



CAR Standard for Performing Diagnostic Obstetric Ultrasound Examinations

The standards of the Canadian Association of Radiologists (CAR) are not rules, but are guidelines that attempt to define principles of practice that should generally produce radiological care. The physician and medical physicist may modify an existing standard as determined by the individual patient and available resources. Adherence to CAR standards will not assure a successful outcome in every situation. The standards should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The standards are not intended to establish a legal standard of care or conduct, and deviation from a standard does not, in and of itself, indicate or imply that such medical practice is below an acceptable level of care. The ultimate judgment regarding the propriety of any specific procedure or course of conduct must be made by the physician and medical physicist in light of all circumstances presented by the individual situation.

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TABLE OF CONTENTS

I. INTRODUCTION	3
II. SONOLOGIST'S CREDENTIALS CRITERIA	3
III. SONOGRAPHER'S CREDENTIALS CRITERIA	3
IV. DOCUMENTATION	3
V. SUPERVISION AND INTERPRETATION OF ULTRASOUND EXAMINATIONS.....	4
VI. QUALITY IMPROVEMENT PROGRAMS	4
VII. EQUIPMENT	4
VIII. TYPES OF FETAL SONOGRAPHIC EXAMINATIONS	4
IX. SONOGRAPHIC TECHNIQUE	5
A. First Trimester Sonography.....	5
B. Second and Third Trimester Sonography.....	5
C. Limited Examination	8
D. Specialized Examination.....	8
X. FETAL SAFETY	8
SELECTED REFERENCES	9

I. INTRODUCTION

These standards have been developed to provide assistance to practitioners performing obstetric ultrasound examinations and are based on the practice guidelines published by the American College of Radiology, American Institute of Ultrasound in Medicine and the American College of Obstetricians and Gynecologists, which we acknowledge.

Obstetric ultrasound should only be performed for a valid medical reason. The lowest possible ultrasound exposure settings should be used to obtain the necessary diagnostic information. In some cases, additional and/or specialized examinations may be necessary. While it is not possible to detect every abnormality, adherence to the following standards will increase the probability of detecting many of the abnormalities that occur.

Extensive experience has shown that ultrasound is a safe and effective diagnostic procedure. While no demonstrable harmful effects of ultrasound have been demonstrated at power levels used for diagnostic studies, quality assurance dictates it is necessary to utilize this imaging technique in the most appropriate and indicated fashion, and that studies be performed by qualified and knowledgeable physicians and/or sonographers using appropriate equipment and techniques. Diagnostic ultrasound examinations should be supervised and interpreted by trained and credentialed physician imaging specialists.

II. SONOLOGIST'S CREDENTIALS CRITERIA

Diagnostic Radiologists involved in the performance, supervision and interpretation of ultrasonography must have a Fellowship or Certification in Diagnostic Radiology with the Royal College of Physicians and Surgeons of Canada and/or the Collège des médecins du Québec. Also acceptable are equivalent foreign Radiologist qualifications if the Radiologist so qualified holds an appointment in Radiology with a Canadian University. Continuing professional development must meet with the requirements of the Maintenance of Certification Program of the Royal College of Physicians and Surgeons of Canada and/or provincial requirements.

III. SONOGRAPHER'S CREDENTIALS CRITERIA

Sonographers should be graduates of an accredited training program or have obtained certification by the Canadian Association of Registered Diagnostic Ultrasound Professionals (CARDUP) or the American Registry of Diagnostic Medical Sonographers (ARDMS). They should be members of their national or provincial professional organization. Continuing medical education should be mandatory consistent with the requirements of the facility and CARDUP or ARDMS.

IV. DOCUMENTATION

Adequate documentation is essential for high quality patient care and such documentation should consist of a permanent record of the ultrasound examination and its interpretation. Appropriate normal and abnormal images should be recorded for each anatomical area together with appropriate measurements. Images should be appropriately labelled with the examination date, patient identification, facility identification and image location and orientation. A written report should be included with the patient's medical record.

The images must be of sufficient quality to record pertinent findings and to be used for comparison with subsequent examinations and enable third party sonologists to confirm the diagnosis.

A permanent record of each ultrasound examination and written report should be retained for a statutory period which should be consistent with clinical needs and relevant legal and local health care facility requirements. Videotape may be used as a supplement to the digital or hard copy images of an ultrasound examination. The videotape record of the ultrasound examination should be retained for the similar statutory period as the remainder of the permanent record. The videotape cassette number and counter number (name or time) must be recorded in a log book or on the printed report to allow for future access.

V. SUPERVISION AND INTERPRETATION OF ULTRASOUND EXAMINATIONS

A sonologist must be available for consultation with the sonographer on a case by case basis. Ideally the sonologist should be on-site and available to participate actively in the ultrasound examination when required. However, if not possible, then the sonologist must be available by telephone or other electronic/digital means for consultation with the sonographer and the referring physician. The sonologist should visit the facility on a regular basis to provide on-site review of ultrasound procedures and sonographer supervision.

Adequate documentation of each examination is critical. Reporting should be in accordance with the CAR Standard for Communication of Diagnostic Imaging Findings.

VI. QUALITY IMPROVEMENT PROGRAMS

Facilities should maintain and regularly update procedure manuals. Procedures should be systematically monitored and evaluated as part of the overall quality improvement program of the facility. Monitoring should include the evaluation of the accuracy of interpretation as well as the appropriateness of the examination. Incidence of complications and adverse reactions should be recorded and periodically reviewed in order to identify opportunities to improve patient care. Data should be collected in a manner which complies with the statutory and regulatory peer review procedures in order to protect confidentiality of the peer review data.

VII. EQUIPMENT

Fetal ultrasound should be performed only when there is a valid medical reason. Studies should be conducted with real time scanners, using an abdominal and/or vaginal approach as appropriate. Real time examination is necessary to confirm a live foetus through the observation of cardiac activity and active movement. The lowest possible ultrasonic exposure settings should be used to gain the necessary diagnostic information with thermal (TI) and mechanical (MI) indices kept below 1. Occasionally, higher intensity may be warranted for short intervals in special circumstances when maternal habitus limits visibility.

The highest frequency transducer providing adequate resolution should be used. Three to 5 MHz abdominal transducers allow sufficient penetration in nearly all patients, while providing adequate resolution. A lower frequency transducer may be needed to provide adequate penetration for abdominal imaging in an obese patient. During early pregnancy a vaginal transducer with a frequency of 7MHz or greater may be necessary to detect the presence of a yolk sac, embryo or cardiac activity. If it is necessary to use a lower frequency transducer with lower resolution, then decisions regarding the presence or absence of these structures should be made with caution.

All probes should be cleaned after each patient examination. Vaginal probes must be covered by a protective sheath prior to insertion. Following the examination, the sheath should be discarded and the probe cleaned in an antimicrobial solution following the manufacturer's guidelines.

VIII. TYPES OF FETAL SONOGRAPHIC EXAMINATIONS

- A. First Trimester Ultrasound Examination
- B. Second or Third Trimester Ultrasound Examination
- C. Limited Examination
- D. Specialized Examination

IX. SONOGRAPHIC TECHNIQUE

A. First Trimester Sonography

First trimester scanning may be performed either abdominally, vaginally or using both methods. If an abdominal scan fails to provide definitive information, a vaginal scan should be performed. Similarly, if a vaginal scan fails to image all areas needed for diagnosis, an abdominal scan should be performed. Doppler of the embryo/foetus should be avoided in the first trimester, except in special high risk circumstances.

- a. The uterus, including the cervix, and adnexa should be evaluated for the presence of a gestational sac. If present, the location of the gestational sac should be documented. The presence or absence of a yolk sac or embryo should be determined. If an embryo is present, the crown-rump length should be recorded.

The crown-rump length is a more accurate indicator of gestational age than mean gestational sac diameter. Correlation should be made with standard tables. If an embryo is not present, the mean diameter of the gestational sac should be determined to estimate gestational age. During the late first trimester, biparietal diameter and other fetal measurements may also be used to establish fetal age.

- b. Presence or absence of cardiac activity should be reported.

Real time observation is critical for this diagnosis. Using vaginal sonography, cardiac activity is usually detectable in embryos 5mm or more in length. If an embryo less than 5mm in length is seen with no cardiac activity, a follow-up scan may be needed to document embryonic life.

- c. Fetal number should be documented.

Multiple pregnancies should be reported only in those instances where multiple embryos are seen. Chorionicity and amnionicity should be determined and reported. Caution should be exercised in the diagnosis of twins in early pregnancy. More than one sac-like structure may be seen due to incomplete fusion between the amnion and chorion and elevation of the chorionic membrane by intrauterine haemorrhage in some patients with vaginal bleeding, and incorrectly thought to represent multiple gestations.

- d. Embryonic/fetal anatomy appropriate for the first trimester should be assessed.

The nuchal region should be assessed, if possible. For patients wishing to assess their individual risk of fetal aneuploidy a very specific measurement of the nuchal translucency (NT) during a specific age interval is necessary. This measurement should be used in conjunction with serum biochemistry as part of a screening program. Performing and reporting NT measurements requires special qualifications (see Standard for performing Nuchal Translucency – to be published)

- e. Evaluation of the uterus (including cervix), adnexal structures and cul-de-sac should be performed.

This will allow recognition of incidental findings of potential clinical significance. The presence, location and size of significant myomas and adnexal masses should be recorded. The cul-de-sac should be assessed for fluid. If there is a significant amount of fluid in the cul-de-sac, the flanks and subhepatic space should be scanned to evaluate for intra-abdominal fluid.

B. Second and Third Trimester Sonography

- a. Fetal cardiac activity, and number, should be documented. In the third trimester, fetal presentation should be reported.

Abnormal heart rate and/or rhythm should be reported.

Multiple pregnancies require the reporting of additional information: chorionicity and amnionicity, placental number, relative fetal position, comparison of fetal size, amount of amniotic fluid on each side of the membrane and when visualized, characteristics such as gender which allow specific fetal identification on follow up examinations.

- b. An estimate of the amount of amniotic fluid (increased, decreased, normal) should be reported.

Physiologic variation with stage of pregnancy must be taken into account when assessing appropriateness of amniotic fluid volume.

- c. The placental location, appearance and its relationship to the internal cervical os should be recorded. The umbilical cord should be imaged and the number of vessels in the cord determined.

It is recognized that apparent placental position early in pregnancy may not correlate well with its location at the time of delivery. An overdistended maternal urinary bladder or a lower uterine contraction can give the examiner a false impression of placenta previa.

Transabdominal, transperineal or transvaginal scans may be helpful in evaluating the internal cervical os and its relationship to the placenta. Transvaginal or transperineal scans may be considered if the cervix appears short or cannot be adequately visualized during the transabdominal scan.

- d. Estimation of gestational age should be accomplished at the time of the initial scan.

First trimester crown-rump measurement is the most accurate method for estimating gestational age. In the second trimester, a combination of biometric parameters such as biparietal diameter, head circumference, femur length and abdominal circumference may be used to estimate gestational age. The accuracy of gestational age estimates decreases with advancing pregnancy.

Late second or third trimester measurements may not accurately reflect gestational age. Initial determination of gestational age should therefore be performed prior to the late second trimester whenever possible.

If one or more previous studies have been performed, the expected gestational age at the time of the current examination should be based on the earliest appropriate examination and the pregnancy should not be redated.

Measurements of structurally abnormal fetal body parts (such as the head in a foetus with hydrocephalus or the limbs in a foetus with a skeletal dysplasia) should not be used in the calculation of estimated gestational age.

- i. Biparietal diameter should be measured at a standard reference level in an axial plane at the level of the cavum septi pellucidi, and the thalamus. The measurement is taken from the outer edge of the near field skull to the inner edge of the far field skull.

If the fetal head is dolichocephalic or brachycephalic, the biparietal diameter alone may be misleading.

On occasion, the computation of the cephalic index, a ratio of the biparietal diameter to fronto-occipital diameter, is needed to make this determination. In such situations, the head circumference or corrected biparietal diameter which takes into account the occipito-frontal diameter may improve the accuracy of gestational age estimation.

- ii. Head circumference is measured at the same level as the biparietal diameter, around the outer perimeter of the calvarium.

Femur length should be measured routinely and recorded after the 14th week of gestation. The long axis of the femoral shaft is most accurately measured with the insonating beam being perpendicular to the shaft, excluding the distal femoral epiphysis.

Both head and femur length measurements demonstrate considerable biological variation late in the pregnancy.

- iii. Abdominal circumference should be determined on a true axial view at the level of the junction of the umbilical vein and portal sinus, and which should include the fetal stomach.

- e. Fetal growth and weight (as opposed to gestational age) should be assessed in the late second and third trimesters.

Abdominal circumference measurement is necessary along with other biometric parameters to estimate fetal weight and may allow detection of intrauterine growth restriction and macrosomia.

If previous fetal biometric studies have been performed, an estimate of the appropriateness of interval growth should be reported. Scans to evaluate growth should be performed at least 2-4 weeks apart, as a lesser time interval may cause confusion as to whether changes are due to growth or measurement technique variations.

Estimated fetal weight should be compared with expected fetal weight for the foetus' assigned gestational age using standard tables or calculation programs. Currently, even the best fetal weight estimation methods can yield errors as high as +/- 15%.

f. Fetal anatomic survey (This section was done jointly with the Society of Obstetricians and Gynaecologists of Canada)

The fetal anatomy is best assessed between 18-22 weeks. The study should include, but not necessarily be limited to, the following fetal anatomy:

i. Head

- ◆ Skull shape
- ◆ Cerebral lateral ventricles
- ◆ Choroid plexus
- ◆ Cavum septi pellucidi
- ◆ Midline falx
- ◆ Cerebellum
- ◆ Cisterna magna

ii. Face and Neck

- ◆ Orbits
- ◆ Lips
- ◆ Nuchal fold (between 16-20 weeks)

iii. Chest

- ◆ Lungs
- ◆ Heart axis, size and position
- ◆ Heart 4 chamber view
- ◆ Cardiac outflow tracts

iv. Abdomen

- ◆ Stomach (presence, position and situs)
- ◆ Bowel
- ◆ Kidneys
- ◆ Bladder
- ◆ Abdominal umbilical cord insertion
- ◆ Number of umbilical cord vessels

v. Spine

- ◆ Cervical, thoracic, lumbar and sacral spine

vi. Extremities

- ◆ All four limbs to the level of the hands and feet
- ◆ Presence or absence of hands and feet

The above protocol for assessment of fetal anatomy should be considered a minimum standard for the fetal anatomic survey.

While not considered part of the minimum required examination, it is desirable to examine other areas of fetal anatomy when fetal position permits.

The fetal anatomic structures should be reported as normal or abnormal (with details) or not adequately seen (with details).

It is recognized that not all malformations of the above-mentioned organ systems can be detected using ultrasonography.

Occasionally it will not be possible to adequately image certain structures (as occurs, for example, when fetal position, low amniotic fluid volume, or maternal body habitus limits the sonographic examination). When this occurs, the ultrasound report should note the structures that were not well seen. Suspected abnormalities may require a targeted evaluation of the area(s) of concern.

g. Maternal anatomy

Evaluation of the uterus (including the cervix) and adnexal structures should be performed when appropriate. This will allow recognition of incidental findings of potential clinical significance. The presence, location and size of adnexal masses and at least the largest and potentially clinically significant myomas should be recorded.

It is frequently not possible to image the maternal ovaries during the second and third trimesters.

Vaginal or transperineal scanning may be helpful when evaluation of the cervix is necessary.

C. Limited Examination

A limited examination may be performed to answer a specific question such as in the following situations: to assess fetal life, assess fetal well-being, fetal presentation, estimate amniotic fluid, follow up fetal growth, evaluate the cervix or to assess a specific area or areas that could not be adequately imaged on prior examination due to fetal or maternal causes. In most cases, a limited examination is appropriate only when a prior complete examination has been done.

D. Specialized Examination

A more detailed or targeted anatomic examination is performed when a fetal anomaly is suspected on the basis of history, biochemical abnormality or a previous sonographic examination.

Other specialized examinations may include fetal Doppler sonography, biophysical profile or a fetal echocardiogram.

X. FETAL SAFETY

Diagnostic ultrasound examination of the foetus is generally considered safe during pregnancy. It should only be performed when there is a valid medical indication. The lowest possible ultrasonic exposure settings should be used to gain the necessary diagnostic information under the as low as reasonably achievable (ALARA) principle.

The use of ultrasound equipment for non-medical purposes such as fetal gender determination and making “keepsake fetal photo albums and videos” is considered by Health Canada to be an unapproved use of a medical device

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