Use of Diagnostic Imaging Procedures and Fetal Monitoring Devices in the Care of Pregnant Women

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Synopsis

Medical devices and diagnostic imaging procedures such as ultrasound, X-rays, and electronic fetal monitoring devices are used in the medical care of many pregnant women today. The responsibility for the safety and effectiveness of these diagnostic technologies is shared by a number of Public Health Service agencies, one of which is the Center for Devices and Radiological Health (CDRH), a unit within the Food and Drug Administration.

The CDRH collaborated with the National Center for Health Statistics (NCHS) in conducting a study of recent trends in the uses of diagnostic ultrasound, medical X-rays, and electronic fetal monitoring devices in the medical care of pregnant women. This study used data from the 1980 National Natality and Fetal Mortality Surveys and the 1987 pretest to the National Maternal and Infant Health Survey. Hospitals and prenatal care providers of the pregnant women contributed information regarding the use of these medical devices.

Between 1980 and 1987, ultrasound use more than doubled, increasing from 33.5 percent of pregnancies in 1980 to 78.8 percent in 1987 ($P<0.001$). More ultrasound examinations were performed earlier in gestation in 1987 than in 1980, with 10.1 percent being performed during the first trimester in 1987, compared with 6.9 percent in 1980 ($P<0.001$). Use of external electronic fetal monitoring devices during delivery also increased significantly between 1980 and 1987, from 33.5 percent to 74.6 percent ($P<0.001$). Use of medical X-rays among women with live births remained relatively unchanged, 15.0 percent in 1980 and 15.3 percent in 1987 ($P=.282$). The implications of these trends are discussed.

THE USE OF ADVANCED MEDICAL technology has become a basic component of maternal and infant health care today. Medical devices and diagnostic imaging procedures, such as ultrasound, X-rays, and external and internal electronic fetal monitoring devices, are now used in the medical care of many pregnant women and their infants.

Several Federal agencies share the responsibility for protecting the public health in the fields of medical device technologies and radiological health. For example, the Center for Devices and Radiological Health (CDRH), a unit within the Food and Drug Administration (FDA), develops and implements national programs that are intended to assure the safety, effectiveness, and proper labeling of medical devices, to control unnecessary human exposure to potentially hazardous ionizing and nonionizing radiation, and to ensure the safe, efficacious use of such radiation.

In 1963 and 1980, the CDRH collaborated with the National Center for Health Statistics (NCHS) in conducting periodic population-based studies to determine the exposure of pregnant women and their infants to medical devices and radiation procedures (*1, 2*). More recently, in 1988, the CDRH collaborated with the NCHS again to design and conduct a national maternal and infant health survey to collect information on the use of medical devices and radiation procedures in pregnancy, delivery, and infancy (see box). The National Maternal and Infant Health Survey (NMIHS) was conducted in 1988 by the NCHS with the cosponsorship of 13 Federal agencies. Data processing for the NMIHS is ongoing and will be completed in late 1990 or early 1991.

A pretest of the NMIHS was conducted in four States between October 1987 and January 1988. We describe the design and methodology of the NMIHS relative to medical devices and diagnostic imaging procedures and present findings from the pretest regarding the use of selected medical devices and diagnostic imaging procedures during pregnancy and delivery.

Contents of the National Maternal and Infant Health Survey Relative to Medical Devices and Diagnostic Imaging Procedures Used in the Medical Care of Pregnant Women and Their Infants

Prenatal Care

Medical X-rays (data collected on frequency, timing, kind, and medical indication)
Diagnostic ultrasound: fetal doptone devices[1], sonograms (data collected on frequency, timing, medical indication)
Chorionic villus sampling: transabdominal, transcervical
Amniocentesis (data collected on frequency, timing, medical indication)
Alpha-fetoprotein testing: amniotic fluid, maternal serum (data collected on frequency, timing, results)[1]
Pregnancy confirmation testing: home use[1], provider-administered

Intrapartum Care

Amnioscopy
Fetal EKG (scalp)
External fetal monitoring: electronic, ultrasound
Internal fetal monitoring
Sonogram of fetus
Monitoring uterine contractions by hand[1]
Periodic auscultation[1]

Neonatal Care

Infant apnea monitor: hospital use[1], home use
Respirator
Diagnostic ultrasound of head or neck
Phototherapy for hyperbilirubinemia[1]
Oxygen therapy: hospital use, home use
Total parenteral nutrition: hospital use, home use
Umbilical artery catheterization
Gavage or tube feeding at home
Infant heart rate monitoring at home

[1] Added to the national survey after the pretest.

Design and Methodology

The NMIHS was the equivalent of a combined national natality, fetal mortality, and infant mortality survey. The objective of the NMIHS was to study factors related to the following poor pregnancy outcomes: fetal loss, low birth weight, infant illness, and infant death. A detailed description of the design and methodology of the entire national survey is published elsewhere (*3*). In the NMIHS, sources of information on the use of medical devices and diagnostic imaging procedures included mothers who experienced a live birth, a fetal loss, or an infant death in calendar year 1987; hospitals where the births and deaths occurred; and prenatal care providers. Mothers, hospitals, and health care providers were asked to provide detailed information on the use of selected medical devices and diagnostic imaging procedures in pregnancy, delivery, or infant care. Data were collected on some devices and procedures relative to the timing of use, frequency of use, medical indications for use, and test results. The adequacy of response rates in the pretest, sensitivity issues, and difficulties in completing the questionnaires were published elsewhere (*4*). Response rates for the pretest were as follows: live birth mothers, 85.8 percent; stillbirth mothers, 82.7 percent; infant death mothers, 82.1 percent; hospitals, 93.0 percent; prenatal care providers, 74.8 percent.

Participation of the mothers in the survey was voluntary. The confidentiality of all information collected was protected by Section 308(d) of the Public Health Service Act (42 U.S.C. 242m). Signed consent statements were obtained from the mothers to request release of data from the medical records of mothers and infants. After the mothers had consented, their hospitals and health care providers were contacted. The mothers, hospitals, and health care providers contributed information through mail questionnaires, or if necessary, by telephone or personal interviews with interviewers from the Bureau of the Census.

We analyzed data from the pretest on the use of ultrasound, X-rays, and electronic fetal monitoring devices as reported by the hospitals and prenatal care providers. The purpose of analyzing the pretest data was to characterize broad trends in recent use patterns of selected medical devices and procedures and to highlight areas that warrant more detailed analyses in the national survey. Data in the pretest were weighted to adjust for an oversampling of mothers with low birth weight, live born infants. We compared the 1987 pretest results with findings from two national surveys conducted in 1980, the 1980 National Natality Survey (NNS) and the National Fetal Mortality Survey (NFMS) (*5,6*). A two-tailed Fisher's exact test was performed to test for statistical significance between the 1987 data and the 1980 data.

Results

Diagnostic ultrasound. The percentages of women with live births and stillbirths exposed to diagnostic ultrasound (sonogram) during pregnancy are shown in table 1. Diagnostic ultrasound use during pregnancy increased significantly between 1980 and 1987. Significant increases occurred among both live births and stillbirths. Diagnostic ultrasound use increased from 33.5 percent to 78.8 percent among women with live births ($P<.001$), and from 53.4 percent to 71.9 percent among women with stillbirths ($P=.026$).

Results on the timing of ultrasound examinations in pregnancy, categorized by trimester of pregnancy, are

shown in table 2. The percentages of ultrasound examinations performed during the first and second trimesters increased significantly ($P<.001$) between 1980 and 1987. Sonograms performed during the first trimester increased from 6.9 percent to 10.1 percent ($P<.001$), and during the second trimester, they increased from 35.1 percent to 57.0 percent ($P<.001$). Sonograms performed during the third trimester decreased significantly between 1980 and 1987 ($P<.001$), from 58.0 percent to 32.9 percent.

The frequencies of medical indications (reasons) for performing an ultrasound examination during pregnancy are shown in table 3. Among women with live births, the most common medical indication reported was to establish dates or gestational age. Approximately 47 percent of the sonograms performed during pregnancy among women with live births were performed for this reason. Among women with stillbirths, the most common medical indication reported was to detect fetal death. Approximately 33 percent of the sonograms performed during pregnancy among women with stillbirths were performed for this reason.

Medical X-rays. The percentages of women with live births and stillbirths exposed to medical X-rays during pregnancy are shown in table 1. Among women with livebirths, use of medical X-rays remained unchanged, 15.0 percent in 1980 and 15.3 percent in 1987 ($P=.282$). Use of medical X-rays decreased among women with stillbirths between 1980 and 1987. The decrease was not statistically significant, however ($P > .05$).

Electronic fetal monitoring devices. The percent of women with live births exposed to electronic fetal monitoring devices during delivery is shown in table 4. The use of external electronic fetal monitoring devices increased significantly between 1980 and 1987, from 33.5 percent to 74.6 percent ($P<.001$). The use of internal fetal monitoring devices also increased significantly, from 16.5 percent in 1980 to 19.7 percent in 1987 ($P<.001$).

Discussion

The NMIHS pretest data suggested a number of broad, interesting trends regarding use of medical devices and diagnostic imaging procedures during pregnancy and delivery. One major finding was the marked increase in use of diagnostic ultrasound in recent years. Between 1980 and 1987, diagnostic ultrasound use increased from 33.5 percent to 78.8 percent among women with live births ($P<0.001$) and from 53.4 percent to 71.9 percent among women with stillbirths

Table 1. Percentage of pregnancies in which diagnostic ultrasound and medical X-rays were used, 1980 and 1987

Medical examination	*1980*[1]	*1987*[2]	*P-value*[3]
Diagnostic ultrasound:			
Live births	33.5	78.8	<.001
Stillbirths	53.4	71.9	.026
Medical X-rays:			
Live births	15.0	15.3	.282
Stillbirths	23.4	10.0	.057

[1] Reference 5.
[2] National Maternal and Infant Health Survey Pretest.
[3] *P*-value based on Fisher's exact test.

Table 2. Percent distribution of ultrasound examinations among women with live births, 1980 and 1987

Trimester	*1980*[1]	*1987*[2]	*P-value*[3]
First (1-12 weeks)	6.9	10.1	<.001
Second (13-28 weeks)	35.1	57.0	<.001
Third (29 or more)	58.0	32.9	<.001
Total	100.0	100.0	...

[1] Reference 6.
[2] National Maternal and Infant Health Survey Pretest.
[3] *P*-value based on Fisher's exact test.

($P=0.026$). The finding that 78.8 percent of all women with live births in 1987 received an ultrasound examination during pregnancy suggested that this imaging procedure was performed on a nearly routine basis in the United States. A number of factors may have spurred the growth of ultrasound use in the last decade, including the perceived safety and benefit of ultrasound examinations in pregnancy, the increased availability and accessibility of ultrasound equipment in physicians' offices and labor rooms, third-party reimbursement payments, and the rapid expansion and advancement of ultrasound technology in obstetric care through the development of new clinical applications.

When the use of diagnostic ultrasound in pregnancy was extensively evaluated 6 years ago by a panel of experts at a National Institutes of Health (NIH) Consensus Development Conference, the panel concluded that the scientific evidence did not allow a recommendation for routine ultrasound screening, and it therefore recommended the selective use of diagnostic ultrasound in pregnancy, based upon medical indications (*7*). More recently, in May 1988, the American College of Obstetricians and Gynecologists stated that more studies were needed to establish the role of routine diagnostic ultrasound use in pregnancy (*8*). Besides these health organizations, various other groups in the United States currently support selective ultrasound, including policy makers, insurance carriers, consumer groups, and the

Table 3. Medical indications for ultrasound examinations in pregnancy among women with live births and stillbirths, 1987 (percentages)

Medical indication	*Live births*	*Stillbirths*
Establish dates or gestational age	47	14
Fetal position determination	23	11
Confirm fetal life	14	6
Placental location	11	6
Fetal growth assessment	9	8
Multiple pregnancy determination	9	8
Pregnancy diagnosis	2	0
Fetal death detection	0	33
Abnormal alpha-fetoprotein	0	11

NOTE: Percents may not equal 100 because of multiple indications and exclusion of some indications from this table.
SOURCE: National Maternal and Infant Health Survey Pretest.

Table 4. Percentage of women with live births exposed to fetal monitoring in delivery: 1980 and 1987

Method	*1980*[1]	*1987*[2]	*P-value*[3]
External	33.5	74.6	<.001
Internal	16.5	19.7	<.001

[1] Reference 5.
[2] National Maternal and Infant Health Survey Pretest.
[3] *P*-value based on Fisher's exact test.

International Childbirth Education Association (*9*). Michael Bracken of Yale University Medical School stated recently in the literature that "routine ultrasound has not been scientifically justified and must still be considered an experimental technique" (*10*). Stephen Thacker of the Centers for Disease Control in Atlanta, GA, assessed the quality of recently published randomized controlled trials on routine ultrasound in pregnancy and found that they failed to demonstrate adequately the usefulness of imaging ultrasound as a screening procedure for all pregnant women (*11*). Bernard Ewigman of the University of Missouri-Columbia School of Medicine also concluded in a recently published review that no improvement in perinatal morbidity and mortality has been shown with routine ultrasound testing compared with selective ultrasound testing (*12*).

Another trend suggested by the pretest was that ultrasound examinations were performed earlier in pregnancy in 1987 than in 1980. The NMIHS pretest showed that the percent of ultrasound examinations performed in the first trimester increased significantly, from 6.9 percent in 1980 to 10.1 percent in 1987 ($P<.001$), while the percent of ultrasound examinations performed in the third trimester decreased significantly, from 58.0 percent to 32.9 percent ($P<0.001$). The trend toward increased ultrasound use during the first trimester of pregnancy highlights another area that needs to be investigated further in the national survey. The first trimester, which lasts from the 1st to the 12th week of gestation, is a period when major organ systems are developing, and the fetus is most susceptible to injuries from external stimuli (*13*). Within the first trimester, the period of organogenesis lasts from the third to the eighth week of gestation. Our finding of a significant increase in first trimester ultrasound use raises the question of whether the increases occurred before or after organogenesis. Although the 1987 pretest data did not allow for reliable analysis of what proportion of first trimester ultrasound exposures occurred before and after organogenesis, data from the main survey, conducted in 1988, will be used to investigate the precise timing of diagnostic ultrasound exposure in relation to organogenesis during the first trimester.

A third trend suggested by the pretest was that, despite the large increases in use of diagnostic ultrasound, medical X-ray examinations during pregnancy were still utilized to some degree. Our data showed that medical X-ray examinations did not decline significantly among women with stillbirths and remained relatively unchanged among women with live births. During the planning stages of the 1987 pretest, the question which would have distinguished between X-ray pelvimetry and other X-ray examinations was excluded from the pretest questionnaire because of time considerations. Therefore, the 1987 pretest data did not distinguish between X-ray pelvimetries and other X-ray examinations. Given the known risks of ionizing radiation to the fetus, however, the current use of medical X-ray examinations during pregnancy is still substantial and deserves continued monitoring in the future.

Recently, a study by the CDRH and the NCHS reported that 7.0 out of 18.1 X-ray examinations per 100 pregnant women were X-ray pelvimetry examinations in 1980 (*14*). The study also demonstrated that the total number of X-ray pelvimetries increased between 1963 and 1980, from 5.1 to 7.0 X-ray pelvimetries per 100 pregnant women. Based on this documentation of a rise in X-ray pelvimetries between 1963 and 1980, the CDRH was instrumental in incorporating the pelvimetry question into the 1988 NMIHS main survey questionnaire to continue to monitor this radiation procedure. Our pretest finding of the small decline in total medical X-ray use in pregnancy between 1980 and 1987 provided another reason for the need to continue to monitor the use of X-ray pelvimetry in pregnancy.

A fourth trend demonstrated by the pretest was a dramatic increase in the use of external electronic fetal monitoring devices during labor and delivery and a modest increase in the use of internal fetal monitoring devices. A significant rise occurred in the use of exter-

nal electronic fetal monitoring devices among women with live births between 1980 and 1987, from 33.5 percent to 74.6 percent ($P<0.001$) and in the use of internal fetal monitoring devices, from 16.5 percent to 19.7 percent ($P<.001$). The greater increase in use of external fetal monitoring devices may be related to the less invasive nature of their use compared with internal fetal monitoring devices.

In summary, findings from the NMIHS pretest suggested recent trends toward nearly routine use of diagnostic ultrasound examinations and external electronic fetal monitoring devices in the medical care of pregnant women, while the use of medical X-ray examinations in pregnancy has not changed substantially.

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Providing Cost Efficient Detoxification Services to Alcoholic Patients

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Synopsis

The literature was reviewed to determine whether social model detoxification programs are safe and adequate for treating persons with alcohol withdrawal symptoms.

The alcohol withdrawal syndrome has three stages. Each stage, more severe than the last, is reached by a smaller percentage of those withdrawing from alcohol. The literature showed that the majority of alcoholics can be detoxified safely in social model programs. These programs presented two main benefits, program cost efficiency and the patients' increased commitment to treatment compared with those treated at medical model programs. Medically operated detoxification programs appeared necessary for patients with a severe withdrawal condition at intake (abnormal blood pressure and pulse) and those with a history of severe withdrawal symptomatology.

The results of the review reiterated the importance of screening clients at intake to ensure the safety of the patient and the appropriateness of the detoxification program.

THE CONCEPT OF DETOXIFICATION as part of a comprehensive system for alcohol related services has been established over the years. Detoxification occupies a central position in the overall management of alcoholic patients.

There has been increasing emphasis on containing