



# Guideline for Ultrasound As Part of Routine Prenatal Care

*This clinical practice guideline (CPG) was developed by an Alberta Clinical Practice Guideline working group and was reviewed and revised in January 2005 to reflect the most recent evidence. This guideline will undergo significant review during the 2007/08 fiscal year.*

## GOALS

This guideline is intended to assist health care professionals caring for pregnant women to:

- ◆ Present a critical appraisal of the evidence based on information regarding the advantages and disadvantages of routinely offering women prenatal ultrasound.
- ◆ Determining the optimal gestational age for performing ultrasound in the context of routine prenatal care.
- ◆ Assist health care professionals in helping patients make an informed decision about having a second trimester diagnostic prenatal ultrasound examination.

## RECOMMENDATION

- ◆ After appropriate discussion as to the potential benefits, limitations, and safety of the examination, women should be offered an ultrasound at 18 - 19 weeks gestation.\*

\* *This recommendation is consistent with guidelines produced by the Canadian Task Force on the Periodic Health Examination (1994) and the Society of Obstetricians and Gynecologists of Canada (1997).*

## EXCLUSIONS

These guidelines do not apply to the use of ultrasound for selective indications which may include:

- ◆ Assessment in the first trimester.
- ◆ Assessment of fetal well-being in the third trimester.
- ◆ Assessment of fetal growth.
- ◆ Investigating and monitoring of multiple gestations.
- ◆ Investigation of suspected congenital anomalies beyond the second trimester.
- ◆ Aid to invasive diagnostic or therapeutic procedures.
- ◆ Investigation of size-dates discrepancies beyond the second trimester.
- ◆ Assessment of post term pregnancy.
- ◆ Investigation of fetal status in pre-term labour or pre-labour rupture of membranes.

## BACKGROUND

Ultrasound has had a significant impact on the practice of obstetrics by providing valuable information about many pregnancy complications. There is good evidence to support the benefit of selective ultrasound use for high risk pregnancies. There has been considerable debate about the value of ultrasound offered routinely for uncomplicated pregnancies. This has been reviewed previously by both the Canadian Task Force on the Periodic Health Examination (1994)<sup>34</sup> and the Society of Obstetricians and Gynecologists of Canada (1995).<sup>12</sup>

## SITUATIONAL ANALYSIS

### **Ultrasound performed for low risk pregnancies as part of routine pregnancy care.**

Many women have come to expect ultrasound screening as a routine part of prenatal care. Lack of information about the benefits, limitations, and risks of the examination, proper preparation, and what to expect during and after the examination may contribute to this expectation. A survey of women from selected prenatal classes in Alberta showed that 68% of the respondents felt all pregnant women should routinely have an ultrasound.<sup>2</sup> Sixteen percent felt that ultrasound should be used only for specific concerns or questions about the pregnancy. Over 50% of women felt very strongly that they should make the decision while 35% felt that the physician should make the decision.

The physician and sonographer were identified as the most important information sources. Women also accessed information on their own. They were supportive of a brochure outlining the appropriateness, limitations and safety of prenatal ultrasound as part of routine pregnancy care.

Coupled with patient's educational needs are the issues of effective utilization of ultrasound, and variation in physician practices. In response to a province-wide physician opinion survey, 21% of respondent physicians felt they needed more information and clearer guidelines about the use of diagnostic prenatal ultrasound.<sup>3</sup> Fully 66% supported having Alberta guidelines on diagnostic prenatal ultrasound as part of low risk pregnancy care.

## RESEARCH FINDINGS

### **Ultrasound in obstetrics has been shown to increase the frequency with which major malformations are detected before birth.**

Major structural malformations occur in 2 - 3% of all newborns, account for 20 - 25% of all perinatal deaths and an even higher percentage of perinatal morbidity.<sup>4-6</sup>

The majority of anomalies occur in infants without a family history of congenital malformations.<sup>7,8</sup> Identification of anomalies provides parents with the opportunity for early counselling with the option of terminating a pregnancy if a severe defect is detected.<sup>9</sup>

### **Ultrasound detection of defects is highly variable**

The sensitivity of ultrasound done prior to 20 weeks gestation to detect anomalies ranges from 25% in physician offices to 71% at tertiary level hospital units. The discrepancy is dependent on:<sup>4-10</sup>

- ◆ Experience of the ultrasonographer/ultrasonologist,
- ◆ Availability of ultrasonologist on site during examination,
- ◆ Quality of equipment, and
- ◆ Type of malformation being considered.

The components of a complete second trimester ultrasound examination are outlined in the Journal of the Society of Obstetricians and Gynecologists of Canada (1997).<sup>12</sup> False positive rates of 0.2 to 1.0/1,000 women scanned are reported. Most initial false positive diagnoses are corrected on follow-up evaluation.

If an anomaly is identified the patient should be counseled and consideration should be given to a prompt referral of the patient to a tertiary care centre for consultation.<sup>13</sup>

Overall about 50% of defects are detected by second trimester ultrasound examination.<sup>14</sup>

Meta-analysis of four randomized controlled trials of routine versus selective ultrasound scanning in pregnancy showed a reduction in perinatal mortality in the routine screening group (odds ratio = 0.64; 95% confidence interval 0.43 to 0.97)<sup>11</sup> Trials with high detection rates of diagnosis of congenital anomalies showed an increased rate of elective abortions and therefore reduced the number of perinatal deaths. Trials with low detection rates of diagnosis of congenital anomalies showed no significant effect on the rate of elective abortion.

Studies do not provide evidence that in utero diagnosis of anomalies statistically significantly improves the affected fetuses chances for survival. However, early detection of fetal anomalies may in certain cases improve outcomes by permitting delivery at tertiary care centres capable of immediate medical and surgical intervention.<sup>13</sup>

Qualitative evidence suggests that women may benefit psychologically or emotionally from advance knowledge of a defect discovered antenatally.<sup>11</sup>

### **Timing of ultrasound to rule out anomalies should be at 18 weeks gestation.**

Ultrasound prior to 17 weeks gestation to rule out anomalies is not advised due to a high false negative rate of detection.<sup>15</sup> Ultrasound after 20 weeks gestation should be offered only for specific medical indications as the subsequent alternatives are usually more limited.<sup>13</sup> At 18 weeks gestation (see Algorithm A) there is sufficient fetal development to facilitate detection of anomalies while allowing for additional information to be obtained and information to be discussed with the patient (couple) to determine available options.

### **Sonographic measurement can provide a good estimate of fetal age in the first half of pregnancy to within 14 days. Some randomized controlled trials suggest routine ultrasound for dating may reduce the number of induced labours.**

Between 25 and 45% of women are unable to provide an accurate menstrual history. The estimated date of confinement derived from the last menstrual period differs by more than two weeks from the actual date of birth in nearly 25% of pregnancies.<sup>16,17</sup> Clinical estimation of gestational age does not improve accuracy. In contrast, 90% of patients deliver within two weeks of the due date determined by ultrasound.<sup>17</sup>

Accurate knowledge of gestational age is a keystone in a health professional's ability to successfully manage the antepartum care of a patient. Not only is this skill of critical importance in the interpretation of antenatal tests, but also in successful planning of appropriate therapy or intervention, including use of tocolytics, timing of caesarean section, induction of labour, and subsequent identification of intrauterine growth restriction.<sup>18</sup> Routine second trimester ultrasound may lower the rate of induction for presumed post-term pregnancy.<sup>19</sup>

The Cochrane database meta-analysis reported significantly fewer low birth weight singleton births and reduced risk of admission to special care nurseries with routine ultrasound.<sup>20</sup> None of the randomized controlled trials have shown dating with routine ultrasound to reduce prenatal morbidity or mortality unless associated with early termination of pregnancy for detected anomalies.<sup>11</sup>

The Genetic and Diagnostic Imaging Committee of the Society of Obstetricians and Gynecologists of Canada (1997) have issued a statement recommending the time ultrasound dating should be done in relation to other screening tests.

An 18 week gestational ultrasound may be sufficient to confirm gestational age in patients having prenatal maternal serum screen for aneuploidy and screening for neural tube defects.<sup>12</sup> However it may be desirable for an ultrasound to be done earlier if the screening test is abnormal especially if procedures such as amniocentesis are required.

**Ultrasound at 18-19 weeks gestation is a poor screening test for detection of intrauterine growth restriction. Neonatal mortality and morbidity are the same whether or not mothers are screened for growth restriction.**

Accurate information on gestational age is necessary to determine the appropriate size and growth rate of fetal structures in the third trimester. Second trimester ultrasound detects fewer than a third of fetuses with intrauterine growth restriction.<sup>21</sup>

**Second trimester ultrasound leads to earlier detection of multiple gestations. Large randomized trials indicate early knowledge of twins does not lead to significant reduction in perinatal morbidity and mortality.**

Six randomized controlled trials showed that twins were detected in 99% of women who had routine second trimester scans and in 64% of women who did not.<sup>11</sup> Data available from four of these trials, however, show a difference of less than 1% in mortality among twins for women with routine scans compared to those without routine scans.<sup>22</sup>

**Second trimester ultrasound is reliable in determining placental location. There is no evidence that routine ultrasound screening improves maternal or fetal outcomes in cases of placenta previa.**

The incidence of low lying placenta is 13% at mid-trimester but only 0.4% at delivery.<sup>23,24</sup> If the placenta covers the internal os at the time of the 18 week gestational ultrasound a subsequent ultrasound at 26-30 weeks (Algorithm B) will usually provide reassurance this no longer persists and, if it does, facilitate further management including additional evaluation and potential discussion related to preferred location for delivery.

## SAFETY

There is no scientific evidence of a deleterious effect of diagnostic ultrasound on the developing human fetus.<sup>25</sup> Low birth weight, dyslexia, increased incidence of cancer such as leukemia and solid tumours, delayed speech, and delayed reading and writing skills have all been suggested. However, these studies have small sample sizes and all have significant design flaws. Larger, better designed studies refute the suggestion of an immediate or delayed deleterious effect of ultrasound on the fetus<sup>26,27</sup> as confirmed in a recent review.<sup>28</sup>

The biggest risk of ultrasound is over interpretation or missed diagnosis.

## PATIENT AUTONOMY

Mothers are strongly affected by watching their fetus during an ultrasound examination. Ultrasound examinations have the potential to be a happy experience but a real or mistaken diagnosis of fetal abnormality can also lead to psychological devastation. Women attach value to the usefulness of the information. They also value ultrasonography for its own sake, and not as an aid for decision making.<sup>31</sup>

Recently, failure to offer ultrasound has surfaced as a valid reason for litigation.<sup>32</sup> To respect patient autonomy, every patient should be informed about the availability of ultrasound examination and should be given information regarding potential benefits and harms of the procedure.

Respect for autonomy obligates the physician to consider the patient's values and determine the patient's preferences for care. Routinely offering diagnostic prenatal ultrasound respects the autonomy of the patient.<sup>29,30</sup>

The patient should be informed that not all anomalies can be detected.

## UTILIZATION

The overall rate of ultrasound examinations appears to be 2.1 scans per delivery.<sup>33</sup> This rate is similar to that occurring in British Columbia and Ontario.<sup>1</sup> Implementation of this guideline should reduce the number of prenatal ultrasounds but more importantly, would facilitate their occurrence at the most appropriate time.

Offering ultrasound examination at 18 weeks gestation would improve the accuracy of diagnosis of fetal anomalies due to the performance of the scan at a time more appropriate for the diagnosis of anomalies. At the same time, the benefits of gestational age dating, diagnosis of twins, detection of intrauterine growth restriction and placental localization are maintained.

## CONCLUSIONS

Few diagnostic technologies have had a greater impact on the practice of obstetrical care than ultrasound. The greatest debate surrounding obstetric ultrasound revolves around the advisability and appropriateness of offering pregnant women diagnostic prenatal ultrasound at 18 weeks gestation as part of routine pregnancy care.<sup>1,21</sup>

There is evidence (Level B\*) to support routinely offering ultrasound at 18-19 weeks gestation based on other intermediate outcomes.<sup>34</sup> The evidence takes into consideration ethical, legal, and psycho-social dimensions as well as utilization data. Physicians and other health professionals should routinely inform patients of second trimester (18 weeks gestation) ultrasound to enable the patient to make an informed choice about this screening.

\* *Level B evidence: There is fair evidence to support the intervention being included in the periodic health examination.*

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## TOWARD OPTIMIZED PRACTICE

### (TOP) PROGRAM

The successor to the Alberta Clinical Practice Guideline (CPG) program, TOP is an initiative directed jointly by the Alberta Medical Association, Alberta Health and Wellness, the College of Physicians and Surgeons, and Alberta's Health Regions. The TOP Program promotes appropriate, effective and quality medical care in Alberta by supporting the use of evidence-based medicine.

#### TOP Leadership Committee

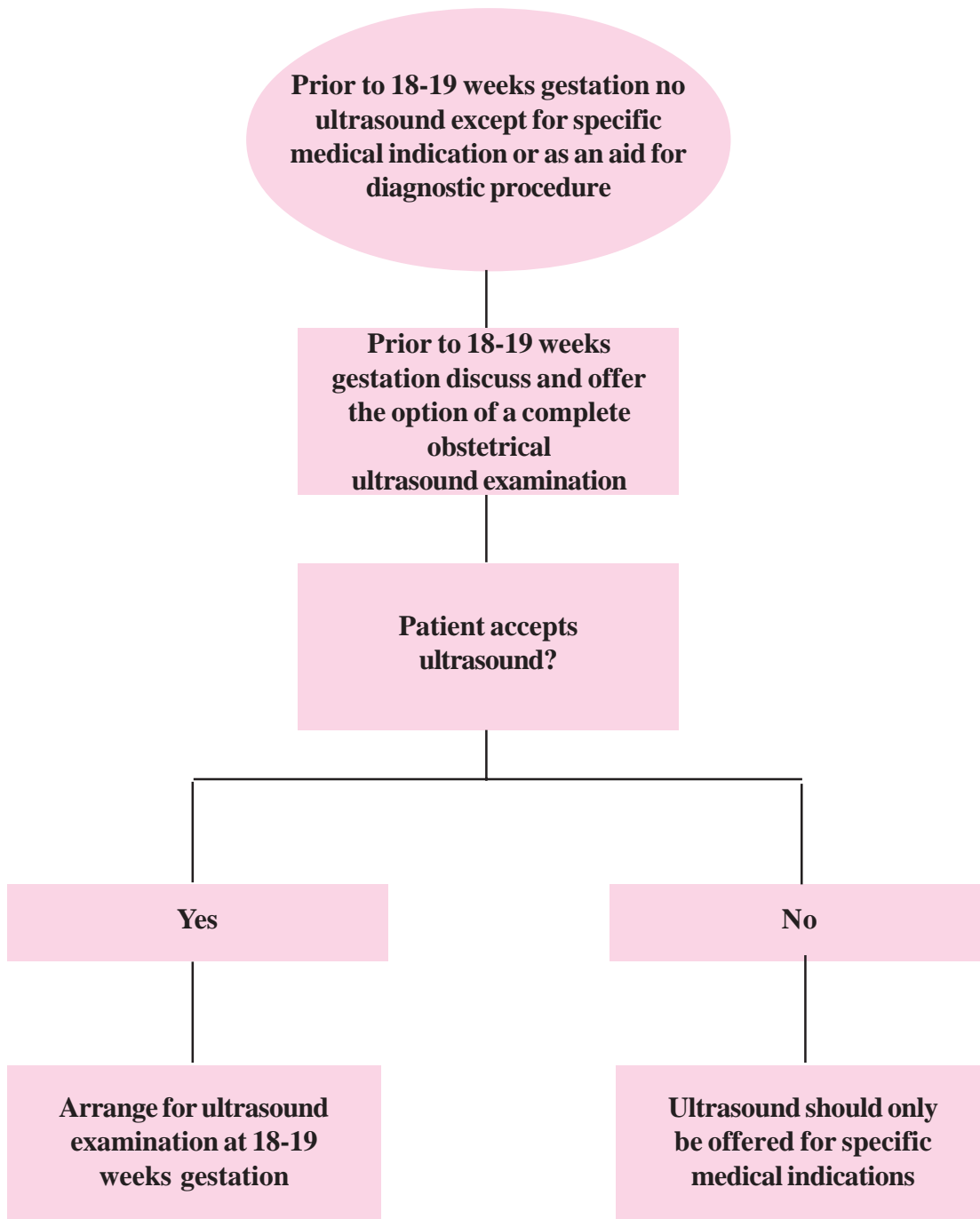
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#### TO PROVIDE FEEDBACK

The Working Group for Prenatal Ultrasound is a multi-disciplinary team composed of family physicians, obstetricians, a perinatologist, neonatologists, a geneticist, radiologist, pathologist, sonographer, midwife, prenatal educator, consumer and Alberta Health representative. The team encourages your feedback. If you have difficulty applying this guideline, if you find the recommendations problematic, or if you need more information on this guideline, please contact:

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# Algorithm A: Ultrasound Use As Part of Routine Pregnancy Care



# Algorithm B: Ultrasound Following Test Results At 18-19 Weeks Gestation

1

**Normal Fetus?**

**Yes**

**No further ultrasound unless for specific medical indications**

**No**

**Counsel patient and consider prompt referral of the patient to a tertiary care centre for consultation. Counsel patient about possible false positive findings**

2

**Does placenta cover internal os?**

**Yes**

**Follow up with ultrasound at 26-30 weeks or if vaginal bleeding**

**No**

**Ultrasound only for specific medical indications**

3

**Multiple fetuses?**

**Yes**

**Follow up with ultrasound monthly or for specific indications**

**No**

**No further ultrasound except for specific medical indications**