STANDARDS FOR DIAGNOSTIC IMAGING

GENERAL ULTRASOUND

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I. Introduction:

Diagnostic Ultrasound is an established safe and effective diagnostic imaging technique which employs the use of high frequency ultrasound waves for both imaging and Doppler examinations. While no harmful effects of ultrasound have been demonstrated at power levels used for diagnostic studies, it is necessary to utilize this imaging technique in the most appropriate and indicated fashion. The total ultrasound exposure should be kept as low as reasonably achievable (ALARA principle).

These standards have been developed by the Advisory Committee on Medical Imaging to provide assistance to practitioners performing ultrasound examinations. They are based on guidelines published by the Canadian Association of Radiologists (CAR).

II. Documentation:

Adequate documentation is essential for high quality patient care and 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 and annotations. 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.

Permanent ultrasound record images must be of sufficient quality to show pertinent findings and to be used for comparison with subsequent examinations and enable third party sonologists to confirm diagnoses. Ultrasound records must be kept in accordance with regulatory and health care facility requirements.

Primary virtual/digital records (ie. Optical Disc, CD, Server) must have appropriate back-up and security as well as a method of retrieval for viewing. Where videotape, optical discs, CD or other separate-unit storage devices are used, catalogues should be kept for easy access.

III. Qualifications/Credentials:

Studies must be performed by qualified and knowledgeable physicians and/or sonographers. (refer to CPSS bylaw 25.1)

Please also refer to Section 32 of the *Radiation Health & Safety Regulations.*

IV. Supervision and Interpretation of Ultrasound:

Diagnostic ultrasound examinations must be supervised and interpreted by trained and credentialed physicians, per CPSS bylaw 25.1.

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, it is recognized that geographic realities do not always permit the presence of an on-site sonologist in all locations. In Saskatchewan, tele-ultrasound may be utilized, requiring the sonologist to be available to review static and real-time imaging remotely. (refer to Guidelines for Tele-radiology)

V. Preventive Maintenance of Equipment:

All ultrasound scanners should have a regular program of preventive maintenance to ensure optimal operation. This could include regular checks using a tissue equivalent phantom as well as checks for adequacy of image recording.

Reprocessing Endocavity Ultrasound Transducers:

Endocavity ultrasound transducers are classified as semi-critical devices by the Public Health Agency of Canada. These transducers contact mucous membranes or non-intact skin and require meticulous cleaning followed by high level chemical disinfection to adequately destroy microorganisms. Personal protective equipment (PPE) must be used by those performing high-level disinfection.

Cleaning:

Manually cleaning the transducer is an essential step before effective disinfection or sterilization. At the bedside, the transducer should be disconnected from the system and the transducer sheath carefully removed and discarded. The transducer should be wrapped in a pad and transported to the reprocessing area.

An enzymatic cleaner with a pH of 6.0 to 8.0 (such as Metrisponge saturated with Metrizyme dual enzymatic detergent) is recommended for a 2 minute clean. A medical instrument brush may be used to remove any debris or body fluids. Manual cleaning should be done within the sink to minimize splashing.

Following cleaning, the transducer should be thoroughly rinsed with water and dried with a soft cloth or paper towel. The transducer cord and base should be wiped thoroughly with a transducer-manufacturer-approved disinfectant (such as Accel, Cavi-Wipes or a glutaraldehyde-based disinfectant.) The transducer should not touch the sink or counter.

Disinfecting:

Following cleaning, the transducer must be immersed up to the transducer manufacturer-recommended level and soaked in a high-level disinfectant (HLD) solution (such as Resert or Cidex OPA) for the minimum time recommended by the solution manufacturer (for Resert -5 minutes, Cidex OPA 10 minutes.) The sink should be wiped with disinfectant wipe. PPE should be removed, and hand hygiene performed.

Following soak time, wearing clean PPE equipment, the transducer must be thoroughly rinsed with water for the recommended length of time and dried with a soft cloth or paper towel. HLD solutions should not be allowed to air dry on the transducer. PPE should be removed and hand hygiene performed.

The disinfected transducer should be taken to the storage rack without touching any surfaces.

Additional Recommendations:
Transducers should be stored in a separate area from cleaning/soaking area.

The area for high-level disinfection should be separate from patient care areas and procedure rooms. A fume hood should be available to vent the high-level disinfection gases.

Ideally, dual sinks are recommended ("dirty sink" for initial cleaning, "clean sink" for rinsing, following HLD soaking). The reprocessing sink should not be used for hand hygiene.

An appropriate chemical test strip specified by the disinfectant manufacturer must be used to test disinfectant minimum effective concentration at least daily, prior to use.

Documentation of each reprocessing procedure is recommended including start of soak time, and identification of the transducer.

A log book should document dates of all high-level disinfection solution changes; solution change frequency must follow manufacturer's recommendation. If required by solution manufacturer, a neutralizing substance should be added to the disinfectant before discarding, according to facility standards.

Automated alternatives to manual soak/high level disinfection of some models of ultrasound transducers are available. They may be acceptable to meet approved standards when used according to manufacturers' instruction. For example, the Trophon EPR offers a closed system with a sealed disinfectant cartridge. No test strips are required. The push-button cycle takes 7 minutes, disinfecting handle and probe with sonically activated hydrogen peroxide mist. Closed HDL systems are acceptable for point-of-care locations.

A review and update of the reprocessing techniques is recommended on an annual basis.

References: Canadian Standards Association International (CSA) Decontamination of Reusable Medical Devices (March, 2008), www.healthcare.philips.com www.gehealthcare.com www.sonographycanada.com www.nanosonics.us/

VI. 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 reviewed periodically in order to identify opportunities to improve patient care.

VII. Standard Scan Types

(a) Abdominal, Renal (including transplant) and Retroperitoneal – Abdominal, renal and retroperitoneal studies should be performed with a real-time scanner, preferably using a sector or convex linear transducer. The transducer or scanner should be adjusted to operate at the highest clinically appropriate frequency. With modern equipment, these frequencies are usually between 2.5 and 8.0 MHz. Transplant kidney ultrasound also requires Doppler capability for assessment of potential post-anastomotic arterial stenosis, as well as intra-renal perfusion patterns.

- Liver: The liver survey should include both long axis (coronal or sagittal) and transverse views. Liver size, shape and contour should be assessed with appropriate attention to lobar distribution. Liver parenchyma should be assessed for overall echogenicity as well as the presence of focal or diffuse abnormalities. Liver and right renal echogenicity should be compared.

- Gallbladder and Biliary Tract: Gallbladder visualization is optimally performed on a fasting patient. Gallbladder evaluation should include long axis and transverse views, using whatever patient positioning best facilitates this. The gallbladder wall should be assessed for morphology and thickening. Gallbladder tenderness (sonographic Murphy's sign) should be documented when present. Luminal long axis and diameter should be measured in cases of gallbladder enlargement. Intraluminal content including sludge and stones should be assessed. Biliary tract assessment includes evaluation of intra- and extra-hepatic bile ducts. Extra-hepatic ducts should be measured, and evaluated from the porta hepatis down through the pancreatic head, as far as visible. Colour Doppler may be necessary to distinguish ducts from vessels. Additional patient positions may be helpful.

- Pancreas: Long axis and transverse projections should be obtained using whatever patient positioning facilitates this. The pancreatic head, uncinate process, body and tail should be evaluated for size, contour, echogenicity and the presence of diffuse or focal disease. The pancreatic duct may be visualized and its caliber, content and margination assessed.

- Spleen: The spleen should be assessed in both long axis and transverse projections, noting size, location, contour and hilar orientation. Echogenicity should be compared with that of the left kidney. The spleen should be evaluated for any focal or diffuse abnormality.

- Kidneys: Long axis and transverse images should be obtained. Renal size, contour, location and abnormal mobility should be documented. Renal parenchymal assessment should include evaluation of both cortex and medulla. The renal sinus area should be evaluated and focal or diffuse abnormality documented. The renal collecting system should be evaluated for focal or generalized dilatation, appearance of the uro-epithelium and content. The peri- renal region should be assessed for abnormality .

In addition to the above, transplant kidneys should be evaluated with Doppler ultrasound to assess post-anastomotic and intra-renal arterial flow patterns.

- Aorta and IVC: The aorta and inferior vena cava should be assessed in long axis and transverse planes. Both vessels should be evaluated from the diaphragm to the bifurcation (usually at the level of the umbilicus) where possible. The adjacent common iliac vessels should be assessed. Specific aortic study should include assessment of vessel size, pulsatility and documentation of thrombus, as well as any obvious flow abnormalities.

The IVC should be assessed for location, size, pulsatility and luminal filling defects.

- Retroperitoneum: Retroperitoneal evaluation includes the abdominal great vessels, pancreas, kidneys, adrenal glands (where visible), regional lymph nodes, retroperitoneal musculature, and the potential retroperitoneal spaces. Long axis and transverse views may be employed.

(b) ANTE-PARTUM – Refer to current SOGC and/or CAR guidelines for obstetrical ultrasound.

(c) SMALL PARTS INCLUDING BREAST, THYROID AND SCROTUM – These parts should be scanned using a real-time higher frequency probe (7-10 MHz).

Breast ultrasound should only be performed with mammographic facilities available and in conjunction with mammograms, where necessary. See CAR standards and guidelines re: Breast Imaging and Intervention.

- Each thyroid lobe should be measured, and imaged in at least three longitudinal and 3 transverse projections. The isthmus should be imaged transversely. Abnormalities should be documented, including size, number and location. Adjacent abnormalities (e.g.lymphadenopathy, venous thrombosis) should also be documented, as should be the parathyroids, where seen. Refer to CAR Guideline: Ultrasound - Thyroid/Parathyroid (2011)

- Each testis should be imaged in at least three longitudinal and 3 transverse projections, with at least one transverse image including enough of each testicle to allow comparison of internal echo-texture, for both focal or diffuse disease. Size, location and morphology should be documented. Each epididymis should be seen longitudinally and transversely. Scrotal skin thickness should be shown. Testicular lesions, hydroceles and other abnormalities should be adequately imaged in two orthogonal planes. Doppler examination may greatly facilitate diagnosis in general, and colour Doppler is essential for assessment of testicular torsion. Refer to CAR Guideline: Ultrasound – Scrotum (2011)

(d) *ECHOCARDIOGRAPHY* – See the Canadian Cardiovascular Society standards document.

(e) *FEMALE PELVIS* – Sonography of the female pelvis should be performed with a real-time scanner, preferably using sector or convex linear transducers. The transducer or scanner should be adjusted to operate at the highest clinically appropriate frequency, realizing there is a trade-off between resolution and beam penetration. Studies performed through the anterior abdominal wall can usually use frequencies of 3.5 MHz or higher, while endovaginal scans should use frequencies of 7 MHz or higher.

All relevant structures should be identified and recorded by the abdominal or vaginal approach, or both when necessary. A prerequisite of adequate pelvic sonography from the abdominal wall is a bladder adequately full to uterine fundus. For endovaginal sonography, the bladder is usually empty. The vaginal transducer may be introduced by the patient, the sonographer or the sonologist. It is recommended that an appropriate chaperone is present in the examining room at all times during vaginal and other endocavity studies.

Using the vagina and uterus as anatomical landmarks, pelvic structures are evaluated individually. Uterine size, shape and orientation, endometrium, myometrium and the cervix should be examined. Uterine length and AP depth are evaluated in its long axis from the fundus to cervix and from anterior to posterior walls, respectively. Width is measured from trans-axial or coronal views. Abnormalities of the uterus should be documented, as should be the endometrial echogenicity and position within the uterus. Endometrial thickness should be measured. The myometrium and cervix should be evaluated for contour changes, echogenicity and masses.

Both ovaries should be identified when possible as reference points for adjacent adnexal structures. When visualized, ovarian size, shape, contour and echogenicity should be recorded, together with position relative to the uterus. The size and echo pattern for adnexal masses should be recorded.

The cul-de-sac and bowel posterior to the uterus should be evaluated for the presence of free fluid or mass and the dimensions of any abnormality should be recorded in orthogonal

planes. Re-examination after an interval may be necessary to differentiate bowel from pathology.

(f) *INTERVENTIONAL GUIDANCE* - Interventional procedures that can be performed with sonographic guidance include, but are not necessarily limited to, cyst or collection aspiration / drainage, line placement, pre-surgical needle localization, fine-needle or core needle biopsy. A full sonographic assessment of the area should be performed first. Free-hand or needle guide techniques may be used. Especially with free-hand technique, a needle path nearer perpendicular to the ultrasound beam will facilitate visualization. Images should be recorded to document the steps of the procedure.

(g) *INTRAOPERATIVE* – Scanning should use a real-time probe, with an appropriate frequency for the region scanned. Appropriate sterile technique should be used where needed. Ultrasound equipment should not be used when unsafe in the context of flammable anaesthetic agents.

The primary aim is for scanning to facilitate the operative procedure, especially in terms of presence, size, number and location of abnormalities, and surgical guidance. This will often be a dynamic process and documentation may be secondary. However, it should not be ignored, and pre / post images (especially for procedures such as thoracentesis and biopsy needle firing) should be considered very desirable.

(h) *MUSCULOSKELETAL* – Musculoskeletal scanning should use real-time, 10 MHz or higher linear probes.

Specific tendons, ligaments, muscles, joints etc. to be examined should be imaged in two orthogonal planes. Different limb / joint positioning may be needed to facilitate imaging of normal or abnormal structures. Mass lesions should be imaged and measured in two orthogonal planes, with appropriate labeling for orientation and position. Settings should be adjusted to distinguish cystic and solid areas as optimally as possible.

(i) *NEUROSONOGRAPHY* – Neonatal brain scanning should use a real-time higher frequency probe (usually 5-10 MHz) with an appropriately small foot plate to scan through the fontanelle. Lower frequencies may be needed for trans-cranial adult brain scanning.

Trans-fontanelle scanning in infants should include appropriately labeled, multiple sagittal and coronal images (at least five of each) of the brain, with settings optimized to see into the posterior fossa, as well as the cerebral hemispheres, ventricular system and any particular abnormality.

(j) *OPHTHALMOLOGICAL* – Scanning should employ probe frequencies of around 8 MHz for A-scan, with axial resolution of 0.1-0.2 mm at 6 dB; and around 10 MHz for B-scan, with axial resolution of 0.2mm at 6 dB.

Eye ultrasound can be divided into four components, and these may be integrated during examination in some patients.

- A-scan: is mostly used for biometry and particularly to measure the length of the eye prior to cataract surgery (to determine the needed intra-ocular lens power). Due care and skill is required to obtain a true AP axial length, not off axis. Other uses include: measuring intra-ocular tumor height and acoustic reflectivity; differentiation between vitreous hemorrhage and other vitreous pathology (e.g. tumor seeding) based on acoustic reflectivity; and occasionally to determine if an intra-ocular foreign body is magnetic by measuring its movement in a magnetic field.

- B-scan: is usually used to determine the status of the posterior segment of the eye, but sometimes extending further out in the orbit. Images are to be obtained axially, sagittally and obliquely (depending upon location in the eye), particularly looking for tumors, retinal detachment and vitreous hemorrhage.

- Standardized A-scan: is currently not available in Saskatchewan (and is limited in availability elsewhere in the world). If and when this modality becomes available, appropriate equipment and training will be needed. Use includes both intra- and extra-ocular imaging (the latter particularly in assessment of ocular musculature and optic nerve sheaths).

- Ultra Biomicroscopic Ultrasound: is again currently not available in Saskatchewan, though has arisen out of work at the University of Toronto, and is apparently rapidly becoming "state of the art" in certain diseases. This modality can be used to visualize fine details in the anterior segment and anterior part of the posterior segment (ciliary body and process) of the eye. Again, when this modality becomes available, appropriate equipment and training will be needed.

(k) *PROSTATE AND SURROUNDING STRUCTURES* – A prostate study should be conducted with a real-time trans-rectal transducer, using the highest clinically appropriate frequency; usually 7 MHz or higher. Because of the relatively high proportion needing biopsy, prostate ultrasound without the facility or potential intention for biopsy should not be performed, except in remote areas to screen for cases that require referral to a center where biopsy is performed. The sonologist must be able to correlate physical and ultrasound findings and recent PSA readings to determine if prostate biopsy is required. The sonologist should be able to perform biopsy adequately, accurately and safely.

(l) The prostate should be imaged in its entirety in at least two orthogonal planes, from apex to base of the gland. In particular, the peripheral zone should be thoroughly imaged. The gland should be evaluated for size, echogenicity , symmetry and continuity of margins. The seminal vesicles should also be examined in two planes from their insertion into the prostate to their cranial/ lateral extents. They should be evaluated for size, shape, position, symmetry and echogenicity. Both vasa deferentia should be evaluated as far as visible. The peri-rectal space, particularly abutting the prostate and rectum should be evaluated. The rectal wall and lumen should be studied if pathology is clinically suspected, here. Refer to CAR Guideline: Ultrasound – Prostate (2011)

(m) *VASCULAR* – Studies should be conducted with real-time linear scanners with an appropriate frequency probe for the anatomy being examined. These will nearly always be 5 MHz or higher for leg veins and 7 MHz or higher for carotids.

Depending on the clinical indication or gray scale sonographic findings, colour Doppler, pulsed Doppler, power Doppler or continuous wave Doppler may provide information which is crucial in making the formal diagnosis. Doppler diagnoses are determined by the presence and direction of flow and by Doppler waveform characteristics. Information obtained on Doppler interrogation should be integrated with the gray scale and clinical findings. Doppler flow analysis combined with real-time gray scale imaging provides the basis for many non-invasive vascular studies.

One should have real-time visual display of velocity (frequency shift) distribution and audible output.

- Extra-Cranial Cerebrovascular Systems: Real-time imaging of the common, internal and external carotid arteries should be performed in longitudinal and transverse planes. Longitudinal images of each should be recorded on both sides. The extent, location and characteristics of atherosclerotic plaque or other vascular / peri-vascular abnormalities should be documented. Transverse images can be recorded as needed to demonstrate an abnormality more clearly. The vessels should be imaged as completely as possible, angling the transducer beneath clavicle and mandible to facilitate this.

Blood flow velocity (or frequency shift) measurements should be made along the full length of accessible portions of the internal, external and common carotid arteries. The Doppler angle should be kept less than 60 degrees whenever possible to maximize reliability of measurement. Maximal peak systolic velocity (frequency shift) spectral measurements should be recorded for each of the common, internal and external carotid arteries. Additional spectral measurements may be helpful, such as end-diastolic velocity and / or ICA/CCA velocity ratios. Velocity (frequency shift) measurements should be recorded in the common carotid artery proximal to the bulb. The Doppler spectrum should be recorded proximal to, at, and distal to any significant stenoses. The location of each stenosis should be documented.

When possible, in their accessible portions, each vertebral artery should be imaged in at least the longitudinal plane, and a record of velocity (frequency shift) spectrum and flow direction made.

Colour Doppler imaging may be used to screen for areas of abnormal blood flow and to select areas for Doppler spectral analysis. Colour Doppler imaging may also be used to clarify the cause of apparent image / pulsed Doppler mismatches and to detect narrow flow channels seen in high grade stenoses.

- Peripheral Venous Doppler: In the legs, transverse non-compressed and compressed images should be obtained of the deep venous system at intervals from the proximal common femoral vein to the distal popliteal vein. During evaluation of veins in the calf, specific areas of clot formation may be occasionally seen, and these should be documented in longitudinal and transverse planes. Baker cysts, enlarged groin nodes and other focal abnormalities should also be documented in two planes.

In the arms, venous Doppler again uses non-compressed and compressed images being obtained from the antecubital fossa proximally, examining basilic, cephalic brachial, axillary and as much of the subclavian veins as possible. It is understood that non-compressible areas (specifically, subclavian vein) and inaccessible portions of vein courses (specifically through the posterior shoulder) make arm Doppler less able to exclude thrombus (say, compared to leg Doppler).

- Intra-Abdominal: Images should be obtained in longitudinal and transverse planes, focusing on particular areas in question e.g. arterial aneurysm, IVC thrombus. Flow patterns should be determined by Doppler.

- Peripheral Arterial: Sonographic examination of peripheral arterial vessels consists of 2D gray scale and pulsed wave Doppler with velocity measurements. Colour Doppler should also be utilized where appropriate. Pressure criteria may be used in conjunction with ultrasound (ABI). Pathologies such as arterial stenosis, occlusions, aneurysms, pseudoaneurysms, graft abnormalities, arteriovenous communications and soft tissue abnormalities close to arteries may be examined with ultrasound. Native arteries in the lower and upper extremity may be examined, as well as bypass grafts in the limbs or surgically created fistulas. For complete information please refer to CAR Standards.