



CAR Standards for Performing and Interpreting Diagnostic Antepartum Obstetric Ultrasound Examination

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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 high-quality 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.

I. INTRODUCTION

These standards have been developed to provide assistance to practitioners performing ultrasound examinations and are based on the standards published by the American College of Radiology and the American Institute of Ultrasound in Medicine. 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 maximize the probability of detecting most of the abnormalities that occur. Diagnostic Ultrasound is an established, effective, diagnostic imaging technique which employs the use of high frequency ultrasound waves for both Imaging and Doppler examinations.

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

Physicians involved in the performance, supervision and interpretation of ultrasonography should be Diagnostic Radiologists and 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.

As new imaging modalities and interventional techniques are developed additional clinical training, under supervision and with proper documentation, should be obtained before radiologists interpret or perform such examinations or procedures independently. Such additional training must meet with pertinent provincial/regional regulations. Continuing professional development must meet with the requirements of the Maintenance of Certification Program of the Royal College of Physicians and Surgeons of Canada.

I. SONOGRAPHER'S CREDENTIALS CRITERIA

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

CARDUP will have a national exam process for sonographers in place by 2004. At that time this will become the accepted standard for sonographers. As an interim measure, individual consideration of training and qualifications by a Task Force consisting of members of relevant societies can be recommended for all those whose training does not fall within appropriate guidelines.

II. 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 and if appropriate image location and orientation. A written report should be included with the patient's medical record.

A permanent record of the ultrasound images and written report shall be retained. 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. The permanent record of each ultrasound examination 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 a useful supplement to the permanent record 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.

III. 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. It is recognized however that the geographic realities in Canada do not permit the presence of an on-site sonologist in all locations. Adequate documentation of each examination is critical. A videotape record may be useful as an adjunct to the hard copy images in difficult cases. Despite the geographic isolation of a community the reports must be timely. Furthermore, the sonologist must be available by telephone 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.

IV. QUALITY IMPROVEMENT PROGRAMS

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.

V. EQUIPMENT

Studies should be conducted with real time scanners, using an abdominal and/or vaginal approach. The lowest possible ultrasonic exposure settings should be used to gain the necessary diagnostic information. Fetal ultrasound should be performed only when there is a valid medical reason. Real time examination is necessary to confirm a live fetus through the observation of cardiac activity and active movement. The highest frequency transducer providing adequate resolution should be used. 3 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 used 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.

VI. TECHNIQUE

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.

a. The uterus 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 an 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 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 and the gestational sac should be evaluated for the presence and size of a yolk sac. Caution should be used in making the presumptive diagnosis of a gestational sac in the absence of a definite embryo or yolk sac. Without these findings an intrauterine fluid collection could represent a pseudogestational sac associated with an ectopic pregnancy. 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 should be appreciated 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. Due to incomplete fusion between the amnion and chorion and elevation of the chorionic membrane by intrauterine hemorrhage in some patients with vaginal bleeding, more than one sac-like structure may be seen in early pregnancy and incorrectly thought to represent multiple gestations.

d. 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 the 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 intraabdominal fluid.

Second and third trimester sonography

a. Fetal life, number, presentation and activity should be documented.

Abnormal heart rate and/or rhythm should be reported.

Multiple pregnancies require the reporting of additional information: chorionicity and amnionicity, placental number, sac number, comparison of fetal size, amount of amniotic fluid on each side of membrane and when visualized, fetal genitalia.

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 visualizing the internal cervical os and its relationship to the placenta. d. Estimation of gestational age should be accomplished at the time of the initial scan using at least a combination of biparietal diameter (or head circumference) and femur length.

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 or third trimester whenever possible.

If one or more previous studies have been performed, the gestational age at the time of the current examination should be based on the earliest examination that permits measurement of crown-rump length, biparietal diameter, head circumference, and/or femur length using the equation: current fetal age = estimated age at time of initial study + number of weeks elapsed since first study. The current measurements should be compared with norms for the gestational age based on standard tables. If previous studies have been performed, interval change in the measurements should be assessed.

Measurements of structurally abnormal fetal body parts (such as the head in a fetus with hydrocephalus or the limbs in a fetus 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 which should include the cavum septi pellucidi, and the thalamus.

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 is required.

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

iii. Femur length should be measured routinely and recorded after the 14th week of gestation. Both head and femur length measurements demonstrate considerable biological variation late in the pregnancy.

e. Fetal growth and weight (as opposed to gestational age) should be assessed in the late second and third trimesters and require the addition of abdominal diameters or circumference.

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.

If previous fetal biometric studies have been performed, an estimate of the appropriateness of interval change should be given. Estimated fetal weight should be compared with expected fetal weight for the fetus' assigned gestational age using standard tables or calculation programs.

Abdominal circumference measurement is necessary to estimate fetal weight and may allow detection of growth restriction and macrosomia

f. The study should include, but not necessarily be limited to, the following fetal anatomy: cerebral ventricles, posterior fossa (including cerebellar hemispheres and cisterna magna) four-chamber view of the heart (including its position within the thorax), spine, stomach, urinary bladder, umbilical cord insertion site and intactness of the anterior abdominal wall, kidneys and all four limbs to the level of the hands and feet.

While not considered part of the minimum required examination, it is desirable to examine

other areas of fetal anatomy when fetal position permits. It is recognized that not all malformations of the above-mentioned organ systems can be detected using ultrasonography.

The above protocol for assessment of fetal anatomy should be considered a minimum standard for the fetal anatomic survey. 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. Evaluation of the uterus (including the cervix) and adnexal structures should be performed. This will allow recognition of incidental findings of potential clinical significance. The presence, location and size of myomas and adnexal masses 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 in evaluating the cervix when the fetal head prevents visualization of the cervix by transabdominal scanning.

Limited examination

A limited examination may be performed in the following situations: to assess fetal life, assess fetal well-being, 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.