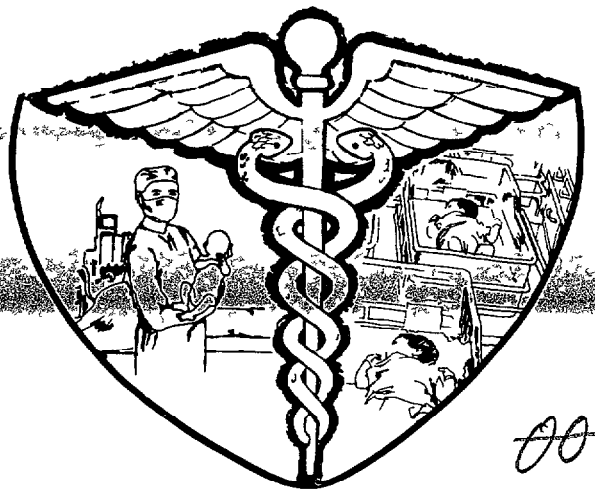
STUDY BY THE STAFF OF THE U.S.

General Accounting Office

A Review Of Research Literature And Federal Involvement Relating To Selected Obstetric Practices

Research literature does not resolve the controversy over U S obstetric practices The literature is generally inconclusive about the benefits versus risks for five selected obstetric practices elective induction of labor, medication to relieve labor pain, preventive use of forceps, routine electronic fetal monitoring, and increasing use of cesarean section The Federal Government has various responsibilities for or interests in various aspects of obstetric practices, including research, regulating drugs and devices, evaluating the quality of medical care, and health education, information, and promotion



UNITED STATES GENERAL ACCOUNTING OFFICE

HRD 79 85A
SEPTEMBER 24, 1979

PREFACE

We reviewed research literature and Federal agency involvement relating to the benefits and risks of selected obstetric practices as a result of the interest shown by the Subcommittee on Health and Scientific Research, Senate Committee on Labor and Human Resources. In April 1978, the Subcommittee held hearings on the implications of various obstetric practices on the health of mothers and children. Several witnesses questioned their safety for the child and elective use of certain practices.

This study summarizes our review of research literature for five selected obstetric practices. In general, research literature was inconclusive about the benefits versus risks of the obstetric practices selected for review. Research studies generally lacked adequate control groups, involved relatively few patients, failed to assess long-term effects, or involved some other shortcoming which limited their usefulness in this area.

This study also describes the activities of Federal agencies, principally the Department of Health, Education, and Welfare, relating to the five obstetric practices we selected for review. However, these activities, as well as recommendations for improvement, are discussed in more detail in our report to the Congress, "Evaluating Benefits and Risks of Obstetric Practices--More Coordinated Federal and Private Efforts Needed," HRD-79-85, issued at the same time.

We received comments on a draft of this study from the Department of Health, Education, and Welfare; the American College of Obstetricians and Gynecologists; and two representatives of the American Academy of Pediatrics. We incorporated their comments or made changes as appropriate.

Gregory J. Ahart, Director
Human Resources Division

Contents

ABBREVIATIONS

ACOG	American College of Obstetricians and Gynecologists
CPHA	Commission on Professional and Hospital Activities
FDA	Food and Drug Administration
FHR	fetal heart rate
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

INDUCTION OF LABOR

Induction of labor for elective reasons has become a controversial procedure. Some medical professionals advocate its elective use while others denounce it as adding unnecessary risk to mother and child. Some research studies noted harm to the infant as a result of elective induction, and some even attributed perinatal deaths to induction. However, others argue that labor after elective induction should be no more hazardous than normal spontaneous labor. They further argue that many of the adverse effects cited are due to misuse of the procedure and are not the fault of induction itself.

The Food and Drug Administration's (FDA's) Fertility and Maternal Health Drugs Advisory Committee says the benefit/risk relationship for elective induction has not been defined, and we found very few studies on the long-term effects of induction on the child. However, even without a defined benefit/risk relationship and long-term study, some researchers have said that in some places in the United States elective induction has gained widespread use.

Federal efforts regarding induction of labor are sporadic and uncoordinated. The Federal Government, through FDA, is responsible for insuring the safety and efficacy of drugs. However, FDA does not periodically check drugs and their labeling. Also, FDA was slow to take action to remove intramuscular sparteine sulfate (a drug used to induce labor) from the market after questions arose about its safety for induction and stimulation of labor. Limited federally funded research on induction of labor has occurred, but in general it has not dealt with the effects on the fetus/child. Also, it appears that medical care evaluations (MCEs) by Professional Standards Review Organizations (PSROs) on induction of labor have been done at only a few hospitals.

DESCRIPTION

Induction of labor--the artificial initiation of the labor process--may be done before, at, or after the expected date of delivery. Inductions are done before the first stage of labor begins. Methods used for induction are either surgical (using mechanical means) or medical (using drugs), or both.

Amniotomy (artificially rupturing the fetal membranes) is the most frequent surgical method, and uterine stimulation by oxytocics is the most frequent medical method. Oxytocics--any drugs which cause the uterus to contract--include oxytocin, sparteine sulfate, and prostaglandins. They can be given by injection or by mouth. The oxytocic drug most commonly used in the United States is oxytocin, which is sold under the names Pitocin and Syntocinon.

The first surgical induction of labor occurred in France in 1609 by artificially rupturing the fetal membranes. This method was first used in the United States in 1810. Medical induction using Pituitrin (an oxytocic drug used before Pitocin) began in the early 1900s. Elective induction increased during World War II. At that time, according to D'Esopo et al., growing demand for obstetric services brought a shortage of professional personnel. Under these circumstances, according to D'Esopo et al., overworked obstetricians often chose to induce labor in suitable cases to give some semblance of order to their chaotic lives.

INDICATIONS FOR INDUCTION

Induction of labor can be done for medical reasons or as an elective procedure. Medical indications, which can be based on maternal or fetal concerns, or both, include the following conditions: diabetes, premature rupture of the fetal membranes, premature separation of the placenta, high blood pressure, maternal-fetal blood incompatibilities, heart and blood vessel disorders, and toxemia of pregnancy. Other nonmedical concerns, such as problems in getting to the hospital and history of previous rapid delivery, can be indications for induction. Elective induction is done for the convenience of the obstetrician or the patient (mother).

EXTENT OF USE

We were unable to obtain any national data on the frequency of induction of labor. However, data are available on inductions performed in several large groups of deliveries. Data on elective induction use are also unavailable on a national level. However, several sources indicate that its use is widespread.

Prevalence of induction of labor

The most comprehensive information we found on the prevalence of induction of labor in the United States was from the 1967 American College of Obstetricians and Gynecologists (ACOG) Hospital Survey. The 2,995 hospitals which supplied

complete information on livebirths, stillbirths, inductions, and cesarean sections reported 2,060,440 total births and 177,198 inductions--an overall induction rate of 8.6 percent. Hospitals reporting 250 to 1,999 annual births and concerned with the care of private patients had the highest induction rates.

More recent and the next most comprehensive data available to us on the frequency of induction of labor were from the Commission on Professional and Hospital Activities (CPHA) on 1,900 U.S. hospitals which report to it. These statistics for a sample of 262,722 deliveries from 1970 to 1976 and 1.3 million deliveries in 1977 showed the following induction percentages:

Type of induction	1970	1971	1972	1973	1974	1975	1976	1977
Surgical	10.7	10.1	9.6	9.9	6.7	7.0	6.5	7.3
Medical	1.5	1.8	2.1	2.4	2.5	2.9	3.1	3.6
Both medical and surgical	0.9	1.0	1.1	1.3	1.1	1.1	0.9	0.9
Total inductions (note a)	13.0	12.9	12.8	13.5	10.4	11.0	10.5	11.8

a/Figures appear as shown. They do not always add up.

CPHA data also showed that the prevalence of induction varied by type (teaching versus nonteaching) and size of hospital and region of the country. For instance, based on a sample group of 262,722 deliveries for 1970 to 1976, the "PAS Reporter" for August 1977 reported induction rates of 16.4 percent for the Northeast; 10.1 percent for the West; 9.5 percent for the North Central; and 7.6 percent for the South. In commenting on the data, Matteson stated:

> "It would appear * * * that patients' and physicians' habits, attitudes and beliefs, as well as varying hospital policies, may underlie the different induction rates by region."

The Collaborative Perinatal Study sponsored by the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) reported that at the hospitals studied, approximately 5 percent of black patients and 10 percent of white patients had induced labors. The percent of induced

labors at individual hospitals ranged from 2.42 to 14.2 percent for white patients and from 1.05 to 10.34 percent for black patients.

Prevalence of elective induction

No national or CPHA data are available on the prevalence of elective induction of labor. However, several books and articles did comment on the frequency of this method. For example, according to the 1966 edition of "DeLee's Obstetrics for Nurses":

> "The elective induction of labor for other than medical indications has increased in popularity in recent years. There are some institutions in which as many as one third of obstetric patients are brought into the hospital on a selected date and the induction of labor initiated."

In a 1975 book, Cibils noted that the annual reports of large maternity hospitals seem to indicate that the proportion of elective inductions is increasing steadily every year, at least in institutions in which inductions are generally a routine obstetric procedure.

Others, too, have stated that elective induction occurs often. For instance, in a 1966 article, Niswander, et al., stated that a significant percentage of labors in U.S. hospitals are electively induced. In a 1974 article Schwarcz et al. commented that:

> "The elective induction of labor has become common practice in Obstetrics. In the United States, in private hospitals, elective induction reaches values up to 35 percent of all the deliveries."

In a 1976 article, Rindfuss and Ladinsky expressed the belief that elective induction of labor is widespread but stated that no data exist to confirm this.

Some U.S. research articles we reviewed did give total deliveries and elective inductions for the hospitals included in their studies, with elective induction percentages ranging from 1.5 to 36.5 percent. In one study, the elective induction percentage was 42.2 percent for consecutive private deliveries.

RESEARCH RESULTS INCONCLUSIVE

The research literature we reviewed was inconclusive in evaluating the risks versus benefits of elective induction of labor. Opinions were diverse in assessing relative risks and benefits of the procedure. Because studies differed markedly in their parameters and test conditions, one cannot easily determine which should be given more credence. In general, the scope of the studies we reviewed was limited. Also, we found very few studies on the long-term effects of induction on the child. Of authors stating an opinion about elective induction, 21 favored it, and 13 were against it. Numerous studies cited possible hazards of induction to offspring, but others found none. Some cited cases of incorrect use of the technique. In the case of sparteine sulfate, it appears that the drug was accepted for use before its safety had been adequately established.

Scope of research limited

The scope of the research studies we reviewed was limited. Most articles were retrospective, and the few prospective ones did not include large study populations. Most of the studies dealt with patients at just one hospital and had poor or no selection of control group. In addition, most articles dealt with short- rather than long-term effects. For example, all of the foreign studies were short term and did not follow up on cases beyond the first week of life. Only one of the U.S. studies we reviewed dealt with long-term effects.

In attempting to reach summary conclusions on the research literature, we reviewed about 450 articles on induction of labor, of which 262 studies noted the effects of induction of labor on the infant. These studies can be categorized as follows:

--123 U.S. studies: 92 on oxytocin and/or amniotomy, 15 on prostaglandins, and 16 on sparteine sulfate.

--139 studies from 25 foreign countries: 92 on oxytocin and/or amniotomy inductions, 46 on prostaglandins, and 1 on sparteine sulfate.

Among these studies were 65 U.S. and 13 foreign studies that specifically included elective inductions of labor.

Long-term studies lacking

One glaring omission is the relative absence of studies to determine if elective induction of labor has any long-term effects on the infant. A number of researchers commented on the need for such studies, yet only one of the studies we reviewed dealt with long-term effects. This was a 1966 retrospective study by Niswander et al. The research compared 131 4-year-olds, born after elective induction, with 147 control cases. The authors were unable to demonstrate that elective induction increases the risk of brain damage for a full-term infant. However, infants born prematurely were not included in the study, and Niswander et al. stated that including them would likely have changed the conclusion.

Effects on the infant

Some of the research studies we reviewed cited various effects on the infant resulting from delivery by induction of labor. However, the literature is conflicting as to whether induction increases perinatal mortality and morbidity. Of the studies we reviewed, nine found no increase in perinatal mortality and morbidity with induction of labor; however, some did cite hazards.

Nineteen studies attributed perinatal death(s) to induction of labor, and nine studies said it may have contributed to perinatal death. For example, in a 1958 study of 6,889 infants delivered after elective induction, Keettel et al. classified 39 deaths (0.6 percent) as directly related to the induction of labor. The primary causes of death were prematurity, prolapsed cord (a hazard of artificial rupture of the membranes--the umbilical cord falls below the fetus), and infections after a latent period of over 24 hours (the time after rupture of the membranes before active labor begins). In a 1963 study on 2,862 elective inductions, Niswander and Patterson reported a perinatal mortality rate of 0.7 percent which they regarded as related to the elective induction of labor. Again, the primary causes of death were prematurity and prolapsed cord.

Other problems can occur in connection with induced labor. For example, if premature infants are born they may develop respiratory distress syndrome. In a 1975 article reviewing 100 consecutive cases of respiratory distress syndrome, Goldenberg and Nelson concluded that untimely physician intervention was responsible for 15 percent of the respiratory distress syndrome cases (9 elective repeat

cesarean sections and 6 elective inductions, all without maturity studies). Also, in another 18 percent (18 cases, including 10 elective inductions and 8 cesarean sections), untimely physician intervention may have been responsible for the occurrence of respiratory distress syndrome.

Hack et al. in a 1976 article noted that, from November 1973 to April 1974, 12 percent of the infants coming to intensive care in their hospital were born after elective intervention (15 cesarean sections and 4 inductions). In 11 of the 19 infants, the obstetric dating (estimate of gestational age of the fetus by the obstetrician) was 3 or more weeks greater than the pediatric age (estimate of gestational age of the infant by the pediatrician). In all, 26 of the studies we reviewed reported cases of prematurity, although many of the studies did not directly attribute the cases to induction. Nineteen of the studies we reviewed reported cases of prolapsed cords, although many of the studies did not specifically attribute this to induction.

Other studies, particularly European studies or those on prostaglandins or sparteine sulfate, reported other adverse effects of oxytocics. Thirteen studies, mainly from Great Britain, reported an increased incidence of neonatal jaundice after induction of labor, particularly when oxytocin was used. Fifty-two studies reported fetal distress or fetal heart rate (FHR) changes, and 35 reported tetanic contractions (prolonged uterine tension) or uterine hypertonus (increased uterine tension). Some studies directly attributed these complications to the use of an oxytocic drug.

In 1978, Rindfuss et al. reported on a study which found a small, but significant, negative effect on the newborn of both elective induction of labor and elective stimulation of labor. The study used a multiple regression analysis of New York City birth certificate data for 1968. When type of hospital was a variable, greater negative effects occurred in municipal hospitals and, to a lesser extent, on service wards of voluntary hospitals. Rindfuss et al. stated:

> "We suspect that the results of studies examining the safety of elective induction have been contradictory because the risk or benefit to the fetus is very small. Small effects are not consistently visible in either prospective studies or in retrospective studies when only a few subjects are used. * * * the question that needs to be answered by both mothers and physicians is whether any such risk to the

neonate, however small, is to be tolerated solely for the sake of convenience."

Induction may not be done correctly

One reason elective induction can affect the infant is that induction can be done incorrectly. However, we have no data on how many of the complications cited in the studies we reviewed were due to incorrect use. We do know that in some of the cases involving prematurity, authors cited improper estimation of gestational age. Also, Niswander and Patterson's observed death rate of 7 per 1,000 (see p. 6) was believed to be a result of poor patient selection and improper oxytocin administration.

In a 1975 book, Cibils commented on physicians' use of oxytocin:

> "The obstetric literature is periodically reporting obstetric catastrophes attributed to the use of oxytocin when the responsibility should better be pinned on its improper administration by careless or negligent physicians. The two most dangerous obstetric complications are caused by giving excessive amounts of oxytocin: [These are] (1) intrauterine fetal asphyxia [suffocation] because of prolonged hypercontractility [excessive tension of the uterus] and (2) rupture of the uterus because of overstimulation. * * * A careful scrutiny of a bad accident attributed to oxytocin will invariably reveal its misuse or inadequate supervision."

Benefit versus risk ratio has not been established

The benefit versus risk ratio of elective induction of labor has not been defined, according to FDA (see pp. 10 to 12). In a 1974 article, Schwarcz et al. stated that so far no one has done any complete studies demonstrating the harmlessness of elective induction.

In the early 1970s, a move in Great Britain favored active management of labor and delivery, including frequent use of elective stimulation and elective induction of labor. A 1976 editorial in the "British Medical Journal" noted that the incidence of induction of labor in England and Wales rose from 15.8 percent in 1964 to 33.5 percent in 1972.

However, by the mid-1970s, Britain's active approach to managing labor and delivery had become the subject of a heated debate. In a 1976 article, Fedrick and Yudkin noted that the British public had raised questions about the value of induction, the dangers to the fetus, the possible harm to the mother, and the alleged increased need for anesthesia as a result of elective induction. Thus, people were beginning to question strongly the benefit of routine elective induction. In commenting on this, ACOG noted that the British experience was not comparable to the situation in this country because U.S. physicians were much more selective in choosing patients for elective induction.

Sparteine sulfate use adopted too quickly

Use of sparteine sulfate, as a drug for inducing labor, appears to have caught on in our country without proof of its worth. Sparteine sulfate first became popular in Europe and then its use spread to the United States. According to one article, based on initial U.S. studies demonstrating its safety, sparteine sulfate was considered safe enough to be given without the constant supervision of a physician. In a few years, however, reports of its dangers began to appear.

In an April 1963 article, Yard reported that sparteine had had a fairly broad trial in obstetrics during the preceding 5 years, with no report of tetanic contraction (prolonged uterine tension) or any suggestion that sparteine affects the incidence of maternal or fetal complications. He stated that sparteine can be administered in a muscle and that the patient receiving it need not be supervised continuously.

However, also in April 1963, two separate case reports appeared on complications with the use of sparteine sulfate. One reported tetanic contractions and intrauterine fetal distress, and the other reported a uterine rupture.

In 1966, Newton et al. reported on a study of 322 pregnant patients who received one or more intramuscular sparteine sulfate injections. Among the results reported were tetanic contractions (four cases), premature separation of the placenta (four cases), and two stillborn babies. Newton et al. concluded that "the intramuscular administration of sparteine is a dangerous, unpredictable method of stimulating or inducing labor," and that "because of its extreme potency and capricious nature, sparteine sulfate can no longer be considered as a 'safe' oxytocic when administered intramuscularly."

FEDERAL EFFORTS LIMITED

The Federal Government has certain responsibilities which relate to elective medical induction of labor. FDA must insure the safety and efficacy of drugs used for the induction of labor, including oxytocics. However, it does not have authority over the surgical induction of labor. The Department of Health, Education, and Welfare (HEW) funds medical research, primarily through institutes of the National Institutes of Health (NIH). HEW also provides funds to PSROs for hospital MCEs. In reviewing these areas of responsibility we found that:

--FDA does not periodically review the safety of drugs on the market and the adequacy of warnings on their labels.

--FDA was slow to act to remove sparteine sulfate from the market even though the drug was found to be dangerous.

--The Federal Government's funding of research on induction of labor appears to have been very limited, and the federally funded studies we were able to identify generally did not deal with the effects of oxytocins on the fetus/child.

--PSROs have done few MCEs on induction of labor.

As far as we could determine, the Federal Government has not funded research on elective surgical induction of labor although it has funded some research on artificial rupture of the membranes in general. Also, PSROs we surveyed had not done MCEs on surgical induction of labor. However, FDA's evaluation of the benefit-to-risk ratio for elective induction applied to both medical and surgical induction.

No periodic review of drugs by FDA

Our report "Evaluating Benefits and Risks of Obstetric Practices--More Coordinated Federal and Private Efforts Needed" (HRD-79-85) describes FDA's responsibility for drug safety and general procedures for regulating the use of drugs. However, FDA has no procedures to periodically review the safety of drugs after they are approved for use. Oxytocic drugs used in induction of labor include Pitocin and Syntocinon given by injection, oral Pitocin tablets, and intramuscular sparteine sulfate. Oral Pitocin and sparteine

sulfate underwent FDA's approval process for new drugs; however, injected Pitocin and Syntocinon did not. FDA informed us that these two drugs have been on the market since before 1938 and thus fall under the "grandfather clause" exempting drugs marketed before 1938 from FDA regulation. Within the last few years, all four of these drugs have come into the spotlight at FDA after a consumer complaint about the use of oxytocic drugs for elective induction of labor.

The parent of a child delivered by elective induction wrote two letters to FDA in April 1977 complaining about elective use of oxytocic drugs. The letter writer said her son, born in 1951, had suffered brain damage, which was probably caused by injected Pitocin used during the elective induction of labor. After these complaints, FDA did the following:

--In July and November 1977 and January 1978, its Obstetric and Gynecology Advisory Committee (now called the Fertility and Maternal Health Drugs Advisory Committee) discussed elective induction of labor.

--At the November 1977 meeting, the committee concluded that existing studies do not allow a benefit-to-risk rate appraisal of oxytocin for elective induction. The committee recommended that physicians be warned of this on the labels of oxytocic drugs given by injection--Pitocin and Syntocinon--and that patients also be warned. The committee also recommended that physicians stop performing elective inductions primarily because of the undefinable benefit-to-risk ratio.

--In June 1978, FDA held a public hearing on elective induction of labor. At this hearing witnesses testified about the advantages and adverse effects of elective induction.

--In August 1978, FDA's Fertility and Maternal Health Drugs Advisory Committee met to discuss the labeling of injectable oxytocic drugs (Pitocin and Syntocinon). The committee recommended labeling changes.

--On August 31, 1978, FDA sent letters to the manufacturers of these two drugs, giving them 60 days to make the suggested labeling changes. The revised labeling is to include a box on the label with the following warning:

"(Name of Drug) is indicated for the medical rather than the elective induction of labor. Available data and information are inadequate to define the benefits to risks considerations in the use of the drug product for elective induction. Elective induction of labor is defined as the initiation of labor for convenience in an individual with a term pregnancy who is free of medical indications."

Since FDA has no system for periodically reviewing drugs and their labels, it seems questionable whether FDA would have looked into the issue of elective induction of labor by oxytocics and taken its recent actions without the impetus of the complaint received in 1977.

FDA slow to act to remove sparteine sulfate from the market

A second matter considered by FDA also involved drugs used in elective induction. In the same meetings in 1977 and 1978, FDA's Fertility and Maternal Health Drugs Advisory Committee decided to recommend removing oral Pitocin and intramuscular sparteine sulfate from the market. The committee concluded that only intravenous oxytocin (Pitocin and Syntocinon) should be used for induction of labor since the action of oxytocics given this way is more predictable. In December 1978, FDA issued notices of opportunities for hearings on its proposed removal of the oral and intramuscular oxytocics from the market. The events leading to these decisions were:

--In 1963, reports on the adverse effects of sparteine sulfate began appearing in the medical literature.

--At the October 1968 meeting of FDA's Obstetrics and Gynecology Advisory Committee, the safety of sparteine sulfate was questioned due to its unpredictable effects. The committee considered the safety of sparteine sulfate and reviewed the labeling but concluded not to withdraw the drug from the market then.

--In June 1971 the Federal Register reported on the results of the evaluation of sparteine sulfate by the National Academy of Sciences-National Research Council, Drug Efficacy Study Group. The Academy evaluated the drug as effective but pointed out that its action is unpredictable. The Federal

Register announcement included a warning to be placed on sparteine sulfate labels stating that "The action of this preparation is quite unpredictable * * *. An occasional case of rupture of the uterus has been reported with the use of sparteine sulfate."

--In October 1975, FDA's Obstetrics and Gynecology Advisory Committee concluded that because the physician cannot stop the action of this drug and because of documented problems of hypertonicity (increased tension) of the uterus, the relative safety of sparteine sulfate intramuscular injection is questionable. Therefore, the committee recommended discontinuing this drug's approval for marketing.

If FDA does finally remove sparteine sulfate from the market in 1979, more than 15 years will have passed since adverse reports on the drug began appearing in the literature, over 10 years since FDA's advisory committee first discussed its safety, and over 3 years since the advisory committee recommended removing it from the market.

Federally sponsored research on induction limited

NIH has supported a few studies on induction of labor. However, we found only one, on oxytocin, which focused on the fetal/infant effects of elective induction of labor. This was a 1978 study by Rindfuss et al. dealing with elective induction and stimulation of labor and the health of the infant. (See p. 7.) This study used research facilities supported by the Center for Population Research, the National Institute of Child Health and Human Development (NICHD). The Center also gave similar indirect support to a 1976 study by Rindfuss and Ladinsky on the prevalence of elective induction of labor.

HEW supported several other studies dealing with induction of labor in general. However, none of these studies dealt with long-term effects on the child. For example, NIH supported a few studies by Hendricks and others in the early 1960s which tested the use of oral or inhalation Pitocin for induction. However, these studies were not directed to fetal/infant effects. HEW also partially supported a study by Hess and Hon (1960) on fetal heart patterns which were observed during oxytocin-induced labor. Several studies in the 1970s on the use of prostaglandins for induction were supported by HEW; however, so far prostaglandins are not approved for use for induction of labor in the United States.

One of these studies (Blackburn et al., 1973) was on the effects on the neonate of induction of labor with a prostaglandin versus oxytocin.

Few PSRO evaluations of induction

PSRO involvement in reviewing induction of labor appears very limited. Only two of the seven PSROs from which we received data on MCEs had reviewed elective induction of labor. One of these reported one MCE and the other reported two.

One study reviewed 50 obstetric patients to determine how many were electively induced by Pitocin. Another study reviewed records of 50 patients for whom labor was electively induced to evaluate their care and outcome. This study found a 4-percent rate of induction failure.

The third MCE on elective induction was made to determine whether elective inductions increase the incidence of complications. A group of 100 patients electively induced with Pitocin were compared with 100 normal deliveries without Pitocin. The complications rate was 11 percent for induced and 18 percent for noninduced cases. The jaundice rate was 10 percent with Pitocin and 4 percent without Pitocin. The prematurity rate was 3 percent for induced cases and 12 percent for normal deliveries without Pitocin.

INVOLVEMENT AND COMMENTS BY PROFESSIONAL ORGANIZATIONS

So far ACOG has not taken a position on the appropriateness or inappropriateness of elective induction of labor. An ACOG representative testified to this effect at the June 1978 hearing on elective induction. ACOG did issue a technical bulletin on induction of labor in May 1978, but this publication dealt mainly with the methods of induction.

In commenting on a draft of this study, ACOG said that some elective labor inductions are appropriate, while others are inappropriate. For example, ACOG considers an elective induction to be appropriate in a case in which the mother lives 50 miles from the hospital, has had two previous rapid deliveries, is at term, and has a "ripe" cervix. On the other hand, ACOG would consider an elective induction inappropriate if it were done only to enable the physician or mother to attend a social event. ACOG also noted that physicians had begun to discontinue using sparteine sulfate in the 1960s for induction after evidence of its hazards began appearing in the medical literature.

CHAPTER 2

MEDICATIONS USED TO RELIEVE LABOR PAIN

Medications are often used to reduce or eliminate the mother's discomfort during labor and delivery. Studies show that virtually all medications used for pain relief in labor and delivery cross the placental barrier. The research, however, did not conclusively demonstrate the biological significance of the effects on the infant or their duration. These remain the major questions to be answered by obstetric drug research. So far, Government involvement in any such long-term research has been very limited. One such study was canceled before completion and two studies yet to be completed are evaluating data from the NINCDS Collaborative Perinatal Project which gathered data on selected births from 1959 to 1966.

Although FDA has approved some obstetric medications as being safe and effective, and required descriptive warnings on drug labels, it has no control over what doctors prescribe and no assurance that pregnant women are advised of such consequences.

ACOG recommends that caution be used in administering obstetric pain relief drugs and that physicians tell their patients about potential hazards.

DESCRIPTION

Many drugs are available to provide varying degrees of relief of labor and childbirth pain. The degree of relief obtained from these drugs is called either analgesia or anesthesia. The milder state, analgesia, means insensibility to pain alone, but anesthesia is insensibility to all feeling.

Three basic methods are available for relieving pain. Ways of administering obstetric anesthesia and analgesia, for example, may be divided into two broad categories--systemic and regional. Systemic methods involve introducing drugs into the patient's bloodstream. Regional or conduction anesthesia is achieved by injecting a local anesthetic drug around the nerves in one region of the body. Psychological conditioning is the third way of dealing with pain. It purportedly influences the patient's response to pain without using drugs. However, according to ACOG, the benefits of many of the techniques of psychological conditioning have never been proven.

Attempts to relieve the pain of labor and childbirth with drugs date from the 1840s when chloroform was first given to a woman in Scotland. According to James (1960), the idea of controlling pain in a particular area of the body was first tried in 1909, but not until 1933 did this method achieve any prominence. Since then use of regional anesthetic techniques for childbirth has increased in the United States and Europe.

INDICATIONS FOR USE

Analgesic and anesthetic medications are used to relieve pain during labor and childbirth. Uterine contractions and cervical dilation cause pain during the first stage of labor. During the second stage, these two factors plus stretching of maternal tissue and episiotomy (a surgical incision to enlarge the vaginal opening) cause pain. Also, the patient's pain can increase because of fear and tension.

EXTENT OF USE

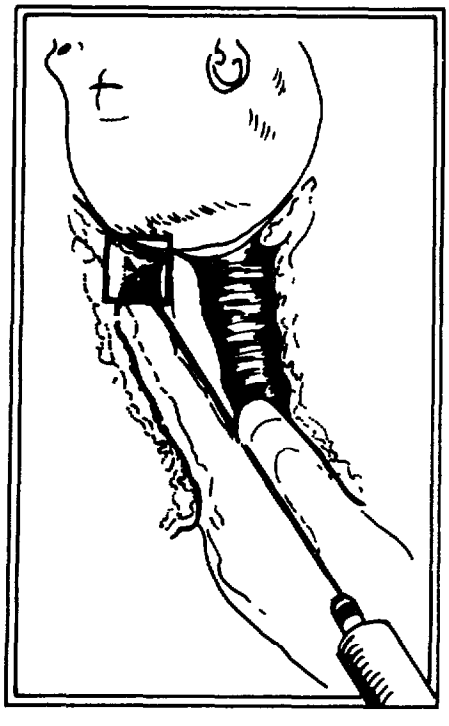
All the data we obtained showed widespread use of obstetric medication in the United States. Some of the more comprehensive statistics came from the National Natality Survey, ACOG, CPHA, and the NINCDS Collaborative Perinatal Project.

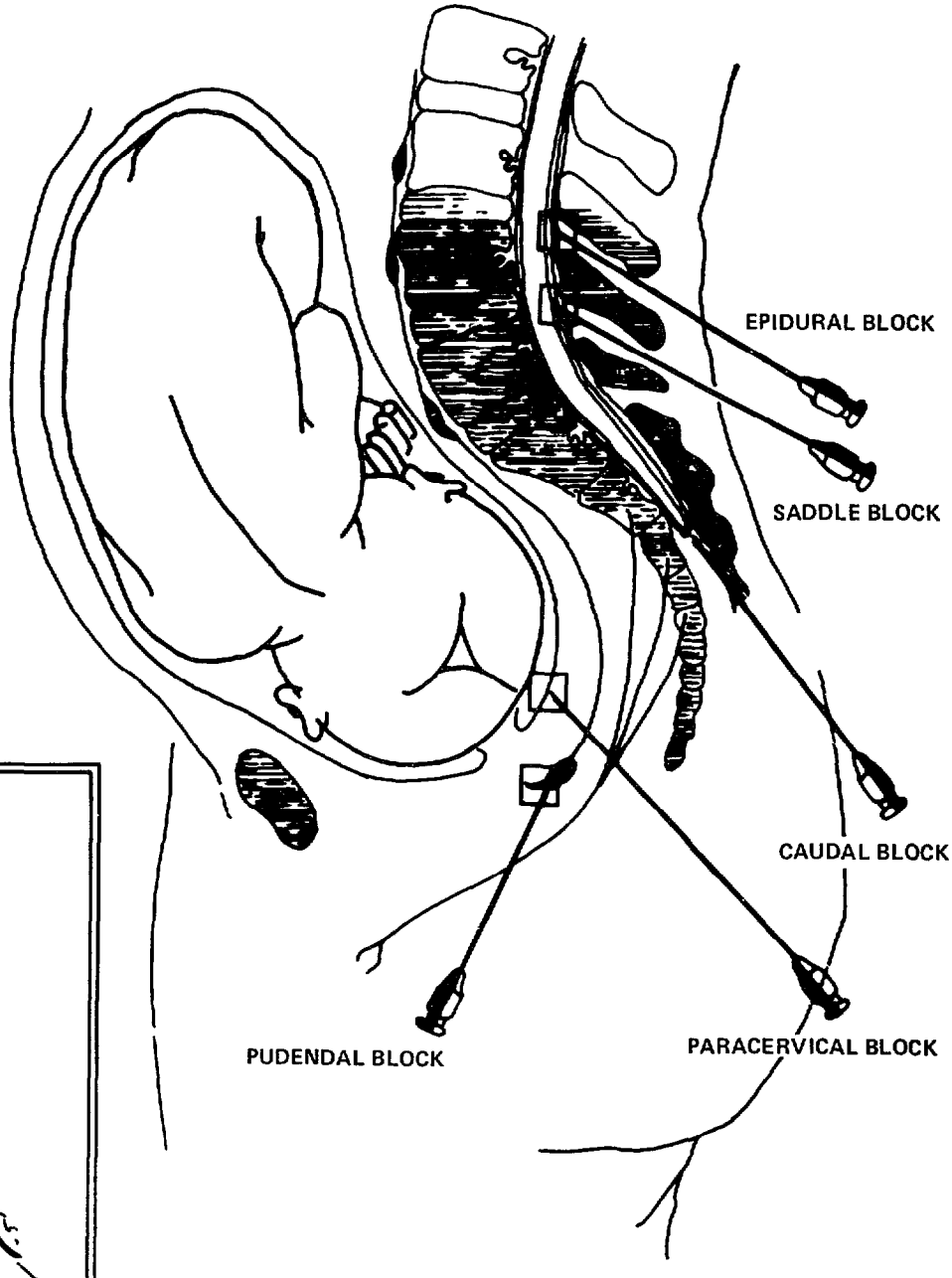
The 1972 National Natality Survey of 2,818,000 legitimate, live, hospital births in the United States during 1972 showed no anesthetics used in 7 percent of the deliveries, one of the various types of anesthetics used in 82 percent, and two or more anesthetics in 11 percent.

The ACOG study of 1967 deliveries showed significant use of obstetric analgesia and anesthesia. Over 80 percent of hospitals responding reported that almost all (80 to 100 percent) of their patients received obstetric analgesia and/or obstetric anesthesia.

We also got data on anesthesia use in normal deliveries in CPHA hospitals. The data for 1970 covered 293,955 patients who had no mention of complications or operations.

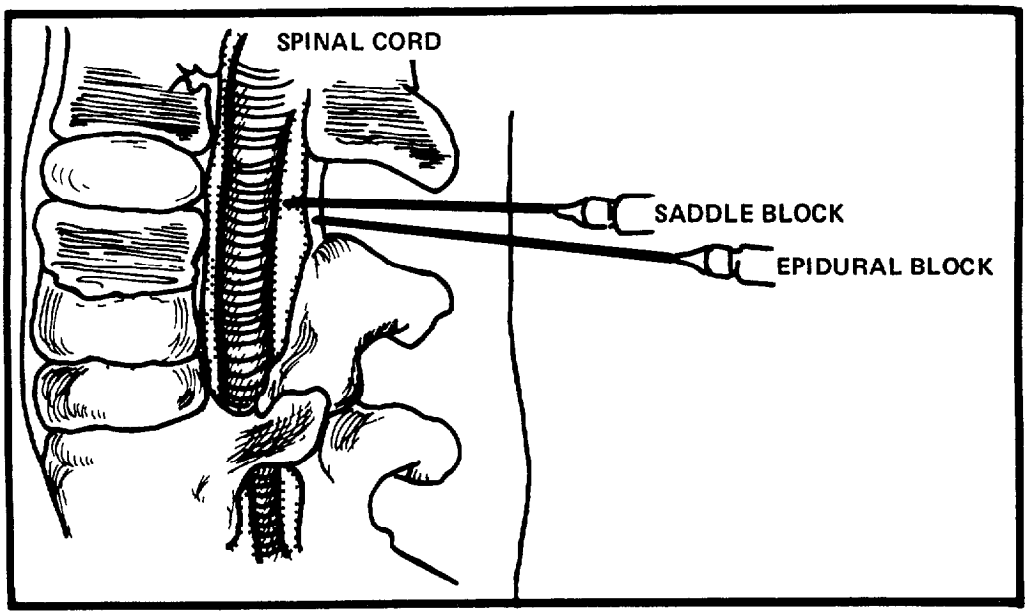
DIAGRAM OF THE VARIOUS METHODS OF BLOCKING OBSTETRIC PAIN

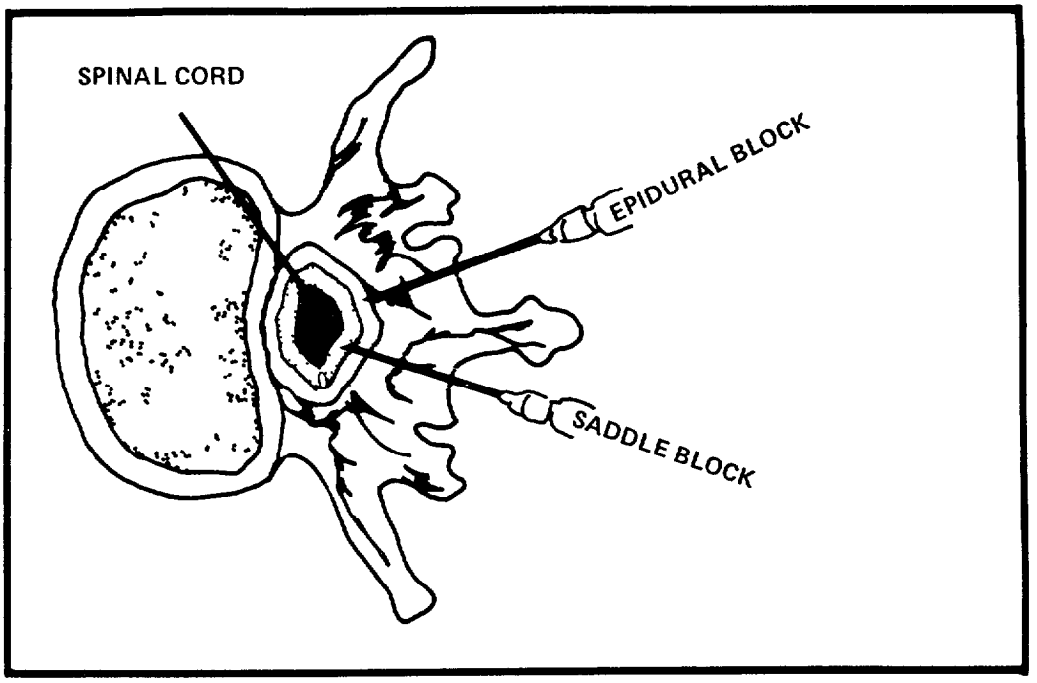




INSERT SHOWS POSITION OF PARACERVICAL BLOCK RELATIVE TO FETAL HEAD THE ANGLES OF THE NEEDLES FOR THE PA RACERVICAL AND PUDENDAL BLOCKS IN THE COMPOSITE DIA GRAM ARE FOR ILLUSTRATIVE PURPOSES ONLY

ALTERNATE VIEWS OF SADDLE AND EPIDURAL BLOCKS





We also got information on anesthesia use in all CPHA hospital spontaneous deliveries in 1977 (909,313 patients). This data showed:

	Anesthesia Received		
	Regional, general, or local	Other	None
	(percent)		
1970	88.6	3.6	7.8
1977	80.8	.4	18.8

CPHA data for 1977 indicated substantial differences in use of anesthesia among types of patients and location. For example, 27.1 percent of the spontaneous deliveries for Medicaid and Maternal and Child Health program patients involved no anesthesia compared to 17.5 percent for other types of patients. Also, no anesthesia was used for 24.4 percent of the spontaneous deliveries in the Northeast compared to 13 percent in the West.

In the NINCDS Collaborative Perinatal Project no anesthetic was used for delivery of 8 percent of the white women and 26 percent of the black women. According to the book, "The Women and Their Pregnancies," such wide variances largely reflect the drug use practices at individual hospitals.

RESEARCH RESULTS INCONCLUSIVE

Although research seemed conclusive that pain-relieving medications given the mother during labor and delivery affect the infant, literature was inconclusive on whether the effects were deleterious and, if so, on their severity and duration. Researchers generally agree that medications given to the mother cross the placenta and enter the fetal bloodstream. However, they disagree on whether this results in any significant or long-term effect on the infant. Also, they disagree on the best method of administering pain-relieving medication and on which medication is best for such relief. For instance, some methods of administering regional anesthesia may better relieve the mother's pain yet affect the fetus more than some other methods using the same medication. Also some medications may better relieve the mother's pain yet affect the fetus more than other medications administered in the same way which provide less pain relief and fewer fetal effects.

Scope of research limited

The scope of the research studies we reviewed was limited. Most dealt only with short-term effects. Many of the studies were of small, statistically insignificant test groups which usually did not involve control groups. Most studies were retrospective, and the number of cases in prospective studies was generally small.

We reviewed about 360 articles on drugs used to relieve labor pain. These included 193 research studies (120 U.S. and 73 foreign) which specifically mentioned effects on the infant. The drugs and techniques used in these studies varied greatly, however, making the number of studies on a particular drug or technique small. The most frequently studied technique was paracervical block (56 studies) and the most frequently studied drug was meperidine (34 studies).

Long-term studies lacking

Generally, we found a lack of studies on long-term effects on the infant of drugs given to the mother during labor and delivery. Most of the 193 studies we reviewed concerning infant effects considered only the period during labor and delivery up until shortly after birth. Of the studies we reviewed, 10 checked on infants for 1 to 6 days after birth, 2 for 10 days, 2 for 1 month (a 1970 and a 1974 study), 1 for 4 or 5 months (a 1978 study), and 1 for 1 year (a 1976 study). None of the studies except one case report did any followup for more than 1 year. Several articles noted the need for further study, particularly to explore any potential long-term effects on the child.

An advance draft report, of an in-progress study by Brackbill and Broman, using NINCDS Collaborative Perinatal Project data indicated strong associations between the medications that had been administered during labor and delivery and the infant's development through the first year of life. The draft report for this study was released prematurely. The study's methodology, findings, and conclusions have been highly criticized, and a panel has been established to evaluate this study.

Effects on the infant can occur

Most of the studies we reviewed did give effects on the infant of drugs given to the mother. However, 18 studies said either no effects occurred to the infant or the ones that did occur were minimal.

The most commonly reported effect was fetal bradycardia (abnormal slowing of the heartbeat). Forty-six studies showed this effect, including 42 which used paracervical block (a type of regional anesthesia). The incidence of bradycardia after paracervical block varied in these studies from 1 to 55 percent of cases.

Some of the cases said the fetal bradycardia was only transient, but others noted neonatal depression set in after fetal bradycardia following use of paracervical block. Also, Shnider et al. (1970) and Asling et al. (1970) noted that neonatal depression occurred more often after fetal bradycardia than it did ordinarily. Shnider et al. (1970) studied 845 paracervical blocks done on 705 patients during the first stage of labor. They reported severe neonatal depression in 10.4 percent of the cases with FHR changes after paracervical block (mostly bradycardia) versus 3.4 percent in cases with no FHR changes. Rogers (1970) reported that fetal bradycardia after paracervical block is relatively harmless if other causes of bradycardia are not present.

All together, 24 of the research studies mentioned depressed infants (such as those with depressed respiration and/or low Apgar scores) as an infant effect, and 12 mentioned the need for infant resuscitation. Some studies attributed depression to FHR changes; others found improperly or excessively administered drugs as a cause. In their study of general anesthesia, Marx and Cosmi (1970) noted that the infants were more depressed at birth when the depth of anesthesia was increased.

Fifteen of the research studies we reviewed attributed fetal/infant death(s) to pain-relieving medications given to the mother during labor and delivery. Beck and Martin (Germany, 1970) reported on a review of 32,652 paracervical blocks at 107 maternity units. Beck and Martin stated that of 37 perinatal deaths (0.11 percent of the patients studied), 27 (0.8 percent of the patients studied) were directly or almost certainly attributable solely to the use of paracervical block. The rates of perinatal death attributed to the block varied by the drug used. They were 0.12 percent for bupivacaine, 0.14 percent for prilocaine, and 0 percent for mepivacaine.

In 1968, Rosefsky and Petersiel (United States) reported on two infant deaths after bradycardia following maternal paracervical block with mepivacaine (a local anesthetic drug). In a 1973 book, Levinson and Shnider noted that reports had

associated at least 50 perinatal deaths with paracervical blocks. Still other articles said perinatal deaths resulted from misuse of a procedure for giving medications. (See next section.)

Some of the research articles we reviewed showed an interest in behavior alterations of infants born of medicated mothers. However, most of these articles looked at these effects on the infant only during the first week of life.

Nineteen articles we reviewed did find behavior alterations in infants born of medicated mothers, but three found no difference in infant behavior. The articles dealt with general, regional, and/or local anesthesia and/or analgesia. Kron et al., in a 1966 study, found that newborns whose mothers received general obstetric analgesia or anesthesia during labor sucked at much lower rates and pressures and consumed less nutrient than newborns of mothers receiving no general analgesia or anesthesia during labor and delivery. Conway and Brackbill (1970) concluded that obstetric anesthesia and analgesia (general and regional) have a significant effect on early infant sensorimotor functioning. Friedman et al. (1978), in a study of 4- and 5-month-olds, found that analgesics tend to be related to a decreased visual attentiveness in infants. One study of infants during the first 10 days of life (Tronick et al., 1976) found that epidural anesthesia produced an initial reduction in the infant's motor function, but this effect was quite transient. Finally, the findings by Goldstein et al. (1976) on 1-year-olds indicated that the use of medications (general, local, or spinal anesthesia) during pregnancy and delivery has effects on the infant which last beyond the perinatal period.

A few studies dealt with drugs for relief of labor pain and instrument delivery. Four studies found an increase in instrument delivery in connection with maternal medication, although two (analgesia) found no such increase. Hoult et al. (Great Britain, 1977) did a prospective study of 486 patients (including 211 receiving epidural analgesia). They found instrument delivery five times more common in the group receiving the epidurals than in the group not receiving this kind of regional analgesia.

Incorrect use of medications can occur

Accidents in administering medications during labor and delivery can adversely affect the fetus. For instance, Bonica (1967) notes that improperly administered local and regional anesthetics can indirectly cause perinatal morbidity

and mortality by affecting the mother and eventually the fetus. Indirect effects include (1) severe maternal hypotension (low blood pressure) and cardiovascular collapse, (2) hypertension (high blood pressure), (3) convulsions, and (4) impairment of uterine contraction. Interference with the uterine blood supply may cause fetal hypoxia (insufficient oxygen to the body tissues).

Also, the receipt of an accidental injection of a local anesthetic may directly affect the fetus. In 1965, Finster et al. reported on four infants who were accidentally injected with mepivacaine (a local anesthetic drug) following attempts to induce caudal anesthesia (a type of regional anesthesia) during labor. Investigators found pinprick lesions on the scalp of each baby. All four infants were depressed at birth and convulsed after artificial ventilation had been instituted. Two of the babies died; the other two survived after exchange transfusions. Guillozet (1975) notes that researchers know little about the frequency and recognition of local anesthetic mishaps in routine obstetrics and less still about the fate of survivors.

One study we looked at noted that improperly administering inhalation drugs (a type of general anesthesia and analgesia) carries grave potential danger to both mother and fetus. Fox (1975) found prolonged use of inhalation drugs can result in neonatal depression, to the point of total apnea (transient stopping of breathing). Also, inadvertent overdose may result in maternal hypotension which may compromise both mother and infant.

FEDERAL INVOLVEMENT LIMITED

We found limited Federal influence on the use of obstetric medications. In reviewing Federal responsibility we found that:

--No regular reviews of drugs are made even though the safety and effectiveness of some were exempt from FDA's requirement to prove safety and effectiveness.

--Package inserts for patients are not required with drugs used during labor and delivery.

--Federally funded research has not concentrated on the long-term effects on the child of drugs given to the mother during labor and delivery. Also, it has been scattered and uncoordinated.

--Very few hospitals have reviewed drugs used during labor and delivery under the PSRO MCE program.

No regular reviews of drugs

FDA is not required to review older drugs or to regularly review all drugs used for obstetrics. But as discussed in our report on obstetric practices (HRD-79-85), all new drugs must be approved by FDA for their safety and effectiveness. Of 31 drugs commonly used to relieve anxiety and the pain of labor and delivery, only 7 were approved after 1962. These went through the complete investigational new drug/new drug application process in which FDA approved both their safety and effectiveness. Seven others had been marketed before 1938 and were therefore exempt from this approval process under the "grandfather clause" of the 1938 act. Also, even the drugs which underwent FDA's approval process were not tested for long-term effects on the infant; only effects present right after birth were noted. According to FDA officials, FDA does not require drug manufacturers to do any followup of effects on the infant.

In our review, we found only one instance between 1967 and 1978 when FDA's Anesthesiology Advisory Committee reviewed the safety for the fetus/infant of a drug used for either analgesia or anesthesia during labor and delivery. We found this occurrence after talks with agency officials and a review of the minutes of committee meetings since 1967. The review in question happened in October 1971 when the committee reviewed the safety of paracervical block anesthesia in obstetrics. In March 1979, an FDA advisory committee held hearings on obstetric pain killers and appointed a subcommittee to analyze studies tc determine the long-term effect of perinatal drugs on infant development.

A number of articles noting a high incidence of fetal bradycardia after paracervical block suggested the possibility of higher fetal levels of the drug than maternal levels and also fetal acidosis (poisoning by acids forming within the body). Using replies from 27 experts in obstetric anesthesia, the committee decided that paracervical block anesthesia should not be eliminated because a less safe alternative might replace it. The committee did recommend a warning on the package insert stating that "Fetal bradycardia frequently follows paracervical block and may be associated with fetal acidosis." In our review of the research literature, we found articles dating from as early as 1961 linking paracervical block with fetal bradycardia. Yet, the committee did not act on the question of its safety until 1971.

Another committee meeting discussed suggested clinical guidelines for general and local anesthetics and suggested general labeling guidelines for local anesthetic drugs.

Patient inserts not required

FDA has no mandatory system for getting drug warnings to patients. Current drug labeling is for physicians, and FDA requires that it contain warnings, contraindications, and possible adverse reactions from drugs. However, FDA has no control over a physician's actual use of a drug or whether the doctor discusses any of the negative aspects of the drug's use with patients.

Some drugs used in obstetrics contain warnings on their labels which would better inform pregnant women. Several labels of obstetric drugs, such as those for carbocaine and marcaine (drugs used for regional anesthesia; paracervical block, for instance), list potential adverse effects: "Fetal bradycardia frequently follows paracervical block and may be associated with fetal acidosis." Marcaine contains an additional warning that, without further clinical evidence, it should not be used to perform paracervical block. Demerol (meperidine) labels caution that "When used as an obstetrical analgesic, meperidine crosses the placenta barrier and can produce respiratory depression in the newborn; resuscitation may be required." Also, several pain-relieving drugs contain warnings against use in premature infants.

Presently, FDA is considering requiring patient package inserts for drugs. The agency held a conference on this topic in December 1978. However, it seems to us that it would be better to give information on the benefits and risks of childbirth practices to patients during the prenatal period.

Federal research on drugs is uncoordinated and not long term

In the past, the Federal Government has not sponsored long-term (1 year or more) followup research on the effects of obstetric pain relief drugs. This is despite the lack of knowledge of the effects of these drugs on the infant. HEW has been the primary funding agency for federally funded research on these drugs. In fact, many HEW agencies have sponsored research on the short-term effects of these drugs. However, this research has not been coordinated or directed to an overall goal.

Of about 360 studies we reviewed on use of drugs for pain relief during labor and delivery, 71 had Federal support, including 69 by HEW and 2 by military hospitals. The 69 studies were funded by at least 5 different HEW organizations. Of the HEW-funded studies, 38 dealt with effects on the newborn. However, these studies dealt only with short-term effects, and the agencies sponsoring them did not appear to coordinate their activities.

We did find a few recent HEW efforts on long-term effects of drugs on the infant, but none of them has been completed. One was a study funded by FDA that was canceled before completion. Another was contracted by NINCDS in March 1978 to determine the relationships between maternal anesthesia-analgesia and the long-term neurological outcome of the child and is scheduled for completion by 1982. In addition, the Brackbill and Broman study, discussed on page 20, used data from the NINCDS Collaborative Perinatal Project to investigate the relationship between obstetric medication and neurobehavioral functioning.

PSRO evaluations limited

PSROs reported very few MCEs on anesthesia and none on analgesia. Those MCEs which have been done concentrated on the use of anesthesia during cesarean sections. Of seven PSROs responding to our questionnaire, three reported MCEs on the use of anesthesia. These PSROs reported a total of six evaluations (four by one PSRO and one by each of the others). Of these, four were on anesthesia for cesarean section and one was on spinal anesthesia. These five found documentation deficiencies only.

The remaining MCE was done to find out if post-anesthesia complications occurred with cesarean section. This evaluation of 40 patient records found no general anesthesia complications and a 2.5-percent complication rate for spinal anesthesia. The information we received from the PSRO did not indicate whether these were maternal or fetal complications or the significance of the complications.

ACOG INVOLVEMENT

ACOG has issued two technical bulletins and one statement within the last 10 years on obstetric analgesia and anesthesia. In the technical bulletins, ACOG noted the need for pain-relieving drugs in labor and delivery and commented

on the drugs' safety and proper use. In the joint statement with the Committee on Drugs of the American Academy of Pediatrics, ACOG noted possible effects of medication given during labor and delivery on infant outcome. ACOG is preparing a third technical bulletin on anesthesia and analgesia.

ACOG's second technical bulletin (dated October 1973) discusses the need for obstetric analgesia and anesthesia and comments on their safety and proper methods of administration. It notes that:

--Pain relief during labor and delivery is important in modern obstetrics and is necessary in good obstetric practice.

--Thoughtfully chosen analgesia can improve labor, and proper anesthesia permits physicians to perform difficult deliveries with safety.

--Poorly chosen analgesia may compromise labor and depress the fetus, and improperly chosen and/or administered anesthesia may cause maternal or fetal morbidity and mortality.

--No adequate, safe, routine analgesia agent exists which is universally applicable to all women in labor.

--All drugs used for pain relief in labor cross the placenta, and most cause some degree of fetal depression. The degree of depression is directly related to the dose of the drug, the route and time of its administration before delivery, and the maturity of the fetus.

--Safety of obstetric anesthesia depends principally on the skill of the anesthetist.

In May 1978 ACOG's Committee on Obstetrics for Maternal and Fetal Medicine and the Committee on Drugs of the American Academy of Pediatrics issued a joint statement on the effect of medication during labor and delivery on infant outcome. This statement was made because of concern about known and unknown effects of drugs on the fetus and newborn when given during labor and delivery. The committees noted that some recent studies found neurological and behavioral changes in the infant which are attributed to maternal analgesia and anesthesia. The statement notes, however, that presently no

long-term studies exist for determining if subtle findings in neurobehavior relate significantly to the infant's later mental and neurological development.

Therefore, the committees recommended that, until further studies are done, physicians should avoid using drugs or drug doses that are known to produce significant changes in the neurobehavior of the infant. However, they note that this is not a ban on using these drugs, but rather a recommendation to administer the minimum effective dose of them in indicated cases. The committees also recommended that the physician discuss with the patient--whenever possible before the onset of labor--the potential benefits and the effects of maternal analgesia and anesthesia both for the mother and the infant.

COMMENTS BY PROFESSIONAL ORGANIZATIONS AND OUR EVALUATION

ACOG provided the following general comments on the use of medication to relieve labor pain.

--Throughout our draft study and the scientific literature, there tends to be confusion about the differences among systemic analgesia, general anesthesia, and the various forms of regional anesthesia. Modern obstetric anesthetia practices today rely heavily upon regional anesthetic techniques, principally continuous lumbar epidural, spinal anesthesia, or local anesthesia. In most of the literature, there is no separation of these various techniques. This is also true of the GAO study where all anesthesia and analgesia is lumped together as one category.

--Research literature on the effects of medication on the infant has been subjected to severe criticism by the FDA staff at a March 1979 meeting. The criticism is based on the small numbers involved, the absence of or poorly collected control groups, the frequent failure to state the type and dose of medication given, the confusion of analgesia and anesthesia, and the large number of different test instruments applied to the infant. Also, there is a lack of studies on the long-term effects on the infant of medications given to the mother, and there are no generally agreed-upon criteria for evaluating long-term effects.

--It should be recognized that there are benefits to the mother of competently administered and appropriately chosen pain relief during labor and delivery.

--Because of the potential risks involved, paracervical blocks should be used judiciously.

In addition, a member of the American Academy of Pediatrics' Drug Committee stated:

--Although long-term studies are needed on the effects of medication to relieve labor pain, it is not certain which drugs have the highest research priority.

--Long-term studies are difficult to do because of the time and cost involved and the effect that patient dropouts would have on the results. The minimal time for followup for learning impairment is 7 years, and the minimum time for followup for malignancy or effects on reproduction is 20 to 30 years.

--It is frequently impossible to isolate effects of medications given during labor and delivery from (1) effects of medication given to the mother during prenatal care and (2) events surrounding labor and delivery. Also, it is difficult to separate events coincidental with pregnancy, labor, and delivery from pure drug effects. Different population groups must be studied to avoid effects that might be linked to genetics.

--Technology only recently became available to determine how drugs were transferred to the infant. The same holds true for sophisticated methods of assessing infant alertness and neurobehavior.

A former chairman of the Academy's Committee on the Fetus and Newborn said:

--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.

We generally concur with the comments of ACOG and the representatives from the American Academy of Pediatrics and do not believe they are inconsistent with the results of our work. With respect to ACOG's comments concerning distinguishing among different types of anesthesia or analgesia, we tried to specify the type where possible or practical. In addition, charts summarizing the findings of research studies we reviewed specify the type of anesthesia or analgesia to the extent such information was reported. These charts are available as indicated in chapter 6.

CHAPTER 3

INSTRUMENT DELIVERY: FORCEPS AND VACUUM EXTRACTION

Critics have questioned the use of forceps as an obstetric practice. Some say forceps deliveries occur too often in the United States. They especially find fault with the liberal "preventive" use of forceps to facilitate delivery of the child and note that in Europe forceps are not used as often as in the United States. European literature also criticizes the use of forceps, stating that vacuum extraction is a safer alternative.

Instrument delivery can sometimes be necessary for medical reasons. It can also be used as a preventive procedure. However, we only found one study which looked at the use of forceps for preventive reasons without the presence of medical indications. This study took place in 1973--over 50 years after preventive use of forceps was advocated by DeLee. According to this study, preventive use of forceps was widely accepted without its benefits or risks ever having been confirmed with clinical evidence.

The Federal Government has not been greatly involved in regulating, evaluating, or funding research on instrument delivery.

DESCRIPTION

Instrument delivery means using either forceps or the vacuum extractor. These are mechanical devices used to facilitate the delivery of the fetal head from the birth canal during the second stage of labor Both may be used for medically indicated or preventive reasons.

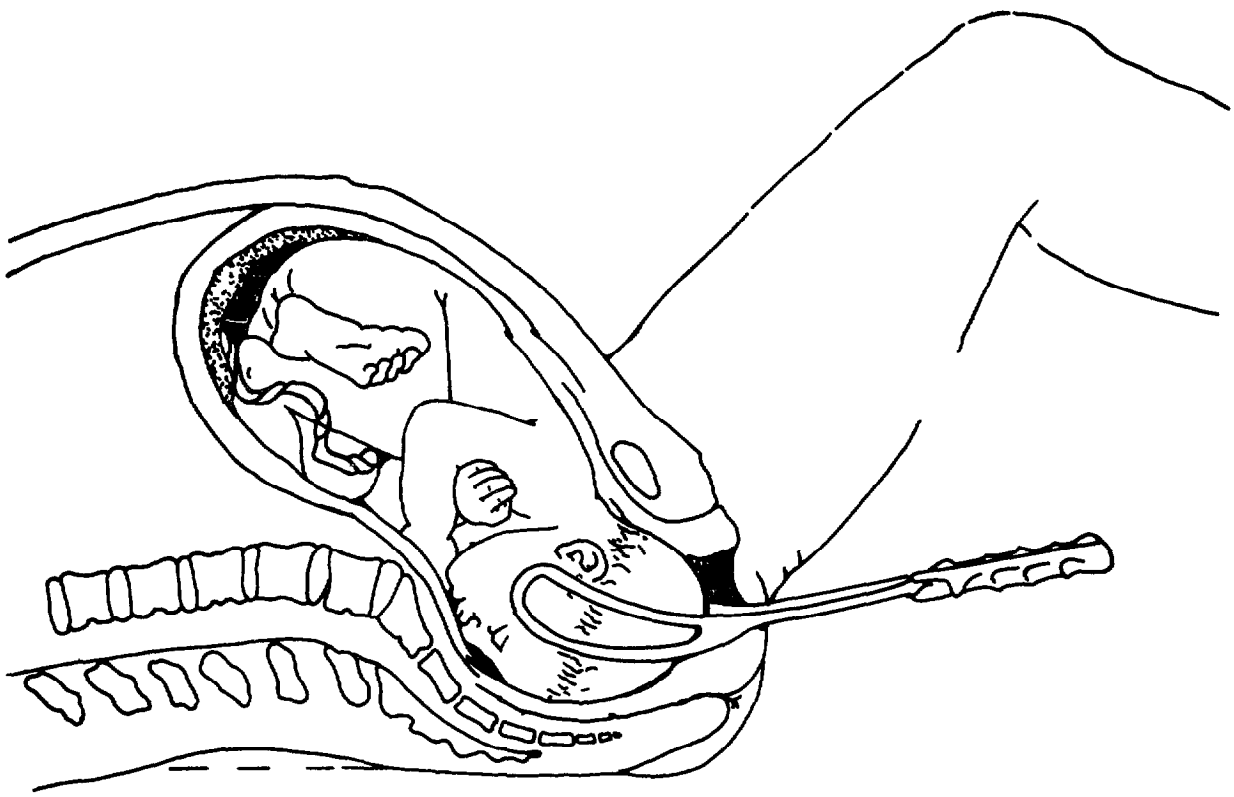
Forceps--an instrument inserted around the fetus' head to lead it through the birth canal--have been used since the 1500s to facilitate delivery. Applying forceps during delivery can occur at different times during the second stage of labor:

High forceps--before engagement when the largest diameter of the fetal presenting part passes into the pelvic brim. (High forceps are rarely used in the United States).

Mid forceps---after engagement of the fetal head has taken place but before meeting the criteria for low forceps

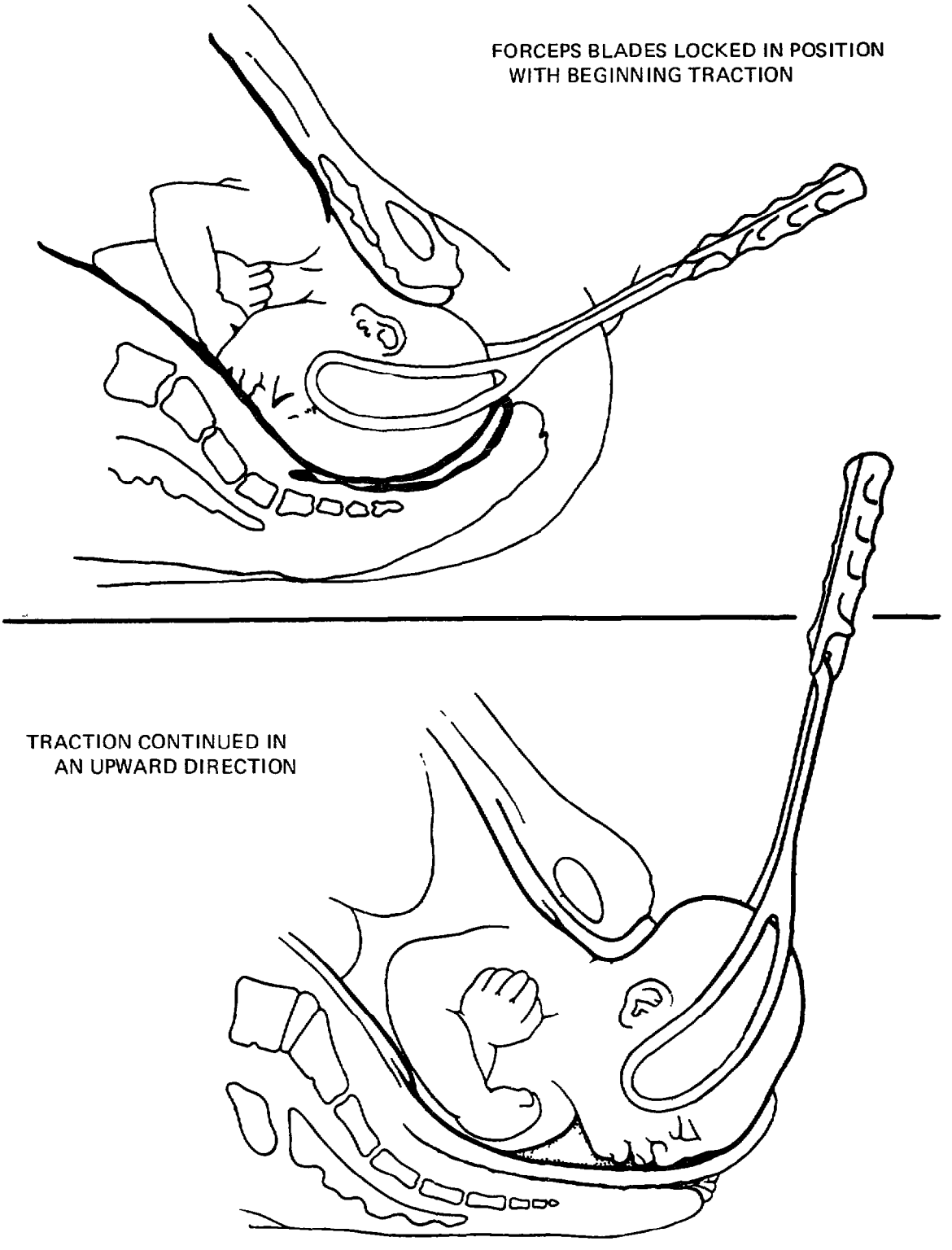
Low forceps---when the head is visible during contraction and the bony part of the head is resting on the pelvic floor. The term outlet forceps is also used sometimes to refer to low forceps applied to a head which is visible and distends the vaginal opening.

Preventive use of forceps means elective use of low forceps in the early second stage of labor.



TRANSVERSE SECTION TAKEN LATERALLY THROUGH THE PELVIC REGION OF MOTHER DURING DELIVERY WITH APPLICATION OF MID FORCEPS TO FETUS

APPLICATION OF LOW FORCEPS



Source 'Operative Obstetrics' Third Edition by Douglas and Stromme

In vacuum extraction a cup is attached to the fetal head by creating a vacuum between the cup and the head. The infant is then pulled from the birth canal by a chain attached to the cup. The pulling is timed to coincide with uterine contractions. The extractor uses different cup sizes to suit the delivery situation. The extractor cup can be inserted through a partially dilated cervix to expedite the first as well as the second stage of labor. The vacuum extractor has existed since the 1700s, but not until the 1950s when Malmstrom of Sweden invented his version of this device did the vacuum extractor prove to be of practical value.

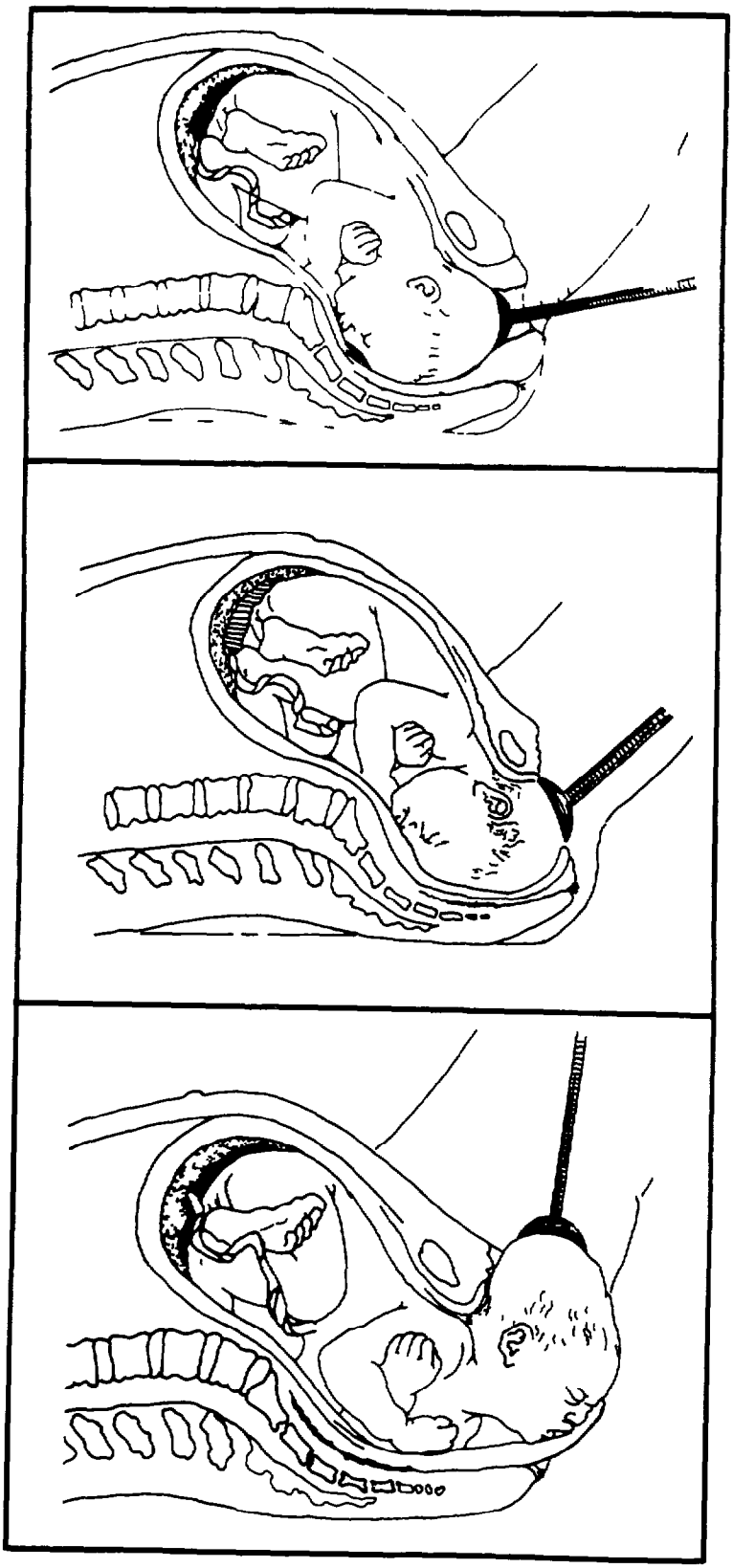
INDICATIONS FOR USE

Reasons for using instrument delivery vary from signs of danger in the mother or fetus to potential hazards to them. The intent behind such deliveries is to decrease the trauma to mother and child which would occur in a spontaneous delivery and to facilitate delivery in circumstances where delivery appears difficult because of ineffective uterine contractions. Fetal indications include FHR irregularities, fetal distress, and a stopping of the infant's rotation in the birth canal. Advocates of preventive use of forceps state that such operations shorten the second stage of labor, protect the pelvic floor and the mother's internal organs from laceration, limit blood loss, and protect the fetus from cerebral damage. Some sources say they also spare the fetal head prolonged pounding against the perineum and the mother from the physical exhaustion of the second stage of labor and unnecessary stretching of her pelvic floor adjacent tissues.

According to the textbook "Williams Obstetrics," one reason for widespread preventive use of forceps is that all methods of analgesia, especially conduction analgesia and anesthesia, interfere with the mother's voluntary expulsive efforts, making low forceps delivery the most reasonable procedure. "Williams Obstetrics" also states that in cases of preventive use of forceps, the obstetrician elects to interfere knowing it is not absolutely necessary because spontaneous delivery may normally be expected within about 15 minutes.

EXTENT OF USE

Several sources we reviewed indicated frequent use of instrument delivery in the United States. However, we could not obtain any national data on the use of low forceps or preventive use of forceps. We obtained data from the 1972 U.S. National Natality Survey on total forceps deliveries



TRANSVERSE SECTIONS TAKEN LATERALLY THROUGH THE CENTER OF PELVIC REGION OF MOTHER DURING DELIVERY SHOWING APPLICATION OF VACUUM EXTRACTOR TO FETUS

and also got information on instrument delivery for several large groups of deliveries.

Use of instrument delivery

Data from the 1972 U.S. National Natality Survey gave us data on forceps deliveries. The survey showed that of 2,818,000 legitimate, live, hospital births occurring in the United States in 1972, 36.8 percent were with forceps.

The next most comprehensive information we found on the frequency of instrument delivery was from CPHA. Its data on the extent of forceps and vacuum extractor use in 1.3 million U.S. deliveries in 1977 showed forceps use in 25.6 percent of deliveries and vacuum extraction in 0.3 percent. Low forceps were used in 23.6 percent of the deliveries. Low forceps usage ranged from 20.5 percent for the western census region to 29.4 percent for the southern census region. An earlier CPHA study in 1963 reported on 1961 data from 142,437 deliveries in 152 hospitals. Results were as follows:

	Annual Hospital Discharges				
	Overall (weighted average)	Under 5,000	5,000 to 9,999	10,000 to 14,999	15,000 or more
	(percent)				
Low forceps	33.7	19.8	37.3	29.9	36.9
Mid forceps	0.9	0.3	0.8	1.0	1.0
High forceps	0.03	0.04	0.06	0.02	0.03

Several authors noted a high incidence of forceps deliveries in the United States, especially as compared with other countries. According to a 1972 book, "The Cultural Warping of Childbirth," although forceps deliveries may rise as high as 65 percent in some U.S. hospitals, the prevalence of all instrument deliveries is much less "in countries where mothers actively participate in the birth of their babies." It stated that deliveries using forceps and vacuum extraction rarely go above 5 percent of all deliveries in these countries. Nyirjesy and Pierce (1964) also commented on the U.S. forceps rate versus the European:

> "It is estimated that between one third and one fourth of the infants born in the United States are being delivered by forceps, in contrast with those born in Europe, where most

obstetrical centers report an incidence of forceps deliveries of less than 5 percent."

Most studies we reviewed (see p. 38) did not give total national figures for use of a particular instrument in the United States and in countries abroad. We did obtain data for Missouri resident births in 1973 and 1976. This showed a total forceps rate of 21 percent in 1973 and 17 percent in 1976. Also, several studies did give the percentage of total deliveries in a particular hospital, either here or abroad, that used forceps and/or vacuum extraction. Instrument delivery ranged from 25 to 61 percent in the U.S. studies and from 1 to 8 percent in foreign studies. The figures from the studies do not provide an accurate estimate of current overall forceps or vacuum extractor use. Nevertheless, they do suggest a much higher incidence of instrument delivery in the United States and a strong U.S. preference for forceps deliveries, although some European countries seem to prefer vacuum extraction.

Preventive use of forceps

We found no definitive data on the extent of use of preventive forceps operations. This included no national data or data from CPHA. However, according to the 1976 edition of "Williams Obstetrics," most U.S. forceps operations are for preventive reasons.

In a 1965 article Pearse commented on the incidence of preventive forceps. He noted that the number of indicated forceps deliveries remains roughly comparable from institution to institution, but the number of elective forceps deliveries varies greatly. He stated that the variation depends primarily on the physician's belief in preventive delivery and on the use of regional anesthesia that removes the added force of abdominal muscle contraction or of general anesthesia that may remove abdominal force or uterine contraction itself.

Data from the 12 hospitals in the NINCDS Collaborative Perinatal Project illustrated wide variations in forceps use from hospital to hospital, including for outlet and low forceps deliveries. Total forceps deliveries as a percent of deliveries (excluding cesarean sections and breech presentations) at these hospitals ranged from 10.33 to 90.45 percent for white patients and 17.96 to 61.56 percent for black patients. The outlet and low forceps rate ranged from 9.32 to 61.14 percent for white patients and 14.94 to 51.12 percent for black patients. Data for resident births in Missouri

showed a low and outlet forceps rate of 16 percent for 1973 and 1976.

RESEARCH RESULTS INCONCLUSIVE

We found diverse opinions in the research literature on the relative risks and benefits of instrument delivery. Although the U.S. research literature we reviewed dealt mainly with forceps, the European literature concentrated on vacuum extraction and comparisons between forceps and vacuum extraction. Only two studies dealt with preventive use (one considered normal deliveries and the other premature labors) and there were only a few studies on long-term effects on the child. In general, the scope of the research was limited. Overall, the research literature was inconclusive in assessing the safety and value of preventive instrument delivery.

Scope of research limited

The scope of the research studies we reviewed was generally limited. Most studies were retrospective. Most were limited to patients at one hospital, and most had no control group.

We reviewed about 65 articles describing studies on forceps deliveries and vacuum extractions. Of these, 51 were research studies mentioning infant effects. These 51 studies included:

--16 U.S. studies: 8 on forceps, 4 on vacuum extraction, and 4 comparing the two.

--35 studies from 18 foreign countries: 19 on vacuum extraction, 5 on forceps, and 11 comparing the two. All but eight foreign studies were done in Europe.

Long-term research lacking

Generally, the studies did not emphasize the long-term effects of using forceps or vacuum extraction. Only four U.S. and five foreign studies followed up on the children more than 1 year after birth, and two of each kept records on them for 4 years. The two from the United States used Collaborative Perinatal Project data. Several studies recommended long-term followup.

Conflicting opinions about infant effects

The research literature we reviewed showed conflicting opinions about the effects of instrument delivery on the infant, including mortality. Twenty-six reported various types of infant head injuries which are caused by either forceps or the vacuum extractor. On the other hand, seven indicated that with proper use, neither forceps nor the vacuum extractor have harmful effects on the infant.

Conclusions varied widely between U.S. and foreign studies which attempted to link forceps use with infant mortality. None of the U.S. articles attributed increased infant deaths to the use of forceps. However, in contrast to the U.S. research, several foreign studies did make this connection. Foreign literature also generally indicated higher mortality in forceps deliveries than in vacuum extractions. For instance, Malmstrom (1963) stated that the leading causes of death for infants delivered by forceps and vacuum extraction were intracranial hemorrhage and asphyxia (suffocation). He commented that intracranial hemorrhage is almost always the direct result of trauma caused by instrument intervention.

Head injuries were widely cited as complications of both vacuum extractor and forceps deliveries. A usual side effect of vacuum extraction is a pronounced soft lump on the infant's head where the vacuum cup was applied. This lump, which is the diameter of the cup, disappears soon after delivery, although a red area may remain for several days. In addition, collections of blood between scalp and skull (cephalohematomas) are frequent, with some studies showing a 2- to 30-percent incidence. Generally, the authors did not cite extractor-induced head injuries as having long-term effects. Such injuries generally disappeared in a few days. Cephalohematomas were not mentioned as often in forceps studies. A number of studies mentioned scalp abrasion and fractures occurring after forceps and vacuum extraction.

Other research linked instrument delivery with cerebral damage. One study of children age 6 to 8 (Naske et al., 1976) found a statistically significant difference in frequency of cerebral damage between children delivered by forceps or vacuum extraction and those delivered spontaneously. However, no statistically significant difference occurred in cerebral damage between children delivered by forceps and those delivered by vacuum extraction. Cases of infant death from cerebral hemorrhage were also reported in several vacuum

extraction studies and one forceps study. On the other hand, a study (Blennow et al., 1977) involving a 14-month followup of vacuum extracted babies concluded that no risk of serious cerebral damage existed.

Other research found other effects on the infant. Several studies noted an increased incidence of retinal hemorrhage, central nervous system injuries, and neonatal jaundice.

Incorrect use of an instrument can occur

The research studies we reviewed which cited effects on the infant did not always indicate whether incorrect use was or may have been a factor. However, several authorities commented that a major problem may exist in the way instruments are used and not in the instruments themselves. In a 1975 article on vacuum extraction, Ott stated that the most serious complications occurred due to misuse of the extractor or other factors. Shute in a 1973 Canadian study cited two fetal deaths and three cases of transient facial nerve paralysis due to incorrect use of forceps.

Many authors have stressed the simplicity and safety of the vacuum extractor, even in the hands of an inexperienced obstetrician. Sjostedt felt that better results with vacuum extraction rather than forceps in research studies was at least partly because the vacuum extractor is safer than forceps even when used by someone relatively inexperienced with it.

Several authors noted the importance of experience in instrument delivery. Sjostedt related Bergman and Malmstrom's view that success in obstetrics depends as much or more on the experience of the obstetrician as on the instrument used. Another author (Chalmers, 1971) reported on inexperienced operators in the United States and Great Britain attempting to use the extractor in difficult and complicated cases. When failure occurred, they blamed the instrument, not their own inexperience and lack of judgment about when to use the vacuum extractor Chalmers noted that it is important to develop experience with the vacuum extractor and skill in routine, "low" cases before trying more difficult ones.

Preventive use of forceps gained widespread use without research support

In a 1973 article on preventive use of forceps, Niswander and Gordon said its widespread use for delivery in the United States was based on DeLee's thesis that this operation could lessen fetal mortality. According to the authors, in 1920 DeLee stated that preventive use of low forceps decreased the risk of brain hemorrhage caused by perineal compression which results from prolonged resistance of the pelvic floor. DeLee said thus, fewer perinatal deaths should occur with the use of forceps.

In the same 1973 article Niswander and Gordon wrote about the safety of the low forceps operation. As far as they could determine, clinical evidence had never confirmed DeLee's thesis. They, therefore, used data from the NINCDS Collaborative Perinatal Project to test the following two hypotheses: (1) the preventive use of low forceps results in a lower perinatal mortality rate than that associated with spontaneous delivery and (2) the preventive use of low forceps has a favorable effect on the later motor and intellectual functions of the child so delivered.

The authors studied 29,577 single births and limited their study to patients who were without evident complications. Children were studied until they reached 4 years. About 65 percent of the births studied were spontaneous and about 35 percent were by low forceps. Niswander and Gordon concluded that in their study preventive use of forceps did not increase the hazard of neonatal death or later neurological impairment of the infant so delivered. However, the authors said whether the operation is protective to the infant is less certain. They did state though that uniform trends in their findings suggest a somewhat more favorable outcome for infants delivered by low forceps than those delivered spontaneously.

Those discussing this study, however, noted several flaws such as (1) a method of delivery was not assigned randomly to patients according to acceptable statistical techniques and (2) patients were treated in many different institutions by physicians of varying competence and training and in hospitals with different philosophies of obstetric care. In responding to these comments, HEW noted that (1) the study was not designed primarily to evaluate methods of delivery and (2) all deliveries were made in major medical centers where the quality and supervision of obstetrical care were commensurate with standards maintained by these centers.

In a 1974 article on 340 premature deliveries, Bajorek et al. (Poland) concluded that use of forceps does not represent a significant protection against injury to the central nervous system of premature infants. They further concluded that preventive use of forceps is less advantageous than spontaneous delivery by means of episiotomy in premature labor without the presence of any fetal threat symptoms.

FEDERAL INVOLVEMENT LIMITED

The Federal Government is involved with forceps and vacuum extraction through its responsibility for regulating devices, funding research, and evaluating medical care. In reviewing Federal involvement in the area of forceps and vacuum extraction we found that:

--FDA is still implementing its regulation of medical devices.

--The Government has funded limited research which so far has not emphasized preventive use of these instruments.

--PSROs have rarely investigated instrument delivery use.

FDA's new regulatory responsibility is still being implemented

The Medical Device Amendments of 1976 (Public Law 94-295) made FDA responsible for ensuring that medical devices are safe and effective. Both forceps and vacuum extractors come under this law. Before these amendments, FDA's only involvement with medical devices came if they were mislabeled or altered. At the time of our review, FDA was in the process of classifying devices under the categories provided by the law. If forceps and vacuum extractors are classified as Class II devices, as proposed at the time of our review, FDA will adopt performance standards for them. These performance standards will regulate materials used in the instruments and not the occasions of their use. We were told that FDA has no plans (or authority) to provide guidance on when the instruments should be used.

Research funding limited

Although the Federal Government did support five of the eight U.S. research studies we reviewed on forceps, it had not supported any of the comparative studies or vacuum

extraction studies. Of the five, two used data from the NINCDS Collaborative Perinatal Project. Only one dealt with preventive use of forceps and this was one of those using data from the Collaborative Perinatal Project. Of the other studies, one dealt with effects on the infant of different amounts of traction, one reported infant outcome at 22 Navy hospitals, and one reported infant outcome of deliveries at one hospital. NIH supported all the federally funded research except the Navy hospital study.

PSRO evaluation almost nonexistent

Only one of the seven PSROs answering our questionnaire responded positively to our question of whether it had done an MCE on instrument delivery. This PSRO reported one MCE on forceps delivery which had noted no deficiencies. None of the seven PSROs reported any MCEs on use of vacuum extraction.

INVOLVEMENT AND COMMENTS BY PROFESSIONAL ORGANIZATIONS

ACOG has not issued any technical bulletins or statements on the use of forceps or vacuum extraction.

In commenting on a draft of this study, ACOG said that, in its opinion, no increased problems result from the use of low forceps, which they believe have potential advantages. In addition, ACOG believes forceps are preferable over the vacuum extractor. A former chairman of the American Academy of Pediatrics' Committee on the Fetus and Newborn agreed and said that there is no clear evidence in the United States that the vacuum extractor provides a safer method of instrument delivery than forceps.

CHAPTER 4

ELECTRONIC FETAL MONITORING

The widespread use of electronic fetal monitoring during labor and delivery in the United States has generated much controversy. Proponents of electronic fetal monitoring contend that its use involves minimal known risks and has contributed to decreased perinatal mortality. Proponents assert that because electronic monitoring provides better information on the infant's status during labor, physicians are able to detect and manage problems earlier than would otherwise be possible.

Others, however, disagree and point out a number of known or potential risks. These include (1) the lack of information on the long-term effects on the infant of external fetal monitoring by ultrasound, (2) infant head injuries, and (3) increased likelihood of cesarean section, some of which may not be medically necessary. According to ACOG, some of these unnecessary cesarean sections may result from inappropriate interpretation of electronic monitoring data. Electronic monitoring may also increase delivery costs. Some also question whether electronic monitoring provides better information than would otherwise be available. Others question its routine use, saying that it should be used only in high-risk pregnancies.

Although our literature review seems to confirm the contention that no information is known on external fetal monitoring's long-term effects on the infant, it did not yield sufficient information to resolve the controversy over the benefits and risks of electronic fetal monitoring or whether it should be used for all or only high-risk pregnancies. Our review showed, however, that some infant head injuries resulted from incorrect application of fetal monitoring electrodes.

Several HEW agencies have funded research on electronic fetal monitoring, although none was directed at assessing external electronic monitoring's long-term effects on infants. For the most part, the HEW-funded studies had limited scopes and did not seem to have been directed toward an overall goal. PSRO evaluation of the need for or appropriateness and quality of electronic fetal monitoring appears to have been minimal. FDA has not yet implemented its responsibilities for ensuring the safety of fetal monitoring devices. It has no authority to regulate how or when fetal monitors are used. In March

1979, NIH held a conference on antenatal diagnosis which discussed benefits and risks of electronic fetal monitoring to develop a consensus opinion.

DESCRIPTION

Electronic fetal monitoring is the surveillance of fetal heart and uterine activity by some kind of electronic detecting and recording device. The oldest type of fetal monitoring was used to measure FHR--the variable most often used to indicate fetal condition. The method involved auscultation (listening) with a stethoscope. Of course, this kind of monitoring offers no way of continuously recording FHR.

Various methods of electronic fetal monitoring can continuously record FHR. Some also pick up uterine contraction rates. These methods are classified as either external (indirect) or internal (direct) monitoring. According to the textbook, "Williams Obstetrics," internal measurement is more precise. In addition to measuring FHR, the methods also measure pressure changes generated by uterine contractions and relate FHR changes to uterine contractions.

Internal or direct electronic fetal monitoring can be performed when:

--The cervix is sufficiently dilated for electrode attachment.

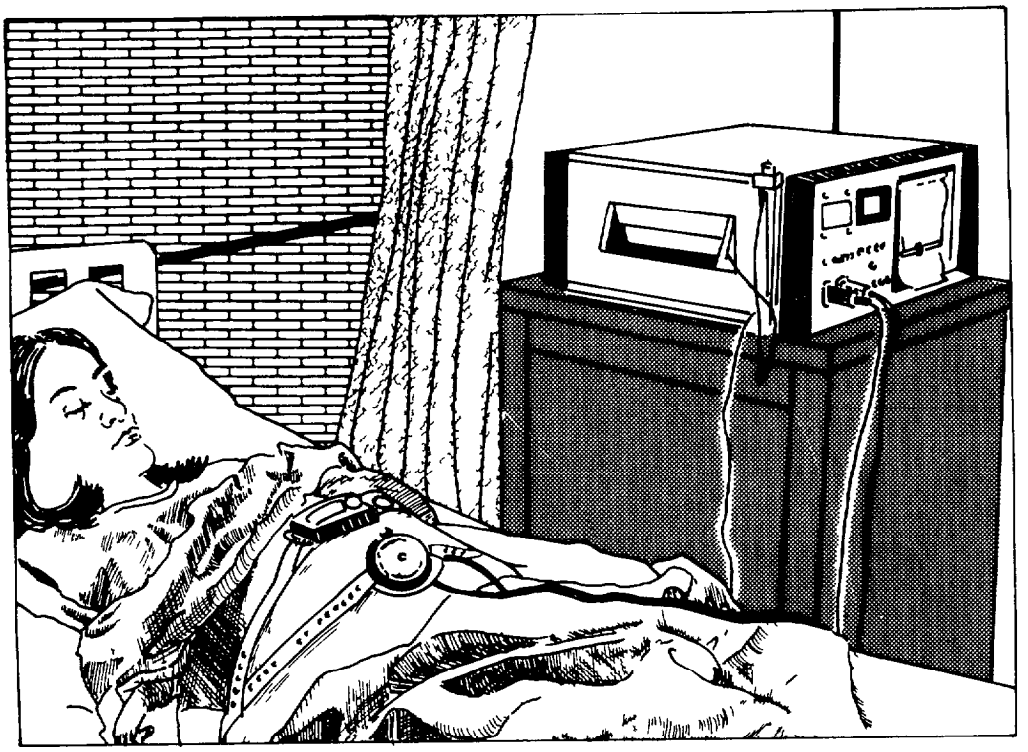
--The presenting part is low enough for electrode attachment.

--The amniotic membranes have ruptured.

This method may also be used during the second stage of labor.

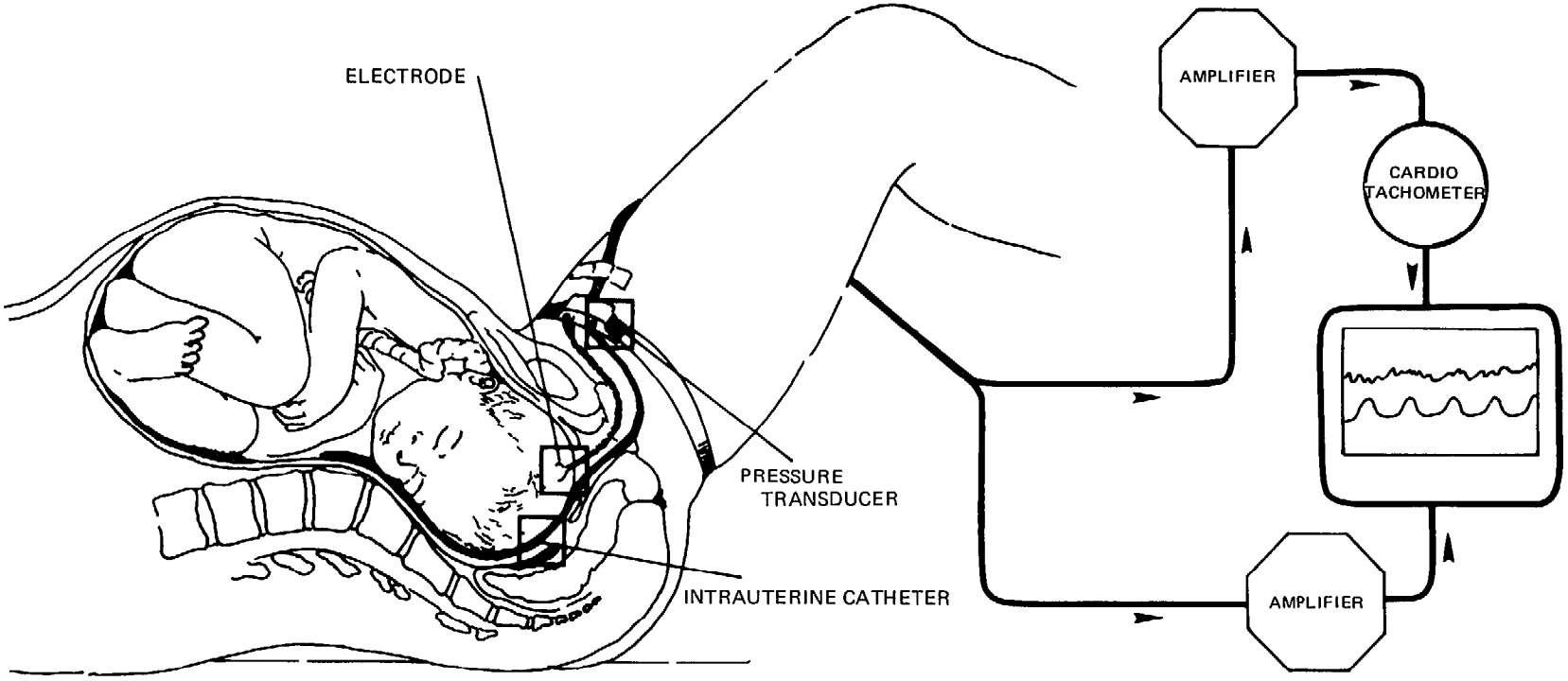
When internal monitoring is used, a clip or screw electrode is attached to the fetal presenting part. A catheter inserted into the lower part of the uterus and attached to a transducer (a device which converts energy from one form to another) measures uterine pressures. The fetal electrocardiogram thus obtained is fed to an amplifier and a signal conditioning circuit. It also measures the time between fetal heart beats and plots a continuous FHR graph. The transducer's output on uterine contractions is amplified and displayed beneath the FHR record on the graph paper used for continuous monitoring.

External or indirect fetal monitoring techniques--phonocardiogram, Doppler-type ultrasound, electrocardiogram, or tocodynamometer--can be used early in labor before dilation since their use does not require the rupture of fetal membranes. The phonocardiogram measures fetal heart activity with a microphone which is attached to the maternal abdominal wall. Also a fetal electrocardiogram can be recorded along with a maternal electrocardiogram. The use of ultrasound techniques is another method which picks up ultrasound pulses which are delivered through the abdominal wall. Still another method is by tocodynamometer or pressure gauge. This device can be strapped to a woman's abdomen to record uterine contractions.



EXTERNAL MONITORING FROM MATERNAL ABDOMEN USING TACO DYNAMOMETER TO DETECT CONTRACTIONS AND AN ULTRASOUND SENSOR TO DETECT HEART RATE MONITORS ALLOW FREEDOM OF MOVEMENT
Source Operative Obstetrics Third Edition, R Gordon Douglas and William B Stromme

INTERNAL ELECTRONIC MONITORING



Source Hospital Practice *September* 1970

INDICATIONS FOR USE

Electronic fetal monitoring can detect signs of fetal distress, such as abnormal heart rate patterns. In some hospitals, electronic fetal monitors are used routinely, while in others, only certain patients are monitored. In the latter situation, patients selected for monitoring are generally in two main categories: those who are in the low-risk group but develop clinical signs of fetal distress and those who are in the high-risk group, or are likely to encounter complications. In the first group indicated alterations in FHR occur, such as slowed heart rate, rapid heart rate, FHR irregularity, and/or the presence of meconium (fetal intestinal discharges) in the amniotic fluid. However, according to Simmons (1972) about 80 percent of the fetal distress occurs among high-risk patients. These would include women over 30 or those with a bad obstetric history, particularly if the fetus had suffered during labor. Other high-risk indications in the mother are toxemia, hypertension, diabetes, renal disease, or induced labor. Clinical dysmaturity of the fetus would be another indication.

EXTENT OF USE

We were not able to obtain any national data on the extent to which electronic fetal monitoring techniques are being used. We were able to obtain some data from CPHA on the use of intrauterine fetal procedures for spontaneous deliveries and cesarean sections and some from a survey done by the Senate Subcommittee on Health and Scientific Research. Also, a publication by the Office of Technology Assessment (OTA) estimated the number of monitoring systems in the United States.

CPHA reported that, of 1.3 million deliveries in its 1977 data base, 132,412 (or 10.4 percent) had intrauterine procedures on the fetus and 14,641 of 170,632 cesarean sections (or 8.6 percent) had intrauterine procedures on the fetus. CPHA informed us that in most cases these intrauterine procedures would be internal monitoring.

A 1978 survey by the staff of the Senate Subcommittee on Health and Scientific Research reported the percentage of patients monitored during 1977 at 63 hospitals across the country. The results of the survey were as follows:

Percentage of patients monitored	Number of hospitals
Over 80 percent	34
50 to 79 percent	21
Less than 50 percent	7
All high-risk patients	1
Total hospitals surveyed	63

In a 1978 report, OTA estimated that 1,000 fetal monitoring systems were in use in the United States by the end of 1972. In this same publication, OTA stated it is probable that all U.S. obstetric services will soon have monitoring capability and that electronic monitoring would be feasible in more than half of the approximately 3 million deliveries a year in this country. However, the report did not estimate what percentage of deliveries are now actually monitored.

RESEARCH RESULTS INCONCLUSIVE

In general, the research studies we reviewed were inconclusive in determining the safety and value of fetal monitoring. Furthermore, most of the research did not look into the long-term effects of external ultrasound monitoring on the fetus. Also, almost all of it dealt with internal rather than external monitoring. Many studies emphasized positive effects of monitoring, including decreased perinatal mortality; many others cited injuries to the infant. For instance, some studies reported incorrect application of fetal electrodes and, in some cases, resultant injuries. Others discussed the relationship between the increased rate of cesarean sections and increased use of fetal monitoring. Still other researchers discussed when to use fetal monitoring, for all patients or only for "high-risk" ones.

Of those reporting a conclusion, 17 concluded that there is improved perinatal outcome with electronic fetal monitoring. However, two other studies (both controlled) found no difference between monitored and auscultated patients. The 1978 OTA study (see p. 55) concluded that:

> "* * * although many believe that electronic fetal monitoring is useful, its relative efficacy and benefit have not been established. Two controlled studies indicate that monitoring by nurses may be equally efficacious and provide additional benefits; a third finds

> EFM [electronic fetal monitoring] to be of some relative benefit. Moreover, fetal monitoring may be associated with considerable risks and financial costs. It is a technology that may well have been diffused prematurely. It is an example of a technology for which guidelines on appropriate indications for use might be needed. Guidelines could suggest what types of patients and delivery situations would result in benefits exceeding the possible risks."

Scope limited and no long-term studies

The scope of the research studies we reviewed was generally limited. None of the research articles we reviewed on electronic fetal monitoring studied long-term effects on the child. However, a number of studies did note that long-term studies are needed. Many researchers merely reported on their hospital's experience with electronic fetal monitoring. Some compared perinatal outcome using routine monitoring with that from premonitoring years. Others compared monitored and unmonitored labors for the same years. However, only two of these studies were controlled.

We reviewed about 135 articles and book excerpts on fetal monitoring. Of these, 62 mentioned effects on the infant of electronic fetal monitoring. These articles included:

--Forty-six U.S. studies: 37 on internal monitoring, 2 on external monitoring (with internal monitoring if problems developed), 6 on both methods, and 1 unknown.

--Sixteen foreign studies: 11 on internal monitoring, 1 on external monitoring, 2 on both methods, and 2 unknown.

The number of cases covered by the studies varied greatly. Twenty-one studies dealt with less than 100 cases, including 10 reports on 1 case, and 8 studies covered over 5,000 deliveries. The large studies recounted individual hospitals' experiences with electronic fetal monitoring and were not controlled studies.

Only three of the studies we reviewed were controlled although some of the research also noted a need for controlled studies. Two of these were foreign and one was a U.S. study. One controlled study was discussed in a 1976 article by Renou et al. (Australia). Three hundred and fifty patients were randomly allocated equally between control and intensive care groups. In the other foreign study, a prospective, random comparison of continuous FHR monitoring with intermittent auscultation was made. In this study, Kelso et al. (1978) studied 504 low-risk patients, 253 of which were monitored with a scalp electrode. The one U.S. controlled study by Haverkamp et al. (1976) was also prospective and random and involved 483 high-risk patients, of which 242 were monitored. It compared the effectiveness of electronic FHR monitoring by scalp electrode with that of auscultation.

Effects on the infant

The research literature noted both positive and negative effects of internal fetal monitoring. None of the studies that we reviewed showed any effects from external monitoring. The research generally emphasized the benefits that can result from internal fetal monitoring, such as lessened perinatal mortality. Some articles did mention scalp injuries due to internal fetal monitoring, but a number of articles noted that these injuries were relatively rare. The controlled study by Kelso et al. (1978) found neither beneficial nor harmful effects as a direct result of continuous FHR monitoring. Also, the controlled study by Haverkamp et al. (1976) showed no improvement in overall perinatal outcome in high-risk pregnancies with the use of electronic monitoring instead of auscultation. The third controlled study (Renou et al., 1976) was stopped "when it became clear that intensive care was associated with improved neurologic and biochemical status of the neonate."

Of the articles we reviewed, 17 cited decreased or lower perinatal mortality. This generally reflected a comparison between years when monitoring was used with those years when it was not. Other studies compared monitored and unmonitored patients in the same year but did not match patients according to medical condition. Several studies particularly noted a decrease in intrapartum stillbirths and attributed this to fetal monitoring. However, Hochuli et al., stated that the risk of death during delivery was only 1 or 2 per 1,000 cases even without electronic fetal monitoring.

A number of articles cited adverse effects of internal fetal monitoring on the infant. The most serious effect was an infant's scalp abscess caused by insertion of a scalp electrode which had allowed infection to take place. In this case the infant died. In all, 14 articles cited cases of scalp abscess. Forty-two was the largest number of scalp abscesses cited (4.5 percent of patients monitored), and the highest incidence rate in a study was 5.4 percent. Cordero and Hon (1971) noted that although scalp abscess is unusual, it represents the major complication of internal fetal monitoring. Other injuries to the infant noted by researchers were scalp hematoma (a swelling filled with blood), eyelid hematoma, scalp infection, scalp abrasions, and fetal bleeding.

Incorrect use of fetal monitoring equipment

Some research found that problems can occur with incorrect use of fetal monitoring. Seven articles commented on injuries to the infant due to incorrect use of scalp electrodes. Several others noted cases of uterine perforation due to incorrect use of the intrauterine catheter utilized in internal monitoring.

The injuries due to misuse varied widely. For instance, Atlas and Serr (1976) reported on a case of an infant born with a superficial laceration extending from the cheek to the right thigh. The laceration was not very serious, but it was due to an electrode being incorrectly applied both to the fetal scalp and the maternal cervix. Yasunaga (1976) reported eight cases of scalp abscess due to misuse, including six from poorly sterilized scalp electrode clips and two resulting from improper electrode application. McCrann and Schifrin (1974) reported one case of traumatic removal of a scalp electrode which resulted in a major fetal hemorrhage. Another case report by Thomas and Blackwell (1975) reported on an infant whose eyelid was penetrated by a spiral electrode. Finally, Goodman et al. (1977) reported on a case in which an electrocardiogram corkscrew lead was inadvertently inserted too deeply into the fetal scalp and caused an abscess.

Effect on the cesarean section rate

Research literature contains diverse views regarding the effect of fetal monitoring on the cesarean section rate. Reports on 13 studies of fetal monitoring discussed its relationship with the cesarean section rate. Of these, 11 said

that fetal monitoring increased the rate, 1 said it decreased it, and 1 said the rate was not increased. In addition, three studies cited an increase in cesarean sections for fetal distress which was discovered through monitoring, but one noted a decrease. Koh et al. (1975) stated that in a few cases cesarean sections were done unjustifiably due to "obstetrician distress" rather than fetal distress.

Some studies compared the cesarean rate before and after fetal monitoring. Others compared monitored and unmonitored patients without matching patients for medical condition. The one U.S. controlled study (Haverkamp et al., 1976), found cesarean sections significantly more prevalent in the monitored group (16.5 percent) than in the auscultated group (6.6 percent). However, the two foreign controlled studies did not attribute increased cesarean sections to fetal monitoring, and the methodology used in the Haverkamp study has been questioned.

OTA, in a 1978 publication, states that the most important risk to mother and child from electronic fetal monitoring is cesarean section and its risks. OTA states that there seems little question that the rise in the U.S. cesarean section rate from 5.5 percent of deliveries in 1965 to 12.5 percent in 1976 is associated with electronic monitoring. OTA notes that, if half of the increased number of cesareans are attributed to normal fetal stress that is interpreted as fetal distress, $175 million has been added to the national health bill from cesarean section associated with use of electronic fetal monitoring, not including costs of death and morbidity of mother and child.

Disagreement about routine monitoring

The research literature conflicts about whether fetal monitoring should be used routinely for all patients in labor or only for those who are high risk. For example, according to Hohe

> "to subject a patient with an otherwise normal labor and a negative prenatal history to either internal or external monitoring frequently results in a complication of interfering with the patient's ability to manage contractions and thus proceed 'naturally' through labor and delivery without anxiety or unnecessary analgesia."

However, according to McCrann and Schifrin (1974) all patients should be monitored because about 25 percent of those considered low-risk become high-risk cases during labor and delivery. Two studies we reviewed recommended monitoring for high-risk patients and five studies recommended monitoring for all patients. Heldfond et al. (1976) said that in response to a questionnaire, 77 percent of the staff at their hospital believed that all patients in labor should have monitoring.

A March 1979 NIH Consensus Development Conference which dealt with electronic fetal monitoring (among other topics) concluded that it should be strongly considered in high-risk cases. However, it also found no evidence that electronic monitoring reduces morbidity or mortality in low-risk patients and concluded that under certain circumstances, mothers or physicians may choose to use it even in low-risk situations.

FEDERAL INVOLVEMENT VARIED

Although Federal research efforts concerning fetal monitoring have been active, other Federal involvement has not been. Only recently have any Federal regulatory moves occurred toward fetal monitoring. Also, MCEs done by PSROs have been limited for this obstetric technique.

Federal regulatory involvement relatively recent

Federal regulation of fetal monitors has been relatively recent. The Medical Device Amendments of 1976 to the Food, Drug, and Cosmetic Act of 1938 gave FDA responsibility to regulate and assure the safety and effectiveness of medical devices. FDA is now classifying fetal monitoring devices under the categories required by the 1976 amendments. At the time of our review, FDA was planning to put fetal monitoring devices into a classification that would require performance standards for them.

Federal funding of research active

Many agencies within HEW, particularly NIH, have funded studies on fetal monitoring. Most of these did not assess the benefit-to-risk ratio or infant outcome of using fetal monitoring. Furthermore, the scope of most of these studies was narrow, and none looked into the long-term effects of monitoring on the infant.

NIH has funded at least four studies on fetal monitoring. NICHD supported a general study on fetal monitoring (Hon, 1972 and 1974) and NIH's Division of Research Resources funded another on fetal surveillance during labor (Schifrin et al., 1973). NIH also supported a study on scalp abscess (Cordero and Hon, 1971). Also, NIH sponsored the Consensus Development Conference on Antenatal Diagnosis including fetal monitoring in March 1979.

HEW's Office of Maternal and Child Health has also funded two studies on fetal monitoring. Both (Haverkamp et al., 1976; Tchilinguirian, 1973) were on monitoring in high-risk pregnancy.

OTA did a study to assess the safety and efficacy of fetal monitoring. This was done because of a request by the Senate Committee on Labor and Human Resources to OTA to examine medical technologies. The 1978 publication which resulted from this study found widespread acceptance of this practice in the United States. It also found effects such as scalp abscesses, lacerations of the fetal scalp, and uterine perforations. According to OTA, "practices associated with the use of fetal monitors may induce the very fetal distress they are meant to detect." OTA concluded that the relative risks and benefits of fetal monitoring have not been established and that electronic fetal monitoring may be a technology that requires guidelines for use. OTA commented on the need for a more coordinated Federal research approach and controlled studies concentrating on long-term infant outcome.

PSRO evaluations limited

Seven PSROs responded to our inquiry; three of them reported MCEs on fetal monitoring (two of them reported one and one reported two). Information from these MCEs was insufficient to draw any conclusions on benefits, risks, or appropriate use.

One evaluation reviewed 60 patient records to compare the infection rate in patients with internal monitoring to the general rate in normal deliveries. The MCE found that the infection rate was less than half of the nationally accepted standard for internal monitoring (10 to 11 percent). No action was recommended. The second MCE reviewed 75 records to determine how many indications were needed before an intrauterine fetal monitor was used. The evaluation was also to document neonatal and fetal mortality. The PSRO did not report the study's findings. Another MCE reviewed 25 unmonitored patients to assure that all patients who should

have been monitored were. The MCE found mostly documentation deficiencies. However, in one case where oral Pitocin was used it was felt that the patient should have been on a monitor. The last of these MCEs was done to determine the infection rates for obstetric patients who did and did not receive internal fetal monitoring. It involved a review of 228 patient records which showed:

--Only 1 percent of all newborns displayed any evidence of infection, and none of these signs were serious. No difference occurred between monitored and unmonitored patients.

--Within the hospital, the rate of infection was not high enough to offset the known benefits of fetal monitoring during labor and delivery.

INVOLVEMENT AND COMMENTS BY PROFESSIONAL ORGANIZATIONS

ACOG has published two technical bulletins on fetal monitoring. In addition, at an April 1978 hearing before the Senate Subcommittee on Health and Scientific Research, an ACOG representative testified that it is ACOG's opinion that the risk/benefit of external fetal monitoring with ultrasound is to the patient's advantage.

The first technical bulletin (June 1975) described FHR patterns and instruments used for fetal monitoring. The second technical bulletin (January 1977) discussed indications for monitoring, implementation of monitoring, and dangers of monitoring. ACOG noted that intrapartum monitoring is important for assessing fetal well-being. It also noted continuous monitoring of FHR and uterine activity during labor should be considered for a pregnant patient with one or more, less optimal conditions (which it defines) who is thus at an increased risk of delivering a sick fetus. The 1977 bulletin notes that the dangers of external monitoring with ultrasound are only theoretical and there is no evidence to suggest that ultrasound is harmful to the fetus. It states, therefore, external monitoring is safe. Potential risks of internal monitoring listed by the bulletin include fetal scalp infection, misapplication, uterine perforation, placenta perforation, and infection.

In May 1979, ACOG's Committee on Obstetrics: Maternal and Fetal Medicine reported its findings following a study of electronic fetal monitoring. The Committee reported, in part, that:

--Electronic fetal monitoring has been documented to be of value in the high-risk, obstetrical patient with the following indications: (1) complications during pregnancy or labor, (2) presence of fetal waste matter in the amniotic fluid, (3) prematurity or overdue pregnancy and intrauterine growth retardation, (4) induced labor, and (5) abnormalities of fetal heart rate.

--A number of situations may arise during labor and delivery in a low-risk pregnancy which increase the risk to the infant and indicate a need for continuous electronic fetal monitoring.

--Either the physician or the patient may choose to use electronic fetal monitoring even in low-risk situations. If electronic monitoring is not used, fetal heart tones should be checked at least every 30 minutes during the first stage of labor and at least every 15 minutes during the second stage of labor, in both instances for a period of 30 seconds after a uterine contraction.

In commenting on the appropriateness of electronic fetal monitoring, a former Chairman of the American Academy of Pediatrics' Committee on the Fetus and Newborn said that:

--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.

CHAPTER 5

CESAREAN SECTION

The dramatic increase in the cesarean section rate in the 1970s has caused much public concern. Cesarean section is definitely a valuable and lifesaving obstetric practice when used under proper circumstances. However, some believe the rise in cesarean births is excessive.

Research literature is inconclusive for determining whether the increase in cesarean sections is necessary. The research cited various reasons for the increase, including physicians' fear of malpractice suits, increased use of electronic fetal monitoring to determine the need for early intervention due to fetal distress, the increasing use of cesarean section for breech presentations, and an increase in "repeat" sections because more "primary" sections are occurring. The research literature is inconclusive as to effects on the infant due to cesarean section; however, many authors cited instances in which babies were delivered prematurely by elective (scheduled) section. The scope of the research studies we reviewed was limited. Most of them were retrospective and only two examined the long-term effects on the infant.

Federal involvement in relation to cesarean sections has also been limited. For instance, the Government had sponsored little of the research we reviewed. HEW has done some research, and PSROs have completed some MCEs. FDA does not regulate cesarean sections.

DESCRIPTION

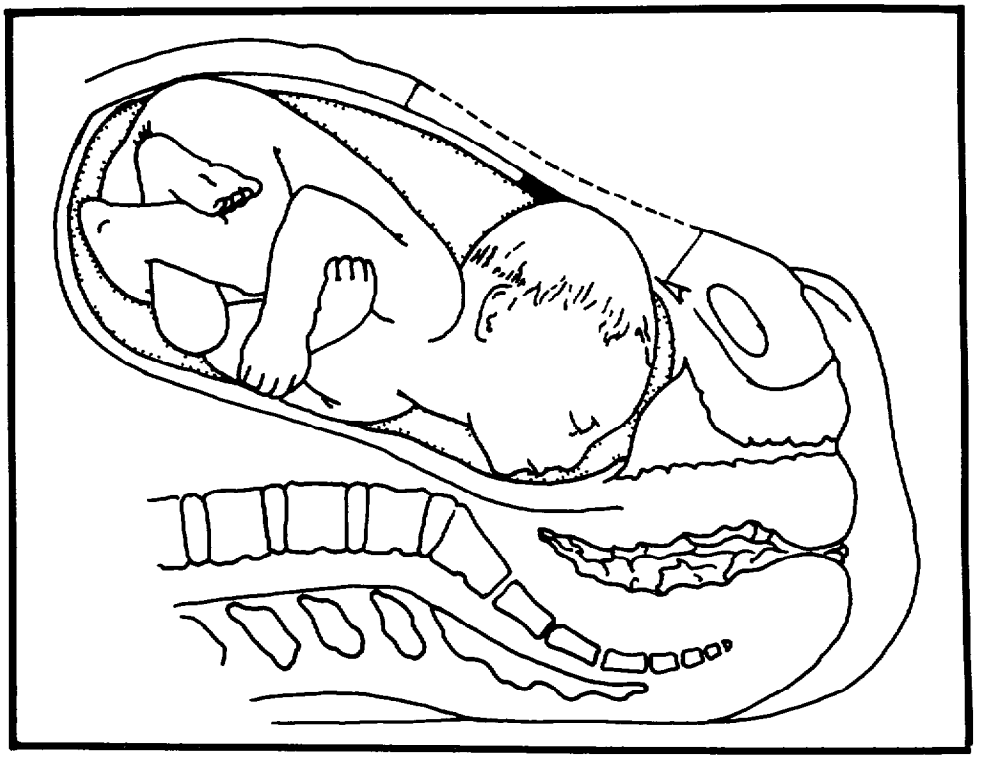
Cesarean section is delivery of an infant through incisions in the abdominal and uterine walls. It can be done before or after labor begins.

Cesarean sections are either primary or repeat sections. A first cesarean section is called primary; succeeding ones are repeat sections. The term "elective" cesarean section refers to those done at a predetermined time. Repeat sections or sections for breech presentation (the baby would be born feet first) might be elective. In such cases, obstetricians decide to do a cesarean section before labor and schedule it for a specific time.

For centuries physicians have been using cesarean section. According to legend, Julius Caesar was born this way. However, until the start of the 20th century a high maternal mortality rate was connected with cesarean section.

Ways of performing cesarean sections

The type of cesarean section differs by the location and direction of the uterine incision. The so-called "classic" incision is made vertically into the uterus above the lower uterine segment. This method is seldom used in modern obstetrics except in emergencies. When performing the most commonly used incision, "low cervical," the physician makes an incision in the lower uterus which is usually crosswise.



DELIVERY BY CESAREAN SECTION SHOWING INFANT'S HEAD AT THE UTERINE INCISION

This incision results in less blood loss, easier repair of tissue, and more complete healing than the classical incision.

INDICATIONS FOR USE

General indications for cesarean section may include a risk to either the mother or the fetus if labor begins or continues; attempted induction of labor fails; and/or an emergency mandates immediate delivery which is not possible or suitable vaginally. Once a physician chooses cesarean section for his patient, subsequent deliveries are usually done in the same way.

A number of conditions may influence the physician's decision to perform cesarean section:

--Cephalopelvic disproportion (fetal head too large for maternal pelvis).

--Previous section(s).

--Maternal organic problems (such as diabetes or toxemia of pregnancy).

--Predelivery hemorrhage due to premature separation of a normally situated placenta or a placenta that covers or adjoins the internal opening of the uterus.

--A woman over 35 having her first child.

--Malpresentation (such as difficult breech or transverse lie of the fetus).

--Prolapse (falling down) of the umbilical cord, uterine inertia, prolonged labor.

--Fetal distress.

EXTENT OF USE

In trying to determine the frequency of cesarean sections, we looked at data from many sources. Much of the data showed a strong upswing in the rate of cesarean sections within the last 10 years.

National data on the frequency of cesarean sections are provided in HEW's 1972 U.S. National Natality Survey. The

survey reported that 7.3 percent of the 2.8 million legitimate, live, hospital births in the United States in 1972 were cesarean sections. HEW also does national health surveys for surgical operations in non-Federal, short-stay hospitals and uses these data to estimate the number of surgical patients and operations. These surveys estimated cesarean sections for 1977 as 455,000 in 3.3 million deliveries (13.8 percent).

The following data which were supplied to the Senate Subcommittee on Health and Scientific Research show that the cesarean section rate has more than doubled since 1971.

Year	Number of cesarean sections	Number of deliveries	Percentage of cesarean sections
1968	172,000	3,435,000	5.0
1971	194,000	3,459,000	5.6
1972	227,000	3,352,000	6.7
1973	246,000	3,238,000	7.5
1974	286,000	3,239,000	8.7
1975	328,000	3,328,000	9.9
1976	378,000	3,329,000	11.4

CPHA also provided us data. CPHA reported that 13.4 percent of 1.3 million U.S. births in 1977 reported to it were cesarean sections. CPHA published data on cesarean sections between 1967 and 1974 at 204 U.S. hospitals reporting to it. Of 2,110,791 deliveries studied, 142,696 (6.8 percent) were cesarean sections. The prevalence of cesarean section increased from 5.1 percent of all deliveries in 1967 to 9.8 percent of all deliveries in 1974. The percentage of cesarean sections varied by the size, location, and type (teaching versus nonteaching) of hospital. For 1977, cesarean sections as a percent of all deliveries by hospital size, U.S. census region, and teaching status were

--11.9 percent for hospitals with less than 200 beds, 13.3 percent for hospitals with between 200 to 399 beds, and 14.6 percent for hospitals with 400 or more beds;

--13.8 percent for the West, 12.4 percent for the North Central, 13.3 percent for the South, and 15.0 percent for the Northeast; and

--12.5 percent for nonteaching hospitals and 14.8 percent for teaching.

Cesarean section rates also vary by State as the following examples illustrate for 1976:

Cesarean Sections

State	Percent of all deliveries
California	14
District of Columbia	18
Missouri	11

Prevalence of selected indications

No national data are available on the incidence of the various indications for cesarean section. However, data were available for some indications, including repeat cesarean sections, fetal distress, cephalopelvic disproportion, breech presentation, and premature rupture of membranes.

Data on repeat sections came from four sources. The most comprehensive was the 1967 ACOG Hospital Survey. It showed that 45 percent of all cesarean sections were repeat sections. The next most comprehensive data came from CPHA. It reported that in 1977 31.6 percent of total cesarean sections reported to it were repeat. CPHA also reported on 120,684 cesarean sections out of 1,255,812 deliveries during 1974 at 1,527 U.S. hospitals. The primary diagnosis for 30 percent of these deliveries was previous cesarean section. The NINCDS Collaborative Perinatal Project found previous sections as the primary indication for cesarean section in 47.4 percent (of 921 cases) of its white patients and 43.1 percent (of 992 cases) of its black patients.

Some of these studies also noted the incidence of other indications for cesarean section. Data from CPHA, for example, showed 9.5 percent of total cesarean sections in 1977 reported to it were for fetal distress. In its analysis of primary diagnoses in 1974, CPHA found 3.8 percent of cesarean sections in the study had a primary diagnosis of fetal distress, 28.1 percent were for cephalopelvic disproportion, 7.7 percent were for breech presentation, and 2.7 percent were for premature rupture of membranes.

RESEARCH RESULTS INCONCLUSIVE

There was general agreement in the research literature we reviewed that cesarean section is a valuable obstetric tool which has increased in safety over the years and that the frequency of use of cesarean section has increased. However, we also found in reviewing the research literature that:

--The scope of the studies we reviewed was limited, and only two looked at long-term effects on the infant.

--Although various reasons were given for the increasing incidence of cesarean sections, it is still unclear whether they are excessive.

--There was a controversy in the literature over whether a repeat section is always necessary when the previous indication no longer exists.

--There is a difference of opinion on the effects of cesarean section on the infant, but prematurity is often cited in the research literature as an effect of an incorrectly timed cesarean section.

Scope of research limited and no long-term studies

The scope of the research studies we reviewed was limited. Almost all of the articles were retrospective, and the only two dealing with long-term effects on the infant used NINCDS Collaborative Perinatal Project data up to 1 year of age. In a 1976 article, Hibbard noted that "What is most needed, and least available is an adequate long-term evaluation of the impact of delivery upon the developing child." Many articles just reported on an individual hospital's cesarean section experiences. Also, in general, no selection of control group occurred.

In attempting to reach summary conclusions on the research literature, we reviewed about 125 articles on cesarean section, of which 101 (67 U.S. and 34 foreign) dealt with effects on the infant or reasons for the increasing cesarean section rate.

Various reasons given for increasing use of cesarean section

The literature gave various reasons for the increased incidence of cesarean sections in the United States during

the 1970s. These included physicians' fear of malpractice suits; use of electronic fetal monitoring to determine if early intervention is needed due to fetal distress; expanding indications for cesarean section to include more breech presentations; and an increase in repeat sections due to a similar increase in primary sections.

Physicians have become increasingly fearful of the threat of malpractice complaints when performing dangerous vaginal deliveries. Therefore, since cesarean births are considered a safer alternative in these cases, doctors choose this operation rather than the riskier vaginal delivery. For example, in a 1976 article Jones discussed replies to questionnaires about cesarean section sent to 50 representative medical school departmental chairmen, other professors, and selected individual obstetricians throughout the United States. Almost all replies mentioned fear of malpractice suits as a reason for performing cesarean sections. Jones noted that "In 1938 * * * no one would have ever thought the malpractice threat would become an indication for cesarean section."

Two articles in nonmedical journals also commented on the influence of the malpractice threat on the increasing cesarean section rate. Brody (1978) noted that with the increase in medical malpractice suits, many doctors refuse to take chances and operate when they have the slightest doubt about the outcome. She stated that one New York family with a brain-damaged child received a $695,000 settlement from two doctors who failed to deliver a baby by cesarean section who was lying sideways in the uterus. Randal (1978) also cited physicians' fear of malpractice suits and noted that compensation awards of as much as $14 million have resulted from the birth of a severely injured infant delivered vaginally.

Another reason cited for the increase in cesarean sections is the use of electronic fetal monitoring for detecting fetal distress. OTA, in a 1978 publication, noted that normal fetal stress may be interpreted as fetal distress and thus lead to cesarean section. Some articles supported the increase in cesarean sections for fetal distress following the use of electronic fetal monitoring, but others stated that not all the sections for fetal distress were necessary. Jones (1976) and Hibbard (1976) both reported an increase in cesarean sections for fetal distress in connection with the increased use of electronic fetal monitoring devices during labor in the 1970s. Hibbard noted that probably most fetuses identified as having evidence of distress would have survived

without electronic monitoring and cesarean section but the question is whether or not they would have been unnecessarily injured. In a 1978 article, Haddad and Lundy reported that only half of the 102 patients in their study who had cesarean section for the management of fetal distress during labor (2.3 percent of the total) should have required primary cesarean section for the management of fetal distress. Articles on electronic fetal monitoring expressed diverse opinions as to whether or not electronic monitoring has resulted in an increase in cesarean sections. (See p. 52.)

Other reasons given for the increase in cesarean sections include:

--Less risk to the mother from this operation and increased medical concern about the welfare of the fetus and fetal outcome.

--A marked reduction in vaginal deliveries for breech babies.

--A more aggressive approach by physicians to the problem of premature rupture of fetal membranes, which cesarean section offers.

--More sophisticated intensive care facilities and personnel available for the management of the premature infant, permitting early delivery by cesarean section of chronically distressed infants.

--Fewer difficult mid-forceps deliveries.

--More repeat sections due to increased primary sections and the tendency to do a repeat section rather than to deliver vaginally.

Hibbard, in a 1976 article, commented on the increase of cesarean section as follows:

"The wisdom of a more liberal utilization of cesarean section is difficult to judge. * * *

"At the present time, a cesarean section seems to be indicated for almost any obstetric difficulty as the only means of avoiding the unpredictable bad result of vaginal birth. The only constraining counter argument is the realization that abdominal delivery still carries additional maternal risk, disability and expense."

Repeat sections may not always be necessary

Study results vary on the proper management of a later pregnancy of a woman previously delivered by cesarean section. Over the years physicians have almost always terminated a pregnancy following a previous cesarean section by performing a repeat cesarean section. This philosophy is commonly expressed as "once a cesarean section, always a cesarean section." The rationale for always doing repeat sections is the danger of rupturing the previous uterine scar if a vaginal birth were to occur. Such a rupture can be fatal to the mother or fetus or both.

The most comprehensive data we obtained on management of pregnancies after previous section were published by CPHA in December 1976. Of 1,255,812 deliveries included in CPHA's 1974 U.S. data, 38,485 were recorded as complicated by a previous section. Of these, 38,127 (99.1 percent) had a repeat section for the 1974 delivery. This left 358 (0.9 percent) who, in 1974, were delivered vaginally although they had had a previous section. In commenting on this data Lowe et al. stated·

> "These 358 deliveries were divided among 253 hospitals, which means that in most hospitals there was only a single vaginal delivery recorded as being complicated by a previous cesarean section. Eight was the most vaginal deliveries, complicated by a previous cesarean section, recorded in any single hospital. For this hospital, these eight cases represented only 6.6% of the deliveries with associated previous cesarean sections.
>
> "From these data, it can be concluded that in most U.S. PAS [Professional Activity Study] hospitals, deliveries complicated by a previous cesarean section are handled with subsequent sections. Even in those hospitals with some vaginal deliveries following previous section, the percent of cases so delivered is relatively small."

Eleven of the research studies we reviewed discussed or compared women with previous sections delivered by repeat section versus vaginally. Of the 11 studies, 9 reported

vaginal delivery after previous cesarean section safe at least in selected cases, and 2 gave no conclusions. In a 1958 study by Jesurun and Simpson, 113 of 222 previously sectioned mothers were delivered vaginally. One death was directly attributed to the delivery method. They concluded that in a well-equipped, well-staffed hospital, vaginal delivery after cesarean section can be done in carefully selected cases with low mortality and morbidity and good fetal salvage. In a 1963 article on 2,094 deliveries of women who had had a previous section (2.1 percent of total deliveries), Douglas et al. concluded that physicians can deliver over half of post-cesarean patients vaginally and the "once a cesarean, always a cesarean" rule no longer applies. They stated that the management of each patient should be individualized, which would decrease repeat sections and increase safety to the mother and infant.

A July 1978 article by Merrill and Gibbs discussed a study of 790 women with previous sections. Of this group, 526 (or 83 percent of 634 who had had only one previous section) were selected for a trial of labor. Of this group, 313 (49 percent of total with one previous section) delivered vaginally. The other 213 had repeat sections, generally for fetal distress or because labor had stopped. They found that perinatal mortality and morbidity were unaffected by trial of labor or method of delivery. Merrill and Gibbs stated:

> "We have confirmed what others have found, namely, that approximately half the patients with a previous single low cervical transverse cesarean section can deliver vaginally. We have also confirmed the relative safety of the procedure when conducted in an environment in which the trial can be terminated and abdominal delivery carried out immediately."

On the other hand, many of the articles we reviewed which dealt only with cesarean section deliveries noted that in all or most cases, a repeat section should be done to avoid the possibility of a uterine rupture during labor, even though the chance of rupture is relatively small.

Research literature conflicting on effects on the infant

Some research studies cited hazards to the infant from cesarean section, particularly that of premature birth caused by inaccurate timing of delivery. However, 11 articles

attributed increased deaths after cesarean section to the problem necessitating the section and not to the operation itself.

Perinatal death and prematurity were two of the infant risks linked to cesarean section by the research studies we reviewed. Twenty-one studies cited cesarean section as a factor in perinatal death. Seventeen of these cited errors in gestational age estimates or poorly timed sections. Five studies attributed perinatal deaths to the anesthesia used. Thirty-seven studies cited cases of prematurity with cesarean sections.

Respiratory distress syndrome is a common complication of prematurity which is common with cesarean section. In 1961, Muller et al. reported that a total of 67 errors in estimating gestational age occurred in a study of 1,462 repeat cesarean sections. This resulted in delivery of premature infants. Four of the 67 sections, supposedly done at or near term, resulted in infant death. In a 1977 article, Maisels et al. reported that of 1,020 consecutive admissions to a regional neonatal center, 38 infants (33 cesarean sections and 5 inductions) were admitted following elective delivery in which no medical condition of the fetus had necessitated immediate delivery. Hyaline membrane disease, which was clearly related to premature delivery, developed in 18 cases (15 cesarean sections and 3 inductions). In none of the infants had any assessment of fetal maturity or size (other than the menstrual history and physical examination) been made. Others reviewing cases of respiratory distress syndrome had similar findings.

Also, some studies found a higher incidence of respiratory distress syndrome or hyaline membrane disease with cesarean deliveries than with vaginal deliveries. For instance, in a 1976 study of 544 infants who died in the first month of life, Leviton et al. found that sectioned infants had a higher incidence of hyaline membrane disease. Five other studies also found an increased incidence of respiratory distress syndrome or hyaline membrane disease with cesarean section. Some research articles recommended waiting for the onset of labor before performing cesarean section. This could prevent the prematurity often caused by untimely physician intervention.

However, other researchers felt that even with the possibility of prematurity, elective cesarean section (one scheduled for a set time) is preferable to vaginal delivery

because arrangements can be made in an orderly way. Also, elective sections help avoid possible uterine rupture which can occur in a vaginal delivery after a previous section. In addition, a representative from the American Academy of Pediatrics noted that a substantial improvement in outcome has accompanied the trend of delivering breech presentations by cesarean section rather than vaginally.

In commenting on a draft of this report, HEW noted that NICHD has supported research that enables physicians to determine fetal maturity and avoid prematurity sometimes associated with scheduled inductions or cesarean sections. NIH's March 1979 Consensus Development Conference included an assessment of methods for predicting fetal maturity and reported on appropriate uses of these methods by physicians. Also, HEW said that it may hold a consensus development conference on cesarean sections within a year.

FEDERAL INVOLVEMENT LIMITED

The Federal Government is involved with the rising number of cesarean sections in three ways: sponsoring research on cesarean section, paying for the operations through various programs, and monitoring hospital care, including obstetric practices, by PSROs through MCEs. However, the Government had not sponsored much of the research we reviewed on cesarean sections. An HEW official told us that HEW's Office of the Assistant Secretary for Planning and Evaluation had sponsored one study on cesarean section at least partly because of HEW's responsibility for paying Medicaid costs. Although PSROs (or hospitals under their jurisdiction) have done more MCEs on cesarean sections than for other obstetric areas, they have not reported many deficiencies, and information available is insufficient to draw conclusions on the necessity or quality of cesarean sections.

Federal research limited and inconclusive

Of the cesarean section studies we reviewed, four dealt with deliveries at military hospitals, two analyzed Collaborative Perinatal Project data, and one HEW-supported study dealt with hyaline membrane disease. None of them looked at long-term effects on the infant, except the ones using Collaborative Perinatal Project data on infants up to 1 year of age. As mentioned, HEW's Office of the Assistant Secretary for Planning and Evaluation did sponsor a recently completed study on cesarean sections, but a report had not yet been

issued. One HEW official told us that this study was done to find out why cesarean sections are on the increase since this rise also increases Medicaid costs. According to this official, HEW has done little other research on cesarean sections. However, HEW's Office of Maternal and Child Health sponsored one study which included a review of the cesarean section rate in California (also not yet published).

HEW also sponsored the NINCDS Collaborative Perinatal Project which gathered some data on cesarean sections. The project showed a cesarean section incidence of 5 percent. These data were used in several studies. However, according to HEW officials, studying this project's data base for the causes of the increase in cesarean sections may not be worthwhile. The data would be outdated at best because the babies in the project were born between 1959 and 1966, which was before the number of cesarean sections began to rise markedly.

PSROs have found little wrong with cesarean sections

Some PSROs or hospitals under their jurisdiction have done MCEs on cesarean section. Those responding to our survey reported 113--or about 1.9 percent of their total MCEs. Of these evaluations, about 41 reportedly probed into the causes and justification for cesarean sections. Only one found any sections unwarranted. Information was not readily available on the criteria used or the quality of the studies, although the scopes and depths of the MCEs on cesarean sections varied considerably. We were told that HEW has initiated efforts to develop criteria for use by PSROs in evaluating cesarean sections.

INVOLVEMENT AND COMMENTS BY PROFESSIONAL ORGANIZATIONS

ACOG had not issued any technical bulletins or statements on cesarean section. ACOG did issue a news release in July 1978, reporting on the July 1978 article by Merrill and Gibbs on planned vaginal delivery after cesarean section. (See p. 67.)

In commenting on a draft of this study, representatives from the American Academy of Pediatrics said:

--The increased cesarean section rate may have contributed to the decrease in infant mortality rates. Improved outcome of breech presentations delivered

by cesarean section should be encouraging. Also, some evidence exists that mortality rates for small infants delivered by cesarean section are lower than for those delivered vaginally.

--The increasing ceasarean 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 once believed to be nonsalvageable, 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.

--One must also note that the higher cesarean section rates for teaching hospitals is usually related to the higher proportion of patients at special risk they serve.

CHAPTER 6

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 prepublication 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 OTA and received information from seven of nine PSROs reporting the largest number of MCEs on obstetrics as of August 1978.

In addition, we obtained information from CPHA on hospital occurrence in 1977 of the five obstetric practices we looked at. 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

APPENDIX I

GLOSSARY OF MEDICAL TERMS

Acidosis	A clinical term commonly used to describe a decreased pH of the blood or a lowered blood bicarbonite.
Amnion	The inner of two fetal membranes forming the sac that encloses the fetus within the uterus.
Amniotic	Pertaining to the amnion.
Amniotomy	Surgical rupture of the fetal membranes in induction of labor.
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.
Apnea	The transient cessation of breathing.
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.
Bupivacaine	A local anesthetic given by injection.
Carbocaine	A brand of mepivacaine (see mepivacaine).
Cardiovascular	Pertaining to the heart and blood vessels.

APPENDIX I

Caudal anesthesia	Regional anesthesia produced by injection of a local anesthetic.
Cephalohematoma	An accumulation of blood under the periostium of any of the cranial bones, especially one induced by the trauma of birth, developing in a newborn.
Cephalopelvic disproportion	The condition when the fetal head is larger than the bony 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.
Congenital	Existing at or before birth.
Contraindicate	To give indication against the advisability of (a particular or usual remedy or treatment).
Dilation	The action of dilating or stretching.
Dysmature	Denotes an infant whose birth weight is inappropriately low for its gestational age.
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.
Engagement	Passage of the largest diameter of the presenting part of the fetus into the pelvic brim.
Epidural	Situated on or outside the outermost, toughest, and most fibrous of the three membranes of the brain and spinal cord.

APPENDIX I

Episiotomy	Surgical incision of the perineum toward the end of the second stage of labor to facilitate delivery and avoid laceration.
Fetal	Pertaining to a fetus.
Fetal distress	Signs of danger in the fetus.
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.
Hematoma	A swelling filled with extravasated (forced out of the proper vessels to the surrounding tissues) blood.
Hyaline membrane disease	This is now commonly referred to as respiratory distress syndrome. (See respiratory distress syndrome.)
Hypertension	High blood pressure.
Hypertonicity	Increased tonicity or tension.
Hypotension	Low blood pressure.
Hypoxia	Insufficient available oxygen to the body tissues.
Indicate	To point out (a particular remedy treatment, etc.) as suitable or necessary.
Induction of labor	Labor brought on by artificial means.

APPENDIX I

Inertia, uterine	Sluggishness of uterine contractions.
Intrauterine catheter	A tube placed inside the uterus used for fetal monitoring.
Intrapartum	During the process of labor.
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.
Malformation	Defective or abnormal formation, deformity.
Malpresentation	A faulty, abnormal, or untoward fetal presentation.
Marcaine	A brand of bupivacaine (see bupivacaine).
Maturity studies	Studies of the degree to which the fetus is mature.
Meconium	Fecal matter discharged by the newborn. It is a dark green substance, consisting of mucus, bile, and epithelial shreds.
Meperedine (demerol)	A narcotic, analgesic, antispasmodic and sedative drug.
Mepivacaine (carbocaine)	A local anesthetic given by injection.
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.
Multiple regression	A method of statistical analysis.

Neonatal depression	A reduction or slowing down of a number of physiological functions: respiration, heart rate, mobility, etc.
Neonate	A baby less than 4 weeks of age.
Obstetrics	The art and science of caring for pregnant women.
Oxytocic	Agent which stimulates uterine contractions, given to speed the process of childbirth.
Paracervical	Around the cervix.
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.
Perineal distention	Swelling of the floor of the pelvis.
Perineum	Loosely, the floor of the pelvis. In obstetrics, the tissues between the lower end of the vagina and the anal canal and lower rectum.
Pitocin	Trademark for oxytocin injection, an oxytocic posterior pituitary hormone preparation.
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; preceding birth.
Prilocaine	A local anesthetic given by injection.
Prolapsed cord	The presence of the umbilical cord beside or ahead of the presenting part.
Prospective	Future; studies carried out on patients or records available now for the future.

Prostaglandin	Active biologic substance which affects the cardiovascular system and the smooth muscles. It stimulates the uterus to contract.
Renal	Of or pertaining to the kidneys or the surrounding regions.
Respiratory distress syndrome (RDS)	A poorly defined disease of newborns, characterized by cyanosis, abnormal respiratory pattern, grunting respiration, and retraction of the chest wall during respiration.
Retrospective	(1) Directed to the past; contemplative of past events, etc. (2) looking or directed backward.
Stillbirth	The birth of a dead fetus.
Stimulate	Excite to functional activity.
Tachycardia	Excessive rapidity in the activity of the heart.
Tetanic contraction	One during which the muscle remains tense for some time.
Toxemia of pregnancy	A specific complication of pregnancy characterized by a sustained rise in blood pressure and often by edema and albuminuria (preeclampsia) and occasionally by convulsions (eclampsia).
Traction	The act of drawing.
Umbilical cord	The attachment connecting the fetus to the placenta.
Uterine rupture	Forcible breaking or tearing of the uterus.
Uterus	The womb; a hollow muscular organ, in which the embryo and fetus develop.

APPENDIX I

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.

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

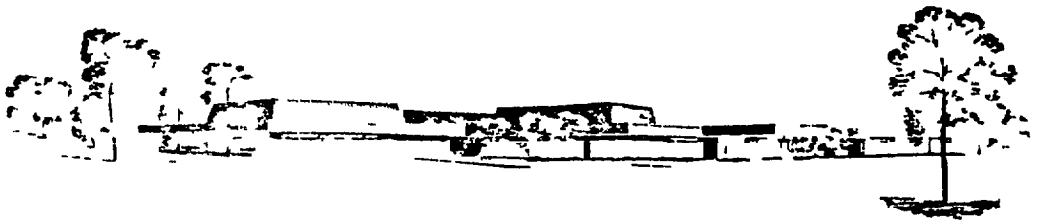
SUMMARY CHART NUMBER EIGHT

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

APPENDIX II



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)

APPENDIX II

MEMORANDUM REPORT

U S PAS HOSPITALS PROVIDING OBSTETRIC SERVICES

General Accounting Office
Rockville, MD

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, ne ve 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 10 7 7 76

APPENDIX II

MEMORANDUM REPORT

U S PAS HOSPITALS PROVIDING OBSTETRIC SERVICES (continued)

Group Title	H-ICDA-2[1] Code Range: Final Diagnosis	H-ICDA-2[1] Code Range: 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

(102035)

* U S GOVERNMENT PRINTING OFFICE 1979 - 620-167/314

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

SPECIAL FOURTH CLASS RATE
BOOK