# Should Ultrasound Be Used Routinely During Pregnancy?

## An Affirmative View

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he controversy over screening obstetric sonography in this country has gone unabated since the late 1970s and early 1980s. Little doubt of the utility of this procedure has existed in European countries, such as Germany and Sweden, which actually mandate its use in their national health services, 1,2 but questions regarding safety and cost effectiveness were not thought to be completely answered by those practicing in this country. Consequently, in 1984 the National Institutes of Health, in a consensus development conference statement on obstetric ultrasound, formulated a list of medical indications for selective obstetric ultrasound examinations (Table 1).3 Since then the controversy has persisted. Many physicians practicing obstetrics have continued to use routine screening sonography, while others have not. In the author's opinion, there are many compelling reasons to use routine scanning in early pregnancy. What follows is a review of these reasons as well as an exploration of their validity.

It should first be emphasized that screening in low-risk populations is generally thought to be best done at 16 to 18 weeks' gestation,<sup>4</sup> even though it is also widely accepted that pregnancy dating is most accurate at an earlier date, at 7 to 9 weeks. Although crown-rump length is generally thought to be a better dating tool than biparietal diameter or femur length,<sup>5</sup> the increasing sophistication of ultrasound equipment allows excellent pregnancy dating to be accomplished at somewhat later screening dates, even up to 20 weeks of gestation. Routine scanning at this time allows greater accuracy in diagnosing abnormalities not detected with earlier screening.

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#### BENEFITS OF ROUTINE ULTRASOUND

#### **Early Pregnancy Dating**

To establish an accurate growth curve, it is essential to scan early, ie, at 16 to 18 weeks. When the initial examination is done later in pregnancy, it is impossible to be certain of gestational age. In a previous study,<sup>6</sup> 66% of 3315 patients delivered within 7 days of their ultrasonic estimated date of delivery, compared with 49% of the same group who delivered within 7 days of their historical estimated date of delivery.

#### **Intrauterine Growth Retardation**

An accurate diagnosis of intrauterine growth retardation cannot be made unless the initial pregnancy dating is done before 20 weeks. An initial sonographic examination when intrauterine growth retardation may first be suspected, such as at 32 to 36 weeks, is notoriously inaccurate unless an earlier determination is available for comparison.<sup>1</sup>

#### **Multiple Pregnancies**

The capacity to be extremely accurate in the diagnosis of multiple pregnancy, even in very early pregnancy, is a highly compelling reason for routine obstetric scanning because pregnancy management intervention is always indicated with this diagnosis. The importance of special management of multiple pregnancy was especially highlighted by Medearis et al<sup>8</sup> in 1979, who were able to show that a 1% incidence of twin pregnancies in Missouri accounted for 10.1% of all perinatal deaths in the state. Early diagnosis of multiple pregnancy should reduce the disproportionate perinatal morbidity and mortality associated with this group. The author's experience at one medical center revealed a fivefold decrease in twin perinatal mortality in a

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# TABLE 1. NIH CONSENSUS ON OBSTETRIC ULTRASOUND: MEDICAL INDICATIONS FOR SELECTIVE OBSTETRIC ULTRASOUND EXAMINATIONS<sup>3</sup>

Estimation of gestational age for patients with uncertain clinical dates, or verification of dates for patients who are to undergo scheduled elective repeat cesarean delivery, indicated induction of labor, or other elective termination of pregnancy

Evaluation of fetal growth

Vaginal bleeding of undetermined etiology in pregnancy

Determination of fetal presentation

Suspected multiple gestation

Adjunct to amniocentesis

Significant uterine size or clinical dates discrepancy

Pelvic mass

Suspected hydatidiform mole

Adjunct to cervical cerclage placement

Suspected ectopic pregnancy Adjunct to special procedures

Suspected fetal death

Suspected uterine abnormality

Intrauterine contraceptive device localization

Ovarian follicle development surveillance

Biophysical evaluation for fetal well-being

Observation of intrapartum events

Suspected polyhydramnios of oligohydramnios

Suspected abruptio placentae

Adjunct to external version from breech to vertex presentation

Estimation of fetal weight or presentation in premature rupture of membranes or premature labor

Abnormal serum *a*-fetoprotein value

- Follow-up observation of identified fetal anomaly
- Follow-up evaluation of placenta location for identified placenta previa

History of previous congenital anomaly

Serial evaluation of fetal growth in multiple gestation

Evaluation of fetal condition in late registrants for prenatal care

population routinely scanned as opposed to a population selectively scanned. $^{6}$ 

#### **Placental Localization**

It is widely known that apparent placenta previa and lowlying placentas frequently are noted in early pregnancy scanning. Although the vast majority of these placentas "migrate" cephalad as the lower uterine segment develops during pregnancy, this finding does alert the physician to be aware of potential problems in the pregnancy.

#### **Fetal Anomalies**

A significant potential benefit of routine screening is the antenatal detection of fetal anomalies. Anomalies are difficult, if not impossible, to diagnose clinically, and most occur in pregnancies without identifiable risk factors.<sup>9</sup> Structural fetal anomalies can be identified as early as 16 to 18 weeks' gestation with sonography.<sup>7</sup> The detection of such lethal fetal abnormalities as anencephaly can aid decision making for selective pregnancy termination. In the case of some anomalies, such as omphalocele or gastroschises, foreknowledge of the abnormality assists in planning a mode of delivery and prompt intervention in the care of the neonate.<sup>10</sup>

Diagnosis of other fetal conditions, such as nonimmune hydrops and obstructive uropathy, may help in the antenatal treatment of the fetus.<sup>7</sup> As fetal surgery becomes more sophisticated, antenatal interventions may increase.

#### **Unsuspected Maternal Abnormalities**

Often overlooked and little discussed are maternal complications, anatomic and otherwise, that may be diagnosed by routine screening. Critically situated uterine fibroids will alert the physician to potential later problems. Adnexal pathology and its implications are obvious. Uterine anomalies, especially duplication anomalies, can also result in a difficult course in later pregnancy. The patient's awareness of such problems and her ability not only to plan with her husband and physician the future course of the pregnancy but also to understand the implications of the treatment regimen are potential benefits.<sup>7</sup>

#### **Behavioral and Psychological Effects**

Emotional benefit is a little-emphasized facet of the controversy on routine screening. There is no question that mothers and fathers are anxious in the first and second trimesters of pregnancy, and the relief of anxiety they derive from a normal screening test result is difficult, if not impossible, to measure. Any practicing obstetric nurse or physician has noted, on almost every occasion following normal findings on a routine sonogram, the immense relief of the expectant couple at the prospect of a healthy offspring.<sup>7</sup> Not to be forgotten is the maternal bonding that occurs as a result of the procedure as well as the paternal awareness of the developing infant. Frequently the father is an overlooked bystander in the pregnancy process; sonography brings him into the family picture at a very early date.

Another potential benefit of routine scanning is the greater ease of obtaining patient compliance for the remainder of the pregnancy. Whether the result of the screening examination is normal or abnormal, the patient's understanding of the pregnancy can motivate her to follow the physician's counsel and advice more willingly and readily.

#### SAFETY OF ULTRASOUND IN PREGNANCY

Even with the increased frequency during the last 20 years of ultrasound use in pregnancy, no evidence to date has revealed any untoward effects on the fetus that can be detected clinically. There have been multiple experimental studies showing that ultrasound has such biologic effects as decreased immune response, changes in sister chromatid exchange frequency, cell death, changes in cell membrane function, reduced cell reproductive potential, and so on. It is necessary to realize, however, that very high energy levels (>100 mW/cm<sup>2</sup>) were used in these studies. In many cases the results have not been reproducible by other investigators. Using diagnostic levels of ultrasound in the clinical situation has not been shown to cause any demonstrable effects on behavior or on neurologic development of the fetus.<sup>11</sup> The few studies showing an association with possible effects have been strongly criticized. The European Committee for Ultrasound Radiation Safety concluded that no short-term growth defects resulting from diagnostic ultrasound have been observed after 20 years. The committee concluded that "routine screening of every woman during pregnancy is not contraindicated by the evidence currently available from biologic investigations."12 Current recommendations by the NIH Consensus Development Panel<sup>3</sup> state that scanning should not be extended to view the baby at length, to obtain a picture, or to determine the sex. These recommendations, however, may have been made without consideration of potential psychologic benefit from these activities.7 It appears that although the safety issue is still unresolved, the overwhelming preponderance of evidence at this time would indicate that no untoward fetal effects using current diagnostic levels of ultrasound can be anticipated.

# ROUTINE VS SELECTIVE ULTRASOUND EXAMINATION

In a series of 3315 patients who were routinely scanned, 519 patients (16%) were identified who failed to be covered under the liberal NIH consensus indications.<sup>6</sup> Correcting for 248 placenta previae that resolved on follow-up scanning, the 271 remaining patients still constituted 8% of the patient population. Pregnancy management intervention in this number of patients would appear significant.<sup>6</sup>

Unfortunately, when selective criteria are used, the scan is usually performed later in pregnancy, when dating conception and assessing growth retardation are less accurate. As already mentioned, maximal clinical information is obtained when the scan is performed at 16 to 18 weeks of gestation.

There have been four randomly controlled prospective studies<sup>13-16</sup> that were designed to evaluate the routine use of obstetric ultrasound, but only the study by Eik-Nes et al<sup>13</sup> was thought to be supportive of routine examination. In this study, three perinatal deaths occurred among the routinely screened patients, whereas eight deaths occurred in selectively examined groups.<sup>13-16</sup> Because all of these studies had small numbers, even when pooled, a large multicenter, prospective, randomly controlled study will be necessary to decide the value of routine vs selective ultrasound scanning. Jack et al<sup>7</sup> estimated that a trial of more than 46,000 women in each group would be necessary to arrive at any meaningful conclusions.

# COST EFFECTIVENESS OF ROUTINE SCANNING

Cost effectiveness, of course, must be related to the other bottom line—fetal outcome. To determine whether routine ultrasound screening is cost effective will require the above-mentioned multicenter, prospective, randomly controlled study for a definitive answer. Such a study can reveal whether unnecessary inductions for misdiagnosed intrauterine growth retardation or postmaturity can be reduced with routine scanning, or whether perinatal morbidity and mortality can be decreased with routine scanning. It is anticipated that large, multicenter, randomized-controlled studies will bear out past favorable observations.<sup>6</sup>

Cost effectiveness has also been examined from a variety of viewpoints. Who is doing the scanning? A radiologist? An obstetrician? A family physician? Obstetricians and family physicians in their offices? Scanning technicians in their own offices? For obvious reasons, the cost range is tremendous, varying from \$50 to \$360 with a median of \$100. An unpublished NIH study indicates the cost-benefit ratio of ultrasound testing is even<sup>17</sup>; that is, for every dollar spent on screening, a dollar is saved for the medical cost.

Cost effectiveness of routine obstetric scanning will be decided only with large randomized clinical trials, and even then, an adverse cost-benefit ratio may be offset by many of the intangibles outlined above.

#### COMMENT

Although the author is firmly convinced that routine scanning in pregnancy is not only beneficial but indicated, some continue to believe that selective scanning is more prudent and, of course, less expensive. It is interesting to note that while a more conservative approach is espoused in theory, in practice routine scanning is performed in most areas of the country, not because of the medical indications listed in the NIH guidelines, but because of patient demand. In fact, it is not uncommon for an ultrasound scan to be done at the initial obstetric visit, although at only several weeks' gestation, often before the patient has seen her physician.

I continue to affirm my conviction that timely and routine scanning in early pregnancy is beneficial.

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### **An Opposing View**

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The ability to visualize the fetus with ultrasonography has dramatically changed the practice of obstetrics. Physicians caring for pregnant women can now determine gestational age and diagnose abnormalities during pregnancy with much greater accuracy than before the availability of sonography. The use of sonography in problem pregnancies, called *selective ultrasound*, is widely accepted.<sup>1-4</sup>

The perceived utility of selective ultrasound, however, has led to the routine use of ultrasound in pregnancy in Great Britain and several European countries.<sup>5-8</sup> An unknown but probably increasing number of physicians in the nificant implications in antepartum management. Mo Med 1986; 83(2):93-98.

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United States have decided to recommend such routine ultrasound testing to their patients. Yet, the report of the National Institutes of Health Consensus Conference on Ultrasound Imaging in Pregnancy stated in 1984 that routine ultrasound testing could not be recommended because of a lack of conclusive evidence regarding its risk and efficacy.<sup>3</sup> More recently, in May 1988, the American College of Obstetricians and Gynecologists stated that more studies were needed to establish its role.<sup>2</sup>

There are several conditions detectable by routine ultrasound testing that are associated with increased morbidity and mortality. These conditions include errors in gestational age, twins, intrauterine growth retardation, congenital anomalies, placenta previa, macrosomia, and fetal malpresentation. In six clinical trials, however, the use of routine ultrasound examination to detect such conditions has not resulted in improved perinatal outcomes.<sup>9-14</sup> This article reviews the evidence that leads to the conclusion that the benefits of routine prenatal ultrasonography have not yet been established.

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# CRITERIA FOR USE OF ULTRASOUND AS A SCREENING TEST

Since routine ultrasonography is performed to detect unsuspected conditions, it is a screening test. As such, routine ultrasound examination must meet several criteria to justify its use.<sup>15</sup> It must have a high enough sensitivity to avoid missing problems, and an acceptably high specificity to avoid working up too many false-positive diagnoses. Patients should find it comfortable, accessible, and quickly performed. It should not cause adverse effects for the mother or fetus. Effective therapy should be available for problems detected. In addition, early diagnosis in the screening phase must offer therapeutic benefits compared with later diagnosis by selective ultrasonography. Finally, the benefits of routine ultrasound testing should justify its cost as measured in economic terms as well as in human suffering.

# SENSITIVITY, SPECIFICITY, AND PREDICTIVE VALUE

The sensitivity, specificity, and predictive value of ultrasound diagnosis varies with the condition detected.<sup>4</sup> Assessment of gestational age, detection of multiple gestation, and diagnosis of congenital anomalies can be attained reliably with sonography under optimal conditions.<sup>4,16–21</sup> Case reports of misdiagnosis of congenital anomalies, however, illustrate the importance of accuracy in prenatal sonography.<sup>22</sup> Mistakes are more likely with universal ultrasound screening, since accuracy is likely to be less than that reported by experts. In addition, false-positive diagnoses are more frequent in screening programs because of the low prevalence of abnormalities in low-risk populations.<sup>15</sup>

Intrauterine growth retardation (IUGR) is a good example with which to illustrate the importance of sensitivity, specificity, and predictive value with routine ultrasound use. In the three clinical trials in which results of screening for IUGR have been reported, there were 162 small-for-gestational-age (SGA) infants born out of 2631 pregnancies (6.2%).<sup>10,12,14</sup> If ultrasound screening for IUGR is 94% sensitive, the highest value reported,<sup>12</sup> 152 IUGR fetuses would have been detected in the pooled sample. Using the only specificity value reported (90%),<sup>12</sup> then 263 of the 2631 non-IUGR infants would have been falsely diagnosed as having IUGR. The positive predictive value of an ultrasound diagnosis of IUGR under these circumstances is only 36.6% (true-positive [152]/true-positive [152] + false-positive [263]).

Women whose fetuses are labeled as IUGR experience not only anxiety and the costs and risks of antepartum testing, but frequently inductions of labor and cesarean sections. Even with the best reported sensitivity and specificity, the diagnosis of IUGR by routine ultrasonography is incorrect nearly twice as often as not. Although the unnecessary interventions that result from these false-positive diagnoses could be justified by the benefit of detecting the truly growth-retarded fetuses, there was no such benefit reported in any of the three trials. Finally, reported accuracy of ultrasound diagnosis of IUGR is commonly lower than that used in this example.<sup>10,14</sup>

#### PATIENCE ACCEPTANCE

In contrast to screening procedures like sigmoidoscopy, an ultrasound examination in pregnancy is not only acceptable to women but often requested by them. Recognizing images of her fetus on the screen is commonly a moving emotional experience for the woman, akin to quickening.<sup>23,24</sup> A photograph is often given to the woman, which becomes "the first baby picture," to be shown to family and friends. A pregnant friend may then ask her physician whether she, too, will get a picture of her baby during pregnancy. Ultrasound imaging of a healthy fetus may be one of the most enjoyable procedures in modern medical practice.

#### SAFETY OF DIAGNOSTIC ULTRASOUND

Ultrasound causes adverse biological effects in animal studies by heating tissue and by causing cavitation, which is the mechanical resonance of microscopic intracellular gaseous bubbles.<sup>25</sup> Definitive evidence excluding adverse bioeffects of ultrasound in humans must come from epidemiologic studies.

The few such studies reported to date have been inconclusive. Abnormal grasp and tonic neck reflexes were found in one study of infants exposed to ultrasound compared with those who were not.<sup>26</sup> Stark et al<sup>27</sup> reported an increased risk of dyslexia in children exposed to ultrasound during pregnancy.<sup>27</sup> In both studies, numerous comparisons were made, making those differences found to be likely due to chance. Other epidemiologic studies have found no increased risk of childhood cancer, hearing loss, decreased birthweight, or congenital anomalies attributable to diagnostic ultrasound exposure.<sup>14,28–32</sup>

This lack of evidence that diagnostic ultrasonography is harmful to the fetus may lead to an assumption that it has no biological risk when used in pregnancy. Yet epidemiologic research on ultrasound bioeffects and confidence in its safety are currently similar to that of the risk of fetal x-ray exposure before 1950.<sup>33</sup> Following several decades of use, adequately designed studies showed a twofold to threefold increased risk of leukemia in children with fetal x-ray exposure, for an incidence of 1:5000.<sup>33</sup> No current epidemiologic study of ultrasound exposure has an adequate sample to rule out an adverse consequence of even 1:2000.<sup>29</sup> Furthermore, no studies have a sufficient followup period to detect conditions in which there is a long latency, such as cancer. The lack of direct evidence linking human fetal ultrasound exposure with adverse outcomes in existing studies, although reassuring, cannot be interpreted to mean that there is no risk.

#### CLINICAL TRIALS OF ROUTINE ULTRASOUND

The efficacy of screening programs can ultimately be established only through clinical trials. At issue in this case is whether a policy of routine ultrasound results in better pregnancy outcomes than one of selective ultrasound use. Will earlier detection of twins, for example, by routine ultrasonography offer an opportunity for more effective treatment than later diagnosis by selective ultrasound testing on the basis of clinical evaluation? What are the outcomes by which routine ultrasound testing should be judged?

The critical outcome measure of any prenatal screening program is its impact on perinatal morbidity and mortality. Measures such as birthweight and admission to special care nurseries, while important, are only proxy measures of neonatal well-being. Secondary benefits, such as a decrease in labor induction for postdate pregnancies, may also occur.<sup>11,13,14</sup> The impact on other interventions, such as increased antenatal hospitalization and inductions for other reasons, however, must also be considered.<sup>14</sup>

Three clinical trials have evaluated the impact of one routine ultrasound examination during pregnancy.<sup>9,11</sup> In a British trial, 1062 patients requesting care received a routine ultrasound examination at 16 weeks' gestation.<sup>9</sup> There was no comparison with selective ultrasound. Physicians were provided with a report of the examination for one half of their patients, whereas the results were withheld unless requested in the other half. In addition, reports were subsequently requested in 30% of the control group for patient management, making the results difficult to interpret. There were no differences in birthweight distribution, Apgar scores at 1 minute, or perinatal mortality between the two groups.

In a trial in the Netherlands, 745 patients were randomly allocated to receive an ultrasound examination between 32 and 36 weeks or to receive usual clinical care.<sup>10</sup> Sensitivity of detection of SGA infants was superior in the ultrasound group (64%) compared with the clinical group (42%). Large-for-gestational-age infants were also detected with greater sensitivity in the ultrasound group (61% vs 13%). Unfortunately, the results of the ultrasound examinations were not provided to the physicians, and no measures of perinatal morbidity or mortality were reported.

The largest randomized trial of routine ultrasound testing was a Swedish study of 4997 patients.<sup>11</sup> The screened group received a single examination at 15 weeks. In the control group, physicians were allowed to order ultrasound examinations for indications after 19 weeks' gestation. Inductions for postdate indication and total inductions were significantly reduced by ultrasound screening (1.7% vs 3.7%, P < .0001 and 5.9% vs 9.1%, P < .0001). There were, however, no differences in operative deliveries. Other interventions, such as antepartum testing and antepartum hospitalization, were not reported. Although all twin gestations were detected by 18 weeks in the routine ultrasound group, the outcomes for twin infants as measured by birthweight, prematurity rate, and Apgar scores were the same in both groups. Furthermore, there were 12 perinatal deaths in each group, and four of the deaths in the screened group were from twin gestations, whereas there were no twin deaths in the control group. Mean birthweight was somewhat higher in the screened group (42 g), particularly among former smokers (75 g). The investigators hypothesize that this benefit resulted from maternal visualization of the fetus on the ultrasound screen, which led to quitting smoking and thereby increasing the birthweight of their fetuses, rather than any management decisions made by physicians as a result of diagnostic information from the screening sonogram.

There have been three clinical trials in which two routine ultrasound examinations have been assessed.<sup>12-14</sup> In a Scottish trial with a sample of 877, all subjects received a first trimester scan.<sup>12</sup> In addition, all patients had crown-rump length and trunk area measured between 32 and 36.5 weeks' gestation, but in only one half was a report given to the physicians. Sensitivity of SGA detection was 94% in the group in which third-trimester screening was reported compared with 31% by clinical detection in the group who received an early ultrasound examination but whose report on the third-trimester ultrasound examination was withheld. Despite this marked improvement in diagnostic efficacy, there were no differences found between the groups in antepartum admissions, induction rates, cesarean section rates, birthweight, Apgar scores, or perinatal deaths.

The other two trials evaluating two routine ultrasound examinations were both conducted in Norway. The trial by Eik-Nes and colleagues<sup>13</sup> involving 1628 patients has been reported only in letter format. The lack of details contained in the published results precludes a meaningful evaluation of the findings.

The study by Bakketeig et al<sup>14</sup> from Norway reported mixed results. One thousand nine patients were involved in a randomized trial of ultrasound screening at 19 and 32 weeks' gestation vs clinical care. Although there were fewer inductions for postdates (1.6% vs 4.0%, P < .05), the total induction rate was not significantly different (6.5% vs 7.9%, P = .40). Of the patients in the screened group, 15.5% were admitted to the hospital antenatally, compared with 9.2% of patients in the control group (P < .005). Only 25% of SGA infants were detected antenatally, perhaps because the study used inexperienced sonologists. Mean birthweight, incidence of low birthweight, and perinatal deaths were not significantly different between the groups.

In summary, clinical trials have not consistently reported significant improvement in perinatal morbidity and mortality attributable to ultrasound screening. None of the trials reviewed, however, had an adequate power to detect a clinically important improvement in perinatal morbidity and mortality. If an outcome measure of neonatal morbidity with an incidence of 5% were used, a sample of 15,500 would be required to achieve a 85% probability of detecting a 20% reduction in that outcome with a 5% risk of a type I error (two-tailed). The largest trial reported had a sample of only 4997, far fewer than required for outcomes occurring at a rate of 5% or less. In the four trials reporting perinatal deaths, there was a total of 44 deaths out of 8571 pregnancies (0.52%). Therefore, on the basis of these trials, the possibility of a beneficial effect of ultrasound screening on perinatal morbidity and mortality cannot be excluded. Future trials that achieve an adequate sample size are needed.

#### **COST-BENEFIT ANALYSIS**

No formal economic analyses have been published that assess the economic and noneconomic costs of routine ultrasound testing and then relate these costs to the benefits of the procedure. Since improvements in outcome are dependent on interventions on pregnancies in which problems are diagnosed early by screening ultrasound tests, it is expected that the cost of prenatal and intrapartum care would increase beyond the cost of providing the screening program.

# WHY IS USE OF ROUTINE ULTRASOUND RECOMMENDED BY SOME?

Since clinical trials have failed to show a benefit of routine ultrasound testing, the safety of fetal exposure to ultrasound has not been definitively established, and it is likely to cost more to screen than not to screen, then it is legitimate to ask why routine ultrasound testing is a controversial issue. Why do some support its use?

The primary reason is that the short-term success of any medical innovation such as ultrasonography is not determined by critical empirical evaluation of its intrinsic worth or risk.<sup>33,34</sup> The use of routine ultrasound testing has spread before adequate evaluation. This occurrence is not unique to ultrasonography; in fact, a pattern of diffusion of medical technology that includes "seven stages in the career of a medical innovation" has been defined.<sup>34</sup> The first stage consists of initial promising reports in the medical literature. In the case of ultrasonography, early literature published in the 1970s emphasized its superior diagnostic capabilities in descriptive studies,<sup>35–45</sup> and such studies continue to be reported at a prolific rate.<sup>46</sup> A recent example is a study reporting the superiority of ultrasound assessment of gestational age in which there is no control group and no measure of outcome reported.<sup>16</sup> These case series provide useful information, but they do not establish ultrasonography as an effective prenatal screening tool.

In the second, third, and fourth stages, professional organizations adopt the innovation, the lay public begins to expect it, then it becomes a standard part of medical care.<sup>3-6</sup> The results of clinical trials (the fifth stage) reviewed in this paper were published between 1980 and 1988.<sup>9-14</sup> The sixth stage consists of critical evaluation of clinical trials.<sup>3,47</sup>

The seventh stage consists of general discrediting of the procedure. Whether discrediting will happen in the case of routine ultrasound testing remains to be determined, since an overall favorable cost benefit may yet be demonstrated in larger clinical trials.

Routine ultrasound testing is controversial because it is in the fourth, fifth, or sixth stage of its career, depending on the geographic location. These stages are by nature controversial. It has progressed through these stages for the same reasons other medical innovations do. Adequate empirical research is expensive, difficult, and time consuming. Physicians and patients make decisions based on uncritical interpretation of early research findings. Physicians prefer diagnostic certainty; ultrasound screening is clearly superior in this regard. Finally, economic, medicolegal, and patient demand increase use of routine ultrasound examination for reasons other than improved perinatal outcome.<sup>48,49</sup>

#### CONCLUSIONS

Current empirical evidence does not support the use of ultrasonography as a screening procedure. No convincing improvement in perinatal morbidity and mortality has been shown with routine ultrasound testing compared with selective ultrasound testing. There remains uncertainty about the safety of fetal exposure to ultrasound. Falsepositive diagnoses are common with routine ultrasound screening, and the financial cost of screening with ultrasound is probably greater than not doing so. For these reasons, ultrasound should not be offered to patients as a routine part of prenatal care. Randomized trials with adequately large samples are needed to resolve the role of routine ultrasound screening during pregnancy.

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