findings of the studies varied widely, the most common being deficiencies in documentation in medical records.

Because of the relatively small number of cesarean section studies, the variety or vagueness of study objectives, the usually small number of cases reviewed (ranging from 9 to 117, except in two cases) and the lack of information on criteria used in the studies, we could draw no conclusions on the safety, appropriateness, quality, or necessity of obstetric practices from the information available from MCEs. HEW believes that the small number of cases reviewed is largely attributable to the small number of cesarean sections done, particularly in smaller hospitals.

Other obstetric practices

Responses from 7 of the 9 PSROs with over 10 MCEs listed as dealing with delivery or cesarean section showed that there were

--6 on drugs used during labor and delivery,

--3 on elective induction and 1 on induction of labor,

--4 on fetal monitoring, and

--1 on forceps and none on vacuum extraction.

NATIONAL CENTER FOR HEALTH CARE TECHNOLOGY

In November 1978 a new National Center for Health Care Technology was established which may consider obstetric practices.

The Health Services Research, Health Statistics, and Health Care Technology Act of 1978 established in HEW the National Center for Health Care Technology. The act requires the Secretary of HEW, acting through the Center, to:

--Undertake and support assessments which consider the safety, effectiveness, and cost effectiveness of health care technologies and their social, ethical, and economic impact.

--Encourage, undertake, and support research, demonstrations, and evaluations concerning health care technologies, including their safety and efficacy.

--Establish priorities, in consultation with the Secretary of HEW and a National Council on Health Care Technology (also established by the act), for its activities giving emphasis to:

"(A) the actual or potential risks and the actual or potential benefits to patients associated with the use of the technology,

"(B) the actual or potential cost of the technology,

"(C) the actual or potential rate of its use, and

"(D) the stage of development of the technology."

The National Council's responsibilities include (1) providing advice on the Center's functions, (2) reviewing certain applications for grants and contracts, (3) advising the Secretary of HEW on the safety, efficacy, effectiveness, and the social and economic impacts of health care technologies,

and (4) developing and promulgating, when appropriate, exemplary standards, norms, and criteria concerning the use of health care technologies. The act defines health care technology as any discrete and identifiable regimen or modality used to diagnose and treat illness, prevent disease, maintain patient well-being, or facilitate the provision of health care services.

In July 1979, the National Council held its first meeting, and the Center was in the process of building its staff to carry out its functions and to start economic analyses of selected medical technologies.

HEALTH EDUCATION, INFORMATION, AND PROMOTION

The National Consumer Health Information and Health Promotion Act of 1976 requires HEW to inform and educate the public about personal health behavior, preventive health services, and the appropriate use of health services. The act authorizes HEW to undertake various activities, such as conducting or supporting new and innovative programs in health and education, developing materials, curriculums, and programs for use by schools, news media, health care providers and others, and developing model curriculums for training educational and health professionals in health education. HEW's Office of Education and Bureau of Community Health Services also administer programs which include or could include health education and information activities.

Representatives from HEW's Bureau of Health Education, Office of Maternal and Child Health, Office of Education, and the Office of the Assistant Secretary for Health told us that to date very little emphasis has been given to providing health education and information material on the benefits and risks of obstetric practices used during childbirth. For example, the director of HEW's Bureau of Health Education said that his office had not made any efforts in this area. However, he believed that developing informational and educational materials on obstetric practices for the public and efforts to instruct or guide health care professionals in explaining obstetric procedures to prospective mothers would be worthwhile.

CHAPTER 4

CONCLUSIONS, EVALUATION OF HEW COMMENTS, AND RECOMMENDATIONS

CONCLUSIONS

Several HEW agencies have responsibilities for or interests in various aspects of obstetric procedures, but no one organization has been given or assumed responsibility for pulling the diverse efforts and interests together into a planned, coordinated approach. HEW could do more to help resolve these problems if it developed a more systematic approach.

FDA regulates some, but not all, aspects of drug and medical device use in obstetrics. Several HEW agencies sponsor research or have responsibilities for health education, information, and promotion. PSROs are responsible for establishing criteria and standards for and evaluating the necessity, quality, and appropriateness of medical care. Many of the activities of HEW agencies have gaps or shortcomings relating to obstetric practices.

In carrying out its responsibility to ensure the safety of drugs, FDA has been hampered by problems and obstacles it faces in obtaining information on long-term effects of drugs both before it approves a drug for marketing and after the drug is marketed.

FDA's drug advisory committees have reacted to some potentially hazardous occurrences by recommending label warnings or, in a few instances, in the case of drugs for induction of labor, recommending removal from the market. However, without a periodic review of drugs this system may miss some needed action or not react in a timely manner. Also, FDA's requirement for a warning label does not necessarily preclude use, and greater effort is needed to get more information to patients during the prenatal period.

The Federal Government lacked a coordinated strategy or overall research plan for evaluating obstetric practices or educating the public on their benefits and risks. Long-term research necessary to prove the safety of various obstetric procedures on infant development is generally not being funded by the Government. One exception is a study sponsored by NINCDS on the long-term effect of various

obstetric drugs based on Collaborative Perinatal Project data, but the conclusions reached on obstetric practices using data from this study have been questioned and are uncertain. Also, the data are on births occurring from 1959 to 1966 and do not always reflect current obstetric practices.

PSROs have conducted relatively few evaluations of obstetric practices other than cesarean section through their MCE program. We could draw no conclusions on the safety, appropriateness, quality, or necessity of obstetric practices from MCEs because of their limited numbers, varying or uncertain scopes, and the lack of available information on criteria used.

Limited emphasis has been given to obstetric practices in the area of health information and education. FDA is considering requiring patient information for drugs.

The recent creation of the National Center for Health Care Technology appears to give HEW a way to help resolve some of the controversy surrounding obstetric practices. NIH's March 1979 conference on antenatal diagnosis aided in this objective.

HEW COMMENTS AND OUR EVALUATION

In bringing our findings to HEW's attention, we proposed that the Secretary of HEW, through the newly created National Center for Health Care Technology, or some other means, convene a panel of representatives from Federal agencies with interests or responsibilities involving obstetric practices, ACOG and other appropriate professional organizations, and consumer groups or other members of the public to develop a plan for reviewing obstetric practices.

Specific activities for consideration by this panel were:

--Evaluating existing research to give the public an assessment of what is known and unknown about the risks and benefits of various U.S. obstetric practices. This evaluation was to address which research data (including the Collaborative Perinatal Project) should be given the most credence. Specific practices to be looked at were (1) elective medical and surgical induction and stimulation of labor, (2) use of drugs for pain during labor and delivery, (3) preventive use of forceps and use of forceps versus the vacuum

extractor, (4) use of fetal monitoring for routine versus high-risk patients only, and (5) the reasons for the increasing cesarean section rate.

--Determining and setting priorities for research, including that on long-term effects on the child (and time to be covered) of various obstetric practices and developing a plan to obtain needed data.

--Determining whether FDA's authority or procedures for regulating drugs and devices need strengthening regarding obstetric practices.

--Determining how to minimize incorrect use of obstetric procedures, such as inducing labor prematurely or performing cesarean section too soon by encouraging PSROs to do more MCEs which are more thorough on obstetric practices and aiding them to develop criteria and standards for such evaluations.

--Emphasizing health education, information, and promotion activities on obstetric practices for health care providers and the public.

HEW agreed with our general conclusions that it should increase its efforts in evaluating obstetric practices and informing the public about the benefits versus risks of obstetric practices. HEW concurred with most of our proposals. In other cases, it specified actions it has initiated or plans to take. A summary of HEW's comments and our evaluation of them follow. In general, we believe that the actions HEW has taken, is taking, and plans to take are responsive to our proposals.

General comments

HEW made the following general comments:

--It may be impossible for ethical and medical-legal reasons to conduct a randomized clinical trial of certain obstetric practices. In some cases, clinical trials would require large sample sizes and considerable time and money. Also, it is possible that the medical practices could change by the time the results of such trials are available.

--HEW allows PSROs or their delegated hospitals to determine their own priorities in choosing MCE topics. Relatively few MCEs cover the obstetrics area because of the larger number of Federal beneficiaries who are admitted to hospitals for general medical and surgical treatment.

--NICHD's March 1979 Consensus Development Conference on Antenatal Diagnosis should be given more attention in our report. HEW noted that the conference dealt with several topics in addition to fetal monitoring, which was the only one discussed in our draft report. Additional topics included, but were not limited to, predictors of fetal distress, fetal maturity, and hereditary disease and congenital defects, as well as ultrasound. Furthermore, HEW said recommendations from this conference will be widely disseminated to the public and the medical profession and should significantly affect these areas of obstetric practice. For example, HEW stated that one of the reports forming the basis for the conference dealt with predictors of fetal maturity and described the results of NICHD-supported research. According to HEW, these results will enable physicians to eliminate almost completely the problems of prematurity and respiratory distress which complicate 15 percent of scheduled cesarean sections.

We generally concur with these comments and have made changes to this report, as appropriate.

Comments on proposals

HEW concurred in our proposals for (1) developing a plan for reviewing obstetric practices, (2) evaluating the adequacy of FDA's authority or procedures for the regulation of drugs, but felt it had ample authority for obstetric devices, (3) encouraging PSROs to devote more effort to evaluating obstetric procedures, and (4) emphasizing health education, information, and promotion activities. HEW said that:

--The National Center for Health Care Technology will place obstetric practices high on its list of priorities for assessment. HEW indicated that it would take a coordinated approach in assessing technologies

related to obstetric practices and said that convening a properly constituted panel with broad representation would be an appropriate early step. Also, although HEW supports our suggestion that the National Center address the issues raised in the report, it said that there will be some delay while the Center becomes fully staffed and operational within the coming year.

--It is concentrating considerable effort on developing sample criteria to assist PSROs establish general standards for quality of care, including components aimed at obstetric care. Also, HEW said that (1) our final report will be useful in drawing PSRO attention to specific issues, (2) our suggestion for evaluating existing research should be helpful in providing PSROs and the program with more data and information on the nature and extent of the problems cited, and (3) PSROs will be directed to investigate the situation locally and take corrective action as necessary.

--It was taking and would take additional action to enhance and coordinate health education, information, and promotion activities on obstetric practices for health care providers and the public.

--Although FDA has ample authority to regulate obstetric devices, it needs additional authority to regulate drugs, especially to impose requirements after drugs are approved for marketing. HEW said that it has sent proposed legislation to the Congress that would give FDA the needed additional authority. Moreover, we are recommending that the Congress consider our findings in its deliberations on proposals to amend FDA's authority for regulating drugs.

HEW said that it did not concur in our proposals to (1) establish a panel to help plan and oversee all HEW activities relating to obstetric practices, (2) evaluate existing research to give the public an assessment of what is known and unknown about the benefits and risks of obstetric practices, and (3) determine and set priorities for research on obstetric practices and develop a plan to obtain needed data. A discussion of HEW's comments on those proposals it disagreed with follows.

Convening a panel for undertaking several activities

We agree with HEW's comment that a panel would not be necessary for all the proposed activities. However, we believe that HEW should designate an organization to be responsible for overseeing and coordinating its range of activities--research, regulation, reimbursement, standard development, medical care quality evaluation, and health education, information, and promotion--as they relate to obstetric practices. We discussed this with HEW officials, who said they concurred.

Our proposals were modified accordingly. We are recommending that HEW designate an organization to be responsible for overseeing and coordinating its range of activities relating to obstetric practices.

Evaluating existing research

In commenting on our proposals relating to evaluating research and setting research priorities, HEW did not seem to question the desirability of the proposed actions, but said that it had either initiated or planned actions which relate to these proposals. While we acknowledge that HEW's initiated or planned activities should help resolve the problems identified, we believe our proposal is appropriate, as discussed below.

HEW said that (1) evaluation of research data is the absolutely essential ingredient of NIH or National Center for Health Care Technology assessments and would apply to obstetric practices and (2) the NIH consensus program places great emphasis on public information, and the National Center is mandated to disseminate the results of its assessments to the public. HEW noted several activities aimed at publicizing the results of its March 1979 Consensus Development Conference on Antenatal Diagnosis.

With respect to those obstetric practices covered in our literature review, HEW said that (1) FDA advisory panels have considered elective induction of labor (resulting in a drug label change) and the use of drugs for pain relief during labor and delivery, (2) an FDA advisory panel has been designated to review all available literature on the latter in detail and develop recommendations for consideration by

the Bureau of Drugs, (3) an NIH consensus development conference has addressed use of electronic fetal monitoring for low- and high-risk patients, and NICHD is developing a study of the usefulness of fetal monitoring for medium-risk patients, and (4) cesarean sections would probably be addressed by an NIH consensus development conference in the next year.

In proposing that HEW evaluate existing research, we intended that HEW help the public understand what is known and unknown about the benefits and risks of obstetric practices. We believe that this is important because of (1) the conflicting information that has been reported in the news media, (2) the questions still being raised about the appropriateness of using NINCDS Collaborative Perinatal Project data to assess obstetric practices, and (3) uncertainty that still exists about some obstetric practices. Also, we noted that FDA's efforts to disseminate the findings of its advisory panels do not always appear to be as extensive as those associated with NIH's consensus development activities or planned by the National Center. Although we believe actions HEW has taken, is taking, or has planned are significant, we believe our proposal is appropriate and does not conflict with HEW's comments.

Setting research priorities and developing a plan to obtain needed data

With respect to our proposal for setting research priorities and developing a plan to obtain needed data, HEW said that NICHD is beginning to develop a 5-year research plan that will include obstetric practices under the topic of high-risk pregnancies. HEW said that the plan should be developed within 1 year. In addition, HEW noted that obstetric practices will be considered by the National Center for Health Care Technology advisory committees and that the NICHD plan would serve as a basis for deliberations.

In proposing that HEW determine and set priorities for research on obstetric practices and develop a plan to obtain needed data, we intended that HEW develop a Department-wide plan that would consider the needs, priorities, and interests of its various agencies, professionals, and consumers. HEW focused its comments on this proposal on activities of the National Center and NICHD. These agencies' efforts are important. However, HEW's comments were unclear as to whether obstetric research efforts of its other component

agencies would be pulled together into a more systematic approach. Therefore, we believe that our proposal is appropriate, and that HEW should see that obstetric research activities of its component agencies are coordinated.

In discussions with us, HEW officials agreed that there is a need to see that obstetric research efforts of component agencies are coordinated. Therefore, we are adding coordination to our proposal that HEW set priorities for obstetric research.

From our findings, HEW's comments, and our evaluation of them, we are making the following recommendations.

RECOMMENDATION TO THE CONGRESS

Because our review was limited to only a few drugs used in only one area--obstetrics--we do not believe that conclusions can be drawn on FDA's overall drug regulation program. However, we do believe that the problems identified will be useful to the Congress in its deliberations on various proposals to revise drug regulation legislation. Therefore, we recommend that the Congress consider our findings on obstetric drug regulation legislation in deciding whether or how to strengthen FDA's authority on procedures for regulating drugs.

RECOMMENDATIONS TO THE SECRETARY OF HEW

We recommend that the Secretary of HEW designate the newly created National Center for Health Care Technology or some other organization to oversee, coordinate, and promote the range of departmental activities--research; regulation; medical care quality evaluation and standard development; health education, information, and promotion; and reimbursement--as they relate to obstetric practices. Specific activities should include:

--Convening a panel of representatives from Federal agencies with interests or responsibilities involving obstetric practices, ACOG, and other appropriate professional organizations, and consumer groups or other members of the public to develop a plan for reviewing obstetric practices.

--Evaluating, consistent with this plan, existing research to give the public an assessment of what is known and unknown about the benefits and risks of various U.S. obstetric practices. This evaluation should also address which research data (including the NINCDS Collaborative Perinatal Project) should be given the most credence.

--Setting priorities for and coordinating the Department's research efforts on various obstetric practices and developing a plan to obtain needed data, including that on long-term effects on the child.

--Determining how to help minimize incorrect use of obstetric procedures, such as inducing labor prematurely or performing cesarean section too soon, by encouraging PSROs to do more thorough MCEs on obstetric practices and aiding them to develop criteria and standards for such evaluations.

--Emphasizing health education, information, and promotion activities on obstetric practices for health care providers and the public.

CHAPTER 5

COMMENTS BY PROFESSIONAL ORGANIZATIONS

ACOG, the American College of Nurse-Midwives, and two representatives from the American Academy of Pediatrics provided informal comments on a draft of this report and the staff study which accompanies it. General comments made by these organizations are summarized below. We have considered the technical comments made by these organizations that relate to specific obstetric practices and have made changes in this report or the accompanying staff study where appropriate.

ACOG

ACOG made the following general comments.

--It agrees with our overall conclusion that research results are inconclusive regarding the benefit/risk relationship of various obstetric practices and that more organized efforts are needed to help answer questions that remain unresolved. It is willing to work with HEW and other interested parties in trying to resolve the issues.

--It is as, if not more, concerned as critics about the benefits and risks of obstetric practices, and wants to see that (1) obstetric procedures are appropriate, (2) the procedures are used in appropriate circumstances, and (3) the procedures are correctly applied. It acknowledges that some incorrect applications have occurred but believes these have been infrequent.

--Some conclusions about the risks or harmful effects of some obstetric procedures may be unwarranted because adverse consequences that sometimes occurred may have resulted from incorrect or inappropriate use of a procedure, as opposed to an inherent problem with the procedure.

--The professional liability aspect of obstetrics and the importance of professional judgment in determining appropriate procedures to use in individual situations need to be considered in any evaluation of obstetric practices. Obstetrics is one of the highest risk categories in terms of professional

malpractice liability. Many obstetricians have switched to other areas because of this. Practicing obstetricians must consider the potential liability aspects of their procedures and the needs of individual patients. Accordingly, obstetrics cannot be practiced in "cookbook" fashion.

--While ACOG does want to cooperate with organizations such as FDA and PSROs which have responsibilities for regulating or evaluating certain aspects of obstetric procedures, it does not believe that such organizations should dictate patient treatment procedures to physicians.

--It questions the validity and usefulness of findings and conclusions on obstetric practices based on data from the NINCDS Collaborative Study. Major changes have occurred in obstetric practices since the 1959-66 period in which children studied were born. For example, today, high forceps are rarely used and general anesthetics are used less frequently. Also, the study's methodology was not appropriate for evaluating obstetric practices.

--It agrees that more public and patient education on childbirth procedures is needed. It does not believe that patient package inserts being considered by FDA are appropriate because they do not and cannot relate the benefits or risks of a particular medication to an individual patient's situation.

AMERICAN COLLEGE OF NURSE-MIDWIVES

The College said that it believes more emphasis should be given--in our report and by HEW--to the need for more and better prenatal care education to prepare couples for childbirth. The College also believes that more research should be directed toward developing the best methods for teaching different target groups about childbirth.

AMERICAN ACADEMY OF PEDIATRICS

Comments provided by a member of the American Academy of Pediatrics' Drug Committee and a former chairman of the Academy's Committee on the Fetus and Newborn are summarized below.

--More and better research is needed to evaluate the benefits and risks of various obstetric practices. In many cases, adequate documentation is not available to prove that the benefits exceed risks or risks exceed the benefits of obstetric practices. However, the obstetric practices in question have been used at the same time as overall infant mortality rates have been declining and when the infant mortality rate for infants weighing 2,500 grams or less has been lower in the United States than in other countries. While it is difficult to ascribe cause and effect relationships between obstetric practices and pregnancy outcome, there is no evidence that obstetric practices have had an overall adverse effect on infant mortality or morbidity.

--Obstetric techniques have been introduced to improve the quality of medical care, not for the convenience of physicians.

--While minimal or no medication for pain relief during childbirth is the ideal goal, it is not always possible to achieve this. Maternal apprehension and pain can have a serious effect on the fetus; in these cases, medication for pain relief is essential. Different women experience varying degrees of pain during childbirth, and many women request medication for pain relief. This need must be considered. It is important to note that today, regional anesthesia is generally used for routine deliveries as opposed to general anesthesia and that use of medication for pain relief is decreasing.

--There is no clear evidence in the United States that the vacuum extractor provides a safer method of instrument delivery than forceps.

--Although nurses may be theoretically able to monitor patients in labor as frequently as suggested by ACOG, it is unlikely that most hospitals would have enough nurses to do so. Electronic monitoring gives physicians much better indications for intervention of labor than signs which were previously used, enables the fetal heart rate to be monitored during uterine contractions, and provides physicians with earlier indication of potential problems. The problems that have been noted with the use of electronic fetal

monitoring are similar to those which would be associated with the introduction of any new medical technology and in some instances involve incorrect use of the technique, such as failure to also take and evaluate fetal blood samples. With better understanding and correct application of the technique, electronic fetal monitoring provides better information on the fetus during labor than is otherwise available.

--The increased cesarean section rate may have contributed to lower infant mortality rates. Improved outcome of breech presentations delivered by cesarean section should be encouraging. Some evidence exists that mortality rates for small infants delivered by cesarean section are lower than for those delivered vaginally. Also, the increasing cesarean section rate is primarily due to changing indications for use of the procedure. Cesarean sections have increased largely because of their use for (1) breech presentations, (2) delivering small infants, and (3) failure of spontaneous labor to progress normally. In evaluating cesarean sections, one must consider both the reasons for and results of the sections. This has not generally been done.

APPENDIX I

GLOSSARY

Analgesia	State of insensibility to pain.
Anesthesia	Loss of feeling or sensation. General anesthesia implies not only a loss of feeling or sensation but also of consciousness and memory. Regional anesthesia implies only a loss of feeling or sensation but no impairment of consciousness or memory.
Apgar score	An evaluation of five factors in the newborn infant: color, pulse, reflexes, activity, and respiration made at 1 and 5 minutes after birth. Two points are possible for each factor; thus, an infant in the best possible condition would have an Apgar score of ten.
Bradycardia	Abnormal slowing of the heartbeat.
Breech presentation	The condition in which the buttocks of the fetus lie directly above or in the birth canal.
Cervix	The lower end of the uterus.
Cesarean section	The operation consisting of cutting through the abdominal and uterine walls, and delivering one or more fetuses of viable size.
Dilation	The action of dilating or stretching.
Elective	Subject to the choice or decision of the patient or physician. Applied to procedures that are only advantageous to the patient, but not necessary to save his life.
Fetal	Pertaining to a fetus.

APPENDIX I

Fetal monitoring	The continuous observation and recording of biological functions considered to be reliable indicators of the fetal condition.
Fetus	The developing young in the human uterus after the second month. It becomes an infant when it is completely outside the mother's body.
Forceps, obstetric	Forceps for grasping and making traction on the fetus to aid delivery.
Gestation	Pregnancy and length of time a pregnancy is carried.
Induction of labor	Labor brought on by artificial means.
Jaundice	Yellowness of the skin, eyes, and secretions, due to the presence of bile pigments in the blood.
Labor	The physiologic process by which the fetus and associated placenta and membranes are expelled from the body.
Morbidity	(1) The condition of being diseased or morbid and (2) the sick rate, or proportion of disease to health in a community.
Mortality rate	Number of deaths expressed in relation to a standard number of persons.
Neonate	A baby less than 4 weeks of age.
Obstetrics	The art and science of caring for pregnant women.
Paracervical block	A type of regional anesthesia produced by injection of local anesthetic around the cervix.

APPENDIX I

Perinatal mortality	Death of a fetus or infant weighing 1,000 grams or over that occurs between 28 weeks of gestation and 4 weeks of age.
Placenta	A spongy structure that grows on the wall of the uterus during pregnancy, and through which the fetus is nourished (also called afterbirth).
Prenatal	Existing or taking place prior to birth.
Uterine	Pertaining to the uterus.
Uterus	The womb; a hollow muscular organ, in which the embryo and fetus develop.
Vacuum extractor	A device for use instead of forceps in facilitating delivery of the fetus in vertex presentations. It is essentially a suction cup which is applied to the infant's head for suction.

APPENDIX II

CHARTS DERIVED FROM DATA OBTAINED FROM THE COMMISSION ON PROFESSIONAL AND HOSPITAL ACTIVITIES

Data obtained from CPHA on 1.3 million deliveries in 1,558 U.S. hospitals in 1977 were used to develop charts 1 to 8. CPHA did not have specific information on the extent to which electronic fetal monitoring was used. However, CPHA provided us data on intrauterine fetal procedures which, according to CPHA, are almost entirely reflective of patients with internal fetal monitoring. The figures for expected payment source (Medicaid and title V or other) and bed size do not add up to the total due to deliveries for which expected payment source was unknown. Also some percentages resulting in subtotals (as total inductions or instrument deliveries) do not add due to rounding.

The memorandum explaining the raw data supplied by CPHA follows the charts.

APPENDIX II

U S CPHA HOSPITALS PROVIDING OBSTETRIC SERVICES

SUMMARY CHART NUMBER ONE

JANUARY TO DECEMBER 1977

ALL UNITED STATES

Diagnosis and procedure group	Non-teaching	Percent	Teaching	Percent	Total	Percent
Total deliveries	814,563	-	461,100	-	1,275,663	-
Total spontaneous deliveries	593,265	72 8	316,048	68 5	909,313	71 3
Total deliveries with both medical induction and amniotomy	7,147	9	4,640	1 0	11,787	9
Total deliveries with medical induction	27,095	3 3	18,254	4 0	45,349	3 6
Total deliveries with amniotomy induction	53,279	6 5	40,290	8 7	93,569	7 3
Total inductions	87,521	10 7	63,184	13 7	150,705	11 8
Total forceps deliveries	198,641	24 4	128,464	27 9	327,105	25 6
A Low forceps	185,155	22 7	116,423	25 2	301,578	23 6
B Medium forceps	13,265	1 6	11,946	2 6	25,211	2 0
C High forceps	221	-	95	-	316	-
Total deliveries with vacuum extraction	1,691	2	2,101	5	3,792	3
Total instrument deliveries	200,332	24 6	130,565	28 3	330,897	25 9
Total cesarean section deliveries	102,203	12 5	68,429	14 8	170,632	13 4
A With previous cesarean section	31,793	31 1	22,094	32 3	53,887	31 6
B With fetal distress	8,671	8 5	7,526	11 0	16,197	9 5
C With failed induction of labor	3,653	3 6	3,788	5 5	7,441	4 4
Total cesarean deliveries with intrauterine fetal procedures	6,672	6 5	7,969	11 6	14,641	8 6
Total deliveries with intrauterine fetal procedures	56,975	7 0	75,437	16 4	132,412	10 4
Utilization of anesthesia in spontaneous deliveries						
A None	104,272	17 6	66,990	21 2	171,262	18 8
B Local	190,789	32 2	100,310	31 7	291,099	32 0
C Inhalation, intravenous, spinal, saddle block, epidural, caudal, nerve or field block	296,079	49 9	147,595	46 7	443,674	48 8
D Other	2,125	4	1,153	4	3,278	4
E Total B and C	486,868	82 1	247,905	78 4	734,773	80 8

APPENDIX II

U S CPHA HOSPITALS PROVIDING OBSTETRIC SERVICES

SUMMARY CHART NUMBER TWO

JANUARY TO DECEMBER 1977

ALL UNITED STATES

Diagnosis and procedure group	Medicaid and Title V	Percent	Other	Percent	Total	Percent
Total deliveries	182,761	-	1,042,558	-	1,225,319	-
Total spontaneous deliveries	137,554	75 3	734,243	70 4	871,797	71 1
Total deliveries with both medical induction and amniotomy	977	5	10,616	1 0	11,593	9
Total deliveries with medical induction	5,100	2 8	38,524	3 7	43,624	3 6
Total deliveries with amniotomy induction	11,470	6 3	80,187	7 7	91,667	7 5
Total inductions	17,547	9 6	129,337	12 4	146,884	12 0
Total forceps deliveries	38,742	21 2	276,618	26 5	315,360	25 7
A Low forceps	35,695	19 5	254,988	24 5	290,683	23 7
B Medium forceps	2,997	1 6	21,373	2 1	24,370	2 0
C High forceps	50	-	257	-	307	-
Total deliveries with vacuum extraction	612	3	2,913	3	3,525	3
Total instrument deliveries	39,354	21 5	279,531	26 8	318,885	26 0
Total cesarean section deliveries	23,610	12 9	140,313	13 5	163,923	13 4
A With previous cesarean section	7,739	32 8	44,142	31 5	51,881	31 6
B With fetal distress	2,617	11 1	12,830	9 1	15,447	9 4
C With failed induction of labor	979	4 1	6,205	4 4	7,184	4 4
Total cesarean deliveries with intrauterine fetal procedures	2,372	10 0	11,854	8 4	14,226	8 7
Total deliveries with intrauterine fetal procedures	20,371	11 1	108,081	10 4	128,452	10 5
Utilization of anesthesia in spontaneous deliveries						
A None	37,224	27 1	128,834	17 5	166,058	19 0
B Local	39,249	28 5	238,496	32 5	277,745	31 9
C Inhalation, intravenous, spinal, saddle block, epidural, caudal, nerve or field block	60,632	44 1	364,267	49 6	424,899	48 7
D Other	449	3	2,646	4	3,095	4
E Total B and C	99,881	72 6	602,763	82 1	702,644	80 6

APPENDIX II

U S CPHA HOSPITALS PROVIDING OBSTETRIC SERVICES

SUMMARY CHART NUMBER THREE

JANUARY TO DECEMBER 1977

ALL UNITED STATES

Diagnosis and procedure group	Hospital size 1-199 beds	Percent	200-399 beds	Percent	400+ beds	Percent
Total deliveries	330,461	-	471,124	-	423,734	-
Total spontaneous deliveries	240,756	72 9	339,790	72 1	291,251	68 7
Total deliveries with both medical induction and amniotomy	2,215	7	4,278	9	5,100	1 2
Total deliveries with medical induction	10,516	3 2	15,455	3 3	17,653	4 2
Total deliveries with amniotomy induction	21,233	6 4	32,259	6 8	38,175	9 0
Total inductions	33,964	10 3	51,992	11 0	60,928	14 4
Total forceps deliveries	79,968	24 2	115,605	24 5	119,787	28 3
A Low forceps	74,768	22 6	107,280	22 8	108,635	25 6
B Medium forceps	5,077	1 5	8,243	1 8	11,050	2 6
C High forceps	123	-	82	-	102	-
Total deliveries with vacuum extraction	629	2	1,705	4	1,191	3
Total instrument deliveries	80,597	24 4	117,310	24 9	120,978	28 6
Total cesarean section deliveries	39,237	11 9	62,640	13 3	62,046	14 6
A With previous cesarean section	11,815	30 1	20,154	32 2	19,912	32 1
B With fetal distress	2,986	7 6	5,772	9 2	6,689	10 8
C With failed induction of labor	1,484	3 8	2,161	3 4	3,539	5 7
Total cesarean deliveries with intrauterine fetal procedures	2,243	5 7	4,915	7 8	7,068	11 4
Total deliveries with intrauterine fetal procedures	20,480	6 2	45,383	9 6	62,589	14 8
Utilization of anesthesia in spontaneous deliveries						
A None	42,157	17 5	61,135	18 0	62,766	21 6
B Local	80,280	33 3	107,592	31 7	89,873	30 9
C Inhalation, intravenous, spinal, saddle block, epidural, caudal, nerve or field block	117,407	48 8	169,726	50 0	137,766	47 3
D Other	909	4	1,337	4	846	3
E Total B and C	197,687	82 1	277,318	81 6	227,639	78 2

APPENDIX II

U S CPHA HOSPITALS PROVIDING OBSTETRIC SERVICES

SUMMARY CHART NUMBER FOUR

JANUARY TO DECEMBER 1977

U S CENSUS REGIONS

Diagnosis and procedure group	North-eastern	North Central	Southern	Western	Total
	(percent)				
Total spontaneous deliveries	72 6	73 1	66 0	73 7	71 3
Total deliveries with both medical induction and amniotomy	8	1 1	7	1 0	9
Total deliveries with medical induction	3 0	3 9	2 9	4 4	3 6
Total deliveries with amniotomy induction	9 9	8 6	5 2	4 8	7 3
Total inductions	13 7	13 6	8 8	10 3	11 8
Total forceps deliveries	24 2	23 9	31 7	22 2	25 6
A Low forceps	22 2	22 0	29 4	20 5	23 6
B Medium forceps	2 0	1 9	2 2	1 7	2 0
C High forceps	-	-	-	-	-
Total deliveries with vacuum extraction	3	2	1	8	3
Total instrument deliveries	24 5	24 1	31 8	22 9	25 9
Total cesarean section deliveries	15 0	12 4	13 3	13 8	13 4
A With previous cesarean section	32 6	33 1	28 5	31 8	31 6
B With fetal distress	10 5	8 9	9 7	9 1	9 5
C With failed induction of labor	3 7	5 2	4 3	3 6	4 4
Total cesarean deliveries with intrauterine fetal procedures	8 2	9 4	6 4	10 4	8 6
Total deliveries with intra-uterine fetal procedures	10 6	10 8	7 9	13 0	10 4
Utilization of anesthesia in spontaneous deliveries					
A None	24 4	18 5	19 1	13 0	18 8
B Local	31 3	35 6	23 2	36 7	32 0
C Inhalation intravenous spinal, saddle block, epidural, caudal, nerve or field block	44 0	45 4	57 3	50 0	48 8
D Other	3	4	3	3	4
E Total B and C	75 3	81 1	80 6	86 7	80 8

APPENDIX II

U S CPHA HOSPITALS PROVIDING OBSTETRIC SERVICES

SUMMARY CHART NUMBER FIVE

JANUARY TO DECEMBER 1977

NORTHEASTERN CENSUS REGION

Diagnosis and procedure group	Non-teaching	Percent	Teaching	Percent	Total	Percent
Total deliveries	112,097	-	132,598	-	244,695	-
Total spontaneous deliveries	81,645	72 8	96,052	72 4	177,697	72 6
Total deliveries with both medical induction and amniotomy	1,193	1 1	655	5	1,848	8
Total deliveries with medical induction	4,336	3 9	2,974	2 2	7,310	3 0
Total deliveries with amniotomy induction	12,383	11 0	11,952	9 0	24,335	9 9
Total inductions	17,912	16 0	15,581	11 8	33,493	13 7
Total forceps deliveries	27,245	24 3	32,018	24 1	59,263	24 2
A Low forceps	25,045	22 2	28,798	21 7	53,843	22 0
B Medium forceps	2,185	1 9	3,207	2 4	5,392	2 2
C High forceps	15	-	13	-	28	-
Total deliveries with vacuum extraction	202	2	502	4	704	3
Total instrument deliveries	27,447	24 5	32,520	24 5	59,967	24 5
Total cesarean section deliveries	15,352	13 7	21,472	16 2	36,824	15 0
A With previous cesarean section	4,983	32 5	7,037	32 8	12,020	32 6
B With fetal distress	1,432	9 3	2,431	11 3	3,863	10 5
C With failed induction of labor	698	4 5	647	3 0	1,345	3 7
Total cesarean deliveries with intrauterine fetal procedures	1,315	8 6	1,720	8 0	3,035	8 2
Total deliveries with intrauterine fetal procedures	11,535	10 3	14,501	10 9	26,036	10 6
Utilization of anesthesia in spontaneous deliveries						
A None	17,132	21 0	26,260	27 3	43,392	24 4
B Local	25,397	31 1	30,147	31 4	55,544	31 3
C Inhalation, intravenous, spinal, saddle block, epidural, caudal, nerve or field block	38,952	47 7	39,319	40 9	78,271	44 0
D Other	164	2	326	3	490	3
E Total B and C	64,349	78 8	69,466	72 3	133,815	75 3

APPENDIX II

U S CPHA HOSPITALS PROVIDING OBSTETRIC SERVICES

SUMMARY CHART NUMBER SIX

JANUARY TO DECEMBER 1977

NORTH-CENTRAL CENSUS REGION

Diagnosis and procedure group	Non-teaching	Percent	Teaching	Percent	Total	Percent
Total deliveries	320,037	-	167,062	-	487,099	-
Total spontaneous deliveries	243,219	76 0	112,907	67 6	356,126	73 1
Total deliveries with both medical induction and amniotomy	3,353	1 0	2,186	1 3	5,539	1 1
Total deliveries with medical induction	10,611	3 3	8,383	5 0	18,994	3 9
Total deliveries with amniotomy induction	24,301	7 6	17,402	10 4	41,703	8 6
Total inductions	38,265	12 0	27,971	16 7	66,236	13 6
Total forceps deliveries	67,299	21 0	48,930	29 3	116,229	23 9
A Low forceps	63,160	19 7	43,876	26 3	107,036	22 0
B Medium forceps	4,064	1 3	5,005	3 0	9,069	1 9
C High forceps	75	-	49	-	124	-
Total deliveries with vacuum extraction	385	1	700	4	1,085	2
Total instrument deliveries	67,684	21 1	49,630	29 7	117,314	24 1
Total cesarean section deliveries	37,083	11 6	23,318	14 0	60,401	12 4
A With previous cesarean section	12,227	33 0	7,746	33 2	19,973	33 1
B With fetal distress	2,821	7 6	2,562	11 0	5,383	8 9
C With failed induction of labor	1,445	3 9	1,704	7 3	3,149	5 2
Total cesarean deliveries with intrauterine fetal procedures	1,975	5 3	3,709	15 9	5,684	9 4
Total deliveries with intrauterine fetal procedures	16,147	5 0	36,302	21 7	52,449	10 8
Utilization of anesthesia in spontaneous deliveries						
A None	45,731	18 8	20,152	17 8	65,883	18 5
B Local	86,235	35 5	40,612	36 0	126,847	35 6
C Inhalation, intravenous, spinal, saddle block, epidural, caudal, nerve or field block	110,207	45 3	51,593	45 7	161,800	45 4
D Other	1,046	4	550	5	1,596	4
E Total B and C	196,442	80 8	92,205	81 7	288,647	81 1

APPENDIX II

U S CPHA HOSPITALS PROVIDING OBSTETRIC SERVICES

SUMMARY CHART NUMBER SEVEN

JANUARY TO DECEMBER 1977

SOUTHERN CENSUS REGION

Diagnosis and procedure group	Non-teaching	Percent	Teaching	Percent	Total	Percent
Total deliveries	215,262	-	112,422	-	327,684	-
Total spontaneous deliveries	143,928	66 9	72,248	64 3	216,176	66 0
Total deliveries with both medical induction and amniotomy	1,163	5	1,000	9	2,163	7
Total deliveries with medical induction	5,317	2 5	4,131	3 7	9,448	2 9
Total deliveries with amniotomy induction	9,782	4 5	7,330	6 5	17,112	5 2
Total inductions	16,262	7 6	12,461	11 1	28,723	8 8
Total forceps deliveries	67,367	31 3	36,349	32 3	103,716	31 7
A Low forceps	62,841	29 2	33,600	29 9	96,441	29 4
B Medium forceps	4,446	2 1	2,729	2 4	7,175	2 2
C High forceps	80	-	20	-	100	-
Total deliveries with vacuum extraction	115	1	260	2	375	1
Total instrument deliveries	67,482	31 3	36,609	32 6	104,091	31 8
Total cesarean section deliveries	26,639	12 4	16,904	15 0	43,543	13 3
A With previous cesarean section	7,298	27 4	5,090	30 1	12,388	28 5
B With fetal distress	2,387	9 0	1,832	10 8	4,219	9 7
C With failed induction of labor	813	3 1	1,049	6 2	1,862	4 3
Total cesarean deliveries with intrauterine fetal procedures	1,166	4 4	1,637	9 7	2 803	6 4
Total deliveries with intrauterine fetal procedures	10,431	4 8	15,341	13 6	25,772	7 9
Utilization of anesthesia in spontaneous deliveries						
A None	23,287	16 2	17,997	24 9	41,284	19 1
B Local	34,528	24 0	15,700	21 7	50,228	23 2
C Inhalation, intravenous, spinal, saddle block, epidural, caudal, nerve or field block	85,494	59 4	38,435	53 2	123,929	57 3
D Other	619	4	116	2	735	3
E Total B and C	120,022	83 4	54,135	74 9	174,157	80 6

APPENDIX II

U S CPHA HOSPITALS PROVIDING OBSTETRIC SERVICES

SUMMARY CHART NUMBER EIGHT

JANUARY TO DECEMBER 1977

WESTERN CENSUS REGION

Diagnosis and procedure group	Non-teaching	Percent	Teaching	Percent	Total	Percent
Total deliveries	167,167	-	49,018	-	216,185	-
Total spontaneous deliveries	124,473	74 5	34,841	71 1	159,314	73 7
Total deliveries with both medical induction and amniotomy	1,438	9	799	1 6	2,237	1 0
Total deliveries with medical induction	6,831	4 1	2,766	5 6	9,597	4 4
Total deliveries with amniotomy induction	6,813	4 1	3,606	7 4	10,419	4 8
Total inductions	15,082	9 0	7,171	14 6	22,253	10 3
Total forceps deliveries	36,730	22 0	11,167	22 8	47,897	22 2
A Low forceps	34,109	20 4	10,149	20 7	44,258	20 5
B Medium forceps	2,570	1 5	1,005	2 1	3,575	1 7
C High forceps	51	-	13	-	64	-
Total deliveries with vacuum extraction	989	6	639	1 3	1,628	8
Total instrument deliveries	37,719	22 6	11,806	24 1	49,525	22 9
Total cesarean section deliveries	23,129	13 8	6,735	13 7	29,864	13 8
A. With previous cesarean section	7,285	31 5	2,221	33 0	9,506	31 8
B With fetal distress	2,031	8 8	701	10 4	2,732	9 1
C With failed induction of labor	697	3 0	388	5 8	1,085	3 6
Total cesarean deliveries with intrauterine fetal procedures	2,216	9 6	903	13 4	3,119	10 4
Total deliveries with intrauterine fetal procedures	18,862	11 3	9,293	19 0	28,155	13 0
Utilization of anesthesia in spontaneous deliveries						
A None	18,122	14 6	2,581	7 4	20,703	13 0
B Local	44,629	35 9	13,851	39 8	58,480	36 7
C Inhalation, intravenous, spinal, saddle block, epidural, caudal, nerve or field block	61,426	49 3	18,248	52 4	79,674	50 0
D Other	296	2	161	5	457	3
E Total B and C	106,055	85 2	32,099	92 1	138,154	86 7

CPHA

Commission on Professional and Hospital Activities

1968 Green Road Ann Arbor Michigan 48105 313 769 6511 800 521 6210 (toll free number for continental US except Michigan)

Vergil N Slee MD President

7 March 1979

Mr Bernie Ungar
General Accounting Office
Park Building, Room 124
Rockville, MD 20857

AN 7-163

Dear Mr Ungar

Enclosed please find 11 seperate reports containing selected PAS data on obstetric patients discharged from all U S PAS hospitals during 1977 Included on the reports is total forceps deliveries broken down by low, medium, and high forceps

If we can be of further assistance to you at this time, please feel free to contact us

Sincerely,

Philip A Vironda

Philip A Vironda
Special Studies Coordinator
Research and Statistics

Enclosures
1 Memorandum Report, AN 7-163
2 Obstretics in U S PAS Hospitals (10 reports, 2 copies)
3 U S PAS Hospitals Providing Obstetrics Services (1 report, 2 copies)

Nonprofit organization sponsored by the American College of Physicians American College of Surgeons American Hospital Association Southwestern Michigan Hospital Council

Samuel P Asper MD MACP
American College of Physicians

Richard H Mulder FACHA Vice Chairman
Member at Large

Richard D Remington PhD
Member at Large

Howard R Taylor FACHA
American Hospital Association

Wanda J Jones
Member at Large

Billy G McCall
Member at Large

Vergil N Slee MD FACP President
Member at Large

Gail L Warden
American Hospital Association

C Tiffany Lafaus FACHA
Southwestern Michigan Hospital Council

Paul F Nora MD FACS
American College of Surgeons

Robert B Talley MD FACP Chairman
American College of Physicians

Harold A Zinzel MD FACS
American College of Surgeons

Professional Activity Study (PAS)

APPENDIX II

As specified in Purchase Order 8113588, CPHA has produced 11 seperate reports containing selected data on obstetric patients discharged from all U S pre-PAS and PAS hospitals The time period of this study is from 1 January through 31 December 1977

All patients originate from one of four census track regions in the United States Two reports from each census division broken down by teaching and nonteaching status represent eight of the 11 reports Two reports, one teaching and one nonteaching, display obstetric patients for all U S Each report is stratified by census region, teaching status, bed size, and source of payment

In these reports, entitled "Obstetrics in U S PAS Hospitals," those patients who have local Anesthesia alone or a combination of local plus any other type of anesthesia have been recorded in group B Patients who have inhalation, intravenous, spinal, saddle block, epidural, caudal, nerve or field block alone or in combination with at least one of the anesthesias listed above have been recorded in group C Patients have been assigned to each of the 13 groups in the following manner

Group Title	H-ICDA-2[1] Code Range Final Diagnosis	Operation
Total number of deliveries	650 0-664 9	
Total number of spontaneous deliveries	650 0-664 9	Any op code excluding 72 0-72 3, 72 5-72 8, 73 5 or 73 8
Total number of deliveries with both medical induction and amniotomy	650 0-664 9	73 0 and 73 1
Total number of deliveries with medical induction	650 0-664 9	73 0
Total number of deliveries with amniotomy	650 0-664 9	73 1

[1] Hospital Adaptation of ICDA (H-ICDA), Second Edition, Commission on Professional and Hospital Activities, Ann Arbor, Michigan, 1973

AN 7-163
Date 5 March 1979
By Vironda
Page 1 of 2

CPHA
Commission on Professional and Hospital Activities 1968 Green Road Ann Arbor Michigan 48105
Nonprofit organization sponsored by the American College of Physicians American College of Surgeons American Hospital Association Southwestern Michigan Hospital Council
CP IA 77 7 76

APPENDIX II

Group Title	H-ICDA-2[1] Code Range Final Diagnosis	Operation
Total number of forcep deliveries[2]	650 0-664 9	72 0, 72 1, 72 2 or 72 3
low forceps	650 0-664 9	72 0, 72 1
medium forceps	650 0-664 9	72 2
high forceps	650 0-664 9	72 3
Total number of deliveries with vacuum extraction	650 0-664 9	72 8
Total number of deliveries with cesarean section	650 0-664 9	74 0-74 9
Total number of cesarean deliveries with one of the following diagnoses		
Previous cesarean section	664 4	74 0-74 9
Fetal distress	664 7	74 0-74 9
Failed induction of labor	650 0-664 9	73 0 or 73 1
Total number of cesarean deliveries with intrauterine fetal procedures, including monitoring	650 0-664 9	74 0-74 9 and 75 3
Total number of deliveries with intrauterine fetal procedures, including monitoring	650 0-664 9	75 3 as any procedure, excluding 99 8

Unlike the first ten reports, the eleventh report titled "U S PAS Hospitals Providing Obstetric Services" displays hospitals by bed size and teaching status from each of four census regions A grand total has been provided that illustrates the total number of hospitals providing prescribed obstetric services on patients during this period of time

Please note that column 2 on the reports entitled "Obstetrics in U S PAS Hospitals" includes patients whose expected source of payment was unrecorded The remaining columns on this report represent only those patients whose source of payment was recorded

sg

[2]In deliveries where more than one method of forceps were used, only the highest forceps have been counted

AN 7-163
Date 7 March 1979
By Vironda
Page 2 of 2

CPHA
Commission on Professional and Hospital Activities 1968 Green Road Ann Arbor Michigan 48105
Nonprofit organization sponsored by the American College of Physicians American College of Surgeons American Hospital Association Southwestern Michigan Hospital Council
CPHA 72 7 76

APPENDIX III

DEPARTMENT OF HEALTH EDUCATION AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON D C 20201

JUN 20 1979

Mr. Gregory J. Ahart
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report entitled, "More Coordinated Federal and Private Efforts Needed To Evaluate the Benefits and Risks of Selected Obstetric Practices." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Thomas D. Morris
Inspector General

Enclosure

GAO note: Some of HEW's comments relate to matters discussed in the staff study (HRD-79-85A) which accompanies this report

COMMENTS OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE ON THE GENERAL ACCOUNTING OFFICE'S DRAFT REPORT ENTITLED "MORE COORDINATED FEDERAL AND PRIVATE EFFORTS NEEDED TO EVALUATE THE BENEFITS AND RISKS OF SELECTED OBSTETRIC PRACTICES"

General Comments

The Department agrees with the general conclusions of this report that HEW should increase its efforts in evaluating obstetric practices and in informing the public about the benefits versus risks of these practices We are also pleased that the report acknowledges that many relevant activities have been instituted [e g , the FDA medical device and drug reviews and the Professional Standards Review Organizations Medical Care Evaluation (PSRO-MCE) studies]

The report recognizes that the newly established National Center for Health Care Technology "may consider obstetric practices " (page 38) Although the Department supports the suggestion that the Center should address issues raised in this report, there will be some delay while the Center becomes fully staffed and operational within the coming year Other considerations related to the Center's involvement are discussed below

In addition, while the NIH consensus development conference concerning Antenatal Diagnosis is mentioned (pages 29, 123, and 124) it is not accorded the significance it deserves. Reference is made only to fetal monitoring, although the conference also dealt with other aspects of antenatal diagnosis as well as including predictors of hereditary disease and congenital defects, fetal maturity, fetal distress, with special attention to amniocentesis, fetoscopy, alpha-fetoprotein measurements and ultrasound The recommendations from this Conference will be widely disseminated both to the public and to the medical profession and should have an important impact in this area of obstetric practices

GAO Recommendation

We recommend that the Secretary of HEW

> Through the newly created National Center for Health Care Technology, or some other means, convene a panel of representatives from Federal

agencies with interests or responsibilities involving obstetric practices, ACOG and other appropriate professional organizations and consumer groups or other members of the public to develop a plan for reviewing obstetric practices

Department Comments

We concur in that the National Center will certainly place obstetric practices high on its list of priorities for assessment. The major input to the Center derives from two entities (1) the Internal Advisory or Operating Committee and (2) the National Council on Health Technology

The Internal Advisory Committee meets monthly and is composed of high level representatives from all of the agencies of the Public Health Service and a liaison representative from HCFA This Committee provides the Department for the first time with a forum where health technology issues can be surfaced, discussed, and actions determined and implementation assignments made A recent example of such activities relates to maternal serum alpha fetoprotein This test was ready for licensing and release by the FDA but it was obvious to both the FDA and CDC that provision had to be made for dealing with the consequences of a positive test in a pregnant woman (e g , repeat tests, ultrasonography, amniocentesis, generic counseling, etc) The issues were discussed at a meeting of the Internal Advisory Committee and as a consequence, a subcommittee has been formed to include the Center, FDA, CDC, HSA, HCFA, and OASH The subcommittee has met several times and will be developing recommendations for a course of action in the near future The FDA has already had close interaction on this issue with consumer groups, the American College of Obstetrics and Gynecology, the American Academy of Family Physicians, and the pediatric societies In the assessment of other technologies related to obstetric practice, a similar approach would be taken

The National Council on Health Care Technology* has recently been appointed and is scheduled to hold its first meeting in July Among its mandates in P L 95-623 are (1) to advise on the setting of priorities among technologies for study by the Center and (2) to develop exemplary standards, norms, and criteria concerning the use of particular health care technologies. While we cannot speak for the Council, it is to be anticipated that the Council will place obstetric practices high on its list of priorities

*The Council, appointed by the Secretary, DHEW, is composed of 18 individuals distinguished in various pursuits related to health care and health care technology, plus ex officio representatives of government health agencies and programs

As indicated below, the NIH Consensus Development Conference on Antenatal Diagnosis has already addressed some of these practices but others will be candidates for study by the Center In the course of these activities, convening of a properly constituted panel with broad representation would be an appropriate early step

In view of the foregoing, we are convinced that it is unnecessary and wasteful to set up yet another separate panel to review "the ways Federal involvement can be improved "

> Some specific activities to be considered by this panel should be to evaluate existing research to give the public an assessment of benefits of various U S obstetric practices This evaluation should also address which research data (including the Collaborative Perinatal Project) should be given the most credence

Department Comments

We do not concur This recommendation has two components (1) informing the public about benefits and risks and (2) evaluation of research data

Concerning the first, it should be noted that one of the objectives of the recent NIH Consensus Development Conference on Antenatal Diagnosis was to provide the public and the practicing community with an assessment of risks and benefits of certain obstetric practices The report cites only one of the technologies dealt with at the Conference It neglects to mention as indicated above that other procedures were also evaluated, including amniocentesis, fetoscopy, alpha-fetoprotein measurements, and ultrasound One of the task force reports forming the basis for the Conference dealt with predictors of fetal-maturity and described NICHD-supported research The results of these studies will now enable physicians to eliminate almost completely the problems of prematurity and respiratory distress which complicate 15% of scheduled cesarian sections Among the groups testifying at this Conference were the Association for Maternal and Child Health, the International Child Birth Education Association, the American Academy of Husband-Coached Child Birth, the March of Dimes, and the Spina Bifida Association All of these organizations will receive the final reports and the recommendations from the conference as soon as they become available In addition, Parents Magazine, Womens' Day, and the Ladies Home Journal have or will shortly publish articles about the meeting The Conference was also widely reported in the lay press The NIH consensus program places great emphasis

on public information and the Center is mandated to disseminate the results of its assessments to the public

Relevant to the second component of the recommendation, evaluation of research data, this is the absolutely essential ingredient of the technology assessments sponsored by the NIH or to be done under the aegis of the Center and would obviously apply to research data concerning obstetric practices

> . Specific practices that could be looked at are (1) elective medical and surgical induction and stimulation of labor, (2) use of drugs for pain during labor and delivery, (3) use of preventive forceps and use of forceps versus the vacuum extractor, (4) use of fetal monitoring for routine versus high-risk patients only, and (5) the reasons for the increasing cesarean section rate

Department Comments

We do not concur Most of these have either been examined or will be in the near future (as indicated above) Of the five areas of obstetric practices that the GAO recommends be reviewed by Federal agencies (page 45), the FDA has already had expert panels review #1 and #2 within the last year No 1 was considered by the Fertility and Maternal Health Drugs Advisory Committee in November 1977 along with a review of the literature This Committee found that the data were inadequate to define the risks and benefits of elective medical induction This conclusion was subsequently confirmed in open hearings held in June 1978 As a consequence, labeling on oxytocin has been changed so that the only approved indications for the use of this drug are in situations where for medical reasons, such intervention is warranted and not where it is contemplated for the sake of personal convenience

No 2 was considered by the Anesthetic and Life Support Drugs Advisory Committee of the FDA which, upon examination of data in the Brackbill-Broman study, concluded that long-term effects had not been established, but there was some indication of possible short-term effects The Committee has appointed a subcommittee to review all the available literature in detail and develop recommendations for consideration by the Bureau of Drugs

The NIH's consensus development conference addressed #4 in March 1979, and #5 will probably be considered at an NIH consensus development conference in the next year Mention

should be made that the NICHD is presently developing a study of the usefulness of fetal monitoring for medium-risk patients. The Institute was advised by an outside group that a trial of fetal monitoring in high risk patients would be unethical in the present state of knowledge about the utility of this technology

> Determine and set priorities for research, including that on long-term effects on the child (and time to be covered) of various obstetric practices and develop a plan to obtain needed data

Department Comments

We do not concur Again there are two parts to this recommendation (1) priorities for research and (2) development of a plan to obtain needed data

There are numerous statements in the report that Federal research on obstetric practices lacks coordination or an overall plan The GAO is apparently unaware of the fact that NICHD is beginning the development of a 5 year research plan through the mechanism of a series of workshops involving leading experts in the country One of the most important topics will be high risk pregnancies including obstetric practices The goal is to have this plan completed within one year

Conditions of medical practice and requirements for human experimentation will be important considerations in the research recommendations As a cautionary note, it is important to point out that at this point it may be impossible for ethical as well as medical legal reasons to conduct a randomized clinical trial of certain practices (electronic fetal monitoring for high-risk patients) Conduct of clinical trials of certain types of practices undoubtedly would require large sample sizes, since the effects to be measured would be small and long-term follow-up would be very costly both in terms of time as well as money Moreover, in this very rapidly changing field of medical practice, there is a real possibility that by the time the results of such a trial are available--the practice may have changed sufficiently to make the data not applicable to the current situation

This NICHD planning effort follows on a series of major workshops which have been held yearly since 1975 and involve 20-25 experts each

(1)	Human parturition	November 1975
(2)	High risk pregnancy	September 1976
(3)	Laboratory assessment of the human fetus at risk	July 1977
(4)	Perinatal hypoxia	May 1978

APPENDIX III

The objectives of these workshops were to set research priorities, needs, and opportunities

It should also be noted that the NICHD through its Center for Research for Mothers and Children (CRMC) has a well developed and comprehensive program in reproductive and perinatal biology This program includes among others, research in (1) management of diabetic pregnancy (2) premature birth (3) clinical use of estriols for management of high risk pregnancies (4) relation of fetal heart rate to fetal oxygenation status (5) maternal infections in pregnancy and (6) maternal smoking and infant birth rate

As indicated earlier, it is our intent to raise the issue of obstetric practices with both the National Council and the Internal Advisory Committee With their assistance, particularly with involvement of those agencies funding obstetrics research, the issue will be examined with the NICHD plan as a basis for their deliberations

> Determine whether FDA's authority or procedures for regulating drugs and devices need strengthening regarding obstetric practices

Department Comments

We concur The Medical Devices Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act provide ample authority for FDA to regulate obstetric devices, additional statutory authority is not needed at this time In accord with the Amendments, the FDA presently is engaged in regulatory proceedings to implement this new authority

The FDA needs additional authority, however, to regulate drugs, especially authority to impose post-approval requirements In the 96th Congress, legislation was introduced--but not enacted--that would have given FDA this much needed authority Specifically, the legislation would have authorized FDA, when necessary, to impose restrictions on distribution and dispensing of drugs and to require manufacturers to engage in other post-approval activities including surveillance of drug use experience, conduct of scientific investigations, and the maintenance and submission of special records and reports The Drug Regulatory Reform Act of 1979, which recently was transmitted to Congress by the Secretary, also contains these provisions Thus, the need for additional legislation is clear although it is unnecessary to refer the matter to an advisory panel as suggested by the report

Determine how to minimize incorrect use of obstetric procedures, such as inducing labor prematurely or performing cesarean section too soon by encouraging PSROs to do more MCEs which are more thorough on obstetric practices and aiding them to develop criteria and standards for such evaluations

Department Comments

We concur The Department is concentrating considerable effort on the development of sample criteria to assist PSROs in establishing general standards for utilization and quality of medical care Among these sample criteria are components directed toward obstetric care and unnecessary surgery Furthermore, the findings of the final GAO report will be particularly useful in drawing PSRO attention to specific issues concerning the quality of obstetric care The GAO recommended evaluation of existing research should also be helpful in providing PSROs and the program with more data and information on the true nature and extent of the problems cited PSROs will be directed to investigate the situation locally, and take corrective action as necessary

Unfortunately, the PSROs are specifically faulted in the report for failure to address sufficiently the quality of obstetric care in the MCE studies The conclusion was that there is a lack of program interest in promoting good quality obstetric care It is our view that using obstetrics as an example of where the program is failing, places a disproportionate emphasis on that particular medical service area. This is especially true where an analysis is based on the frequency of MCE reports with this topic heading Under current guidelines the program does not specify the topic areas for MCE studies that are conducted by PSROs, or delegated hospitals MCE subject matter is based solely on locally perceived priorities as determined by the number of discharges, and these are usually divided among four service areas, including obstetrics, medical, surgery, and pediatrics, and also the emergency room, X-ray, pathology, and radiology The vast majority of patients reviewed by PSROs under Title XVIII (Medicare), Title XIX (Medicaid), and Title V (Children's Programs) are treated under medical or surgery It can be therefore understood that most MCE topics will address services of internal medicine and surgery rather than pediatrics or obstetrics The lack of large numbers of MCEs addressing obstetrics does not therefore imply a lack of PSRO interest in obstetric issues

Emphasize health education, information, and promotion activities on obstetric practices for health care providers and the public

Department Comments

We concur. Both the Office of Disease Prevention and Health Promotion and the NICHD will enhance their activities concerning obstetrics, aiming at both providers and the public. There are, however, activities already which are aimed at promoting information dissemination and education of physicians and the public about obstetric practices The task force reports and the outcome of the NIH-NICHD Consensus Development Conference on Antenatal Diagnosis will be published as a monograph and will be distributed free of charge to physicians In addition, two articles discussing the Conference have appeared in the Journal of the American Medical Association and others in a variety of medical publications, in the Ladies Home Journal and in Womens' Day as previously mentioned

The current standards of prenatal care observed by HSA's Bureau of Community Health Services programs and projects already include education concerning procedures that may be used during hospitalization for delivery The content of such education will be periodically reviewed and updated Close cooperation between service agencies and the Bureau of Health Education of the Center for Disease Control is indicated and will be fostered.

Finally, the Office of Population Affairs in the Office of the Assistant Secretary for Health is preparing a review of Federal Policies and programs in all aspects of reproduction and women's health (e.g , pregnancy and family planning) Some of the issues raised in this report are addressed in the review which upon publication will also stimulate interest and tend to foster increased emphasis in the agencies concerned with obstetric practices

APPENDIX III

Technical Comments

There is a great deal of repetition in the document that could profitably be deleted. In virtually every section there is a reiteration of FDA's responsibility, the lack of long-term studies, the failure of the Federal government to support more research, etc Since these findings refer to each of the five practices discussed, it would seem economical to place them at the end as a summary Exceptions could follow each section, thus requiring only one statement of these matters. The paper would be considerably shortened and the reader might find his way through it more quickly were this suggestion to be adopted

Page 3, line 5, last paragraph The sentence "The length of this stage depends entirely on the amount of resistance the infant must overcome." This needs to be qualified to include other factors which may result in dysfunctional labor (e g , congenital malformation of the baby and inadequate uterine contractions)

Page 13, line 2, first paragraph There are a number of collaborative perinatal projects, the reference should be the "NINCDS Collaborative Perinatal Project "

Page 16, beginning with line 9 To reflect accurately responsibilities involved, sentence should read "In addition, local PSROs could do more to establish medical care standards and criteria, and encourage hospitals to perform additional medical care evaluation studies in the area of obstetrics "

Page 17, line 4 We suggest that "PSROs MCEs of obstetric practices have been infrequent, due to priorities placed on medical and surgery, which involve large numbers of admissions "

Page 32, line 3, paragraph 2 The sentence "Some have criticized the project because patients were not selected randomly, and no control group was set up against which to weigh the data found." The following should be inserted into the report The NINCDS Collaborative Perinatal Project is a cohort study in which 50,000 women were enrolled between 1959 and 1966 at twelve major medical centers. Women seeking obstetrical care at these twelve medical centers were enrolled in the NINCDS Collaborative Perinatal Project, either all women at a given center or on a random-selection basis The Project was designed to study cerebral palsy, mental retardation, and other neurological and sensory disorders of infancy and childhood In the cohort of children followed, those children with cerebral palsy are the study cases and those children without cerebral palsy are the controls

Page 32, line 6, paragraph 2 The sentence reads "Also it has been noted that the material presents problems of interpretation because the data are so vast and so heterogeneous that it is impossible to collate the many factors that may affect the final interpretation " The vast amount of data collected presents many problems of analysis and interpretation, but by using multivariate analytic techniques, the interrelationship of large numbers of factors can be determined.

Page 34, last sentence of paragraph 2 While the Collaborative Perinatal Project data are stated to be "quite old," the report in numerous places calls for long-term (longitudinal) studies. If children are to be followed from birth to age 7 or 8 years or older so that definitive diagnoses can be made (particularly learning disorders), it is inherent in the design of the study that a significant time-span will have lapsed during the course of the study

Page 35, line 14 It would be more correct to state that "PSROs and hospitals are encouraged to conduct MCEs on all patients rather than just Federal patients in order to obtain a better analysis of practice patterns "

Page 36, line 2 We suggest an additional sentence " emphasis to this area Most topics selected for MCEs have centered on more frequent medical-surgical admissions HEW has not issued guidelines "

Page 36, line 22 We suggest an additional sentence " objectives or findings One reason for this is that some of the information is protected under guidelines governing the confidentiality of patients and practitioners Therefore "

Page 37, line 10 To avoid a misleading impression we suggest this read, " study objectives, the occurrence of small numbers of cases, particularly in smaller hospitals (ranging from ")

Page 42, top of page The beginning of the sentence is missing.

Page 75, first sentence of paragraph 2 The Brackbill and Broman study is best described as "in progress "

Page 85, line 8, paragraph 2 Same comment as above Brackbill and Broman study is "in progress "

Page 89, line 10, paragraph 3 Questions concerning the Brackbill and Broman study have not dealt with the "data base," but rather with the "analytic methodology " The second study underway has <u>not</u> been presented for professional or public discussion

APPENDIX III

Page 105, last line of paragraph 2 Two flaws of the study are cited In regard to the first point, the study was not designed primarily to evaluate methods of delivery (see comment concerned with page 32, line 3, above) In regard to the second comment, all deliveries were made in major medical centers which were either university-based or university-affiliated and the quality and supervision of obstetrical care were commensurate with the standards maintained by these centers.

(102035)

*U S GOVERNMENT PRINTING OFFICE 1979 - 620-167/313

Single copies of GAO reports are available free of charge Requests (except by Members of Congress) for additional quantities should be accompanied by payment of $1 00 per copy

Requests for single copies (without charge) should be sent to

U S General Accounting Office
Distribution Section, Room 1518
441 G Street, NW
Washington, DC 20548

Requests for multiple copies should be sent with checks or money orders to

U S General Accounting Office
Distribution Section
P O Box 1020
Washington, DC 20013

Checks or money orders should be made payable to the U S General Accounting Office NOTE Stamps or Superintendent of Documents coupons will not be accepted

PLEASE DO NOT SEND CASH

To expedite filling your order, use the report number and date in the lower right corner of the front cover

GAO reports are now available on microfiche If such copies will meet your needs, be sure to specify that you want microfiche copies

AN EQUAL OPPORTUNITY EMPLOYER

UNITED STATES
GENERAL ACCOUNTING OFFICE
WASHINGTON, D C 20548

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE,$300

POSTAGE AND FEES PAID
U S GENERAL ACCOUNTING OFFICE

THIRD CLASS