Lower Mainland Medical Imaging Guideline

ABCD-21-15-90182

TITLE:	**PREGNANCY SCREENING AND RADIATION SAFETY**
MODALITY:	**Bone Density, Computed Tomography, Echocardiography, Fluoroscopy, Interventional/Angiography, Mammography, Magnetic Resonance Imaging, Nuclear Medicine, Radiography, Ultrasound**
AUTHOR(S):	**Dr. Yogesh Thakur, Medical Physicist**
APPROVED BY:	**Medical Imaging Executive Committee**
DATE APPROVED:	**October 14, 2015**

1. Purpose

This Clinical Practice Standard (CPS) ensures all female patients of childbearing age are screened for pregnancy prior to undergoing an imaging examination or procedure, in accordance with Provincial and Federal Regulations.

2. Statement

All Vancouver Coastal Health Authority Medical Radiation Technologists and Nuclear Medicine Technologists must verify the pregnancy status for all female patients of reproductive age prior to any use of ionizing radiation (Mammography, Radiography, Radioscopy [fluoroscopy and angiography], Computed Tomography, Nuclear Medicine and Bone Density examinations). Additionally, screening is required to establish whether a female of childbearing age is nursing prior to a nuclear medicine exam.

3. Exception

The pregnancy screening process may be omitted if: the patient cannot respond due to their medical condition or a medical crisis has occurred where Medical Imaging is deemed necessary for effective clinical care.

If either situation arises, an alternate source of medical history is to be consulted, where applicable.

4. Policy

Federal and Provincial regulations state that medical imaging departments must screen female patients of childbearing age (ages: 11-55) to determine the patient's pregnancy status (HCSC35, DAP). This screening process is intended to minimize risk to the fetus/embryo. The screening process is dependent on the imaging modality and the anatomical region to be examined. A guide to fetal risk and the radiation dose associated with common diagnostic examinations on the MI Quality Teamsite. **Note:** HCSC35 is under revision with respect to pregnancy screening and the use of protective equipment (e.g. lead) to cover the gonads or a potential fetus. This document includes recommendations in the HCSC35 revision, which is yet to be published.

For nuclear medicine exams, pregnancy screening is extended to include patients who are breast feeding, or those patients who have close contact with infants (IAEA - BSS39, ICRP 84).

4.1. Fetal Risk

Fetal risk from ionizing radiation is considered low in the majority of ionizing radiation examinations. However, a risk still exists and VCH strives to follow the ALARA principle (As Low As Reasonably Achievable). A clinical guidance document describing fetal risk from ionizing radiation is available on the VCH medical imaging intranet page and MI Quality Teamsite.

4.2. Pregnancy Screening Process

VCH Technologists must screen patients of childbearing age to determine pregnancy status.

4.3. Site Signage

An advisory notice must be prominently displayed in all reception/change room areas with the following or similar text: "If it is possible that you may be pregnant, please notify the physician or technologist before your examination."

Similar signage in other languages is suggested for sites where local demographics include large populations of non-English speaking residents.

4.4. Pregnancy Status Categories

Pregnancy screening is required for all females of childbearing age (ages: 11-55). Screening questions will establish: 1) No Chance Pregnant, 2) Possibly Pregnant, Status Unsure/Uncertain, and 3) Definitely Pregnant.

4.5. Documenting Status

Pregnancy status must be recorded in the patient's electronic record via RIS or other electronic system, including results for all follow-up tests conducted. Where applicable, it is recommended that the requisition is scanned and uploaded to the patient's imaging record in PACS or other image informatics system.

4.6. Imaging Modality Base Process

A flowchart for modality specific screening process and use of radiation related radiation Personal Protective Equipment (PPE) is provided in Appendix A.

4.7. Staff Responsibilities

4.7.1. Clerical Staff

- As best practice, request pregnancy status at time of booking. When possible, book female patients during the first 10 days of their next menstrual cycle where chance of pregnancy is least likely.
- Inform the patient that if their pregnancy status changes prior to their scheduled exam (confirmed pregnancy or possible pregnancy), to inform the hospital of this status change.
- Upon notification of pregnancy status change, inform the ordering physician to consult with a radiologist to determine appropriate action.

4.7.2. Medical Radiation Technologist/Nuclear Medicine Technologist

- If the patient is within childbearing age, must follow the screening process per modality as specified in Appendix A
- Request LMP, if necessary
- Document pregnancy status in the RIS, PACS or other electronic medical record system.

4.7.3. Radiologist and/or Referring Physician

- If patient is pregnant, determine whether the exam must proceed, should proceed or if an alternate imaging exam is appropriate,
- Communicate fetal risk to the patient, when required,
- Counsel patient, if requested.

4.7.4. Quality Coordinators/Regional Practice Leads

- Perform compliance audits.

4.7.5. Medical Physicists/Radiation Safety Officer

- Maintain and update this policy,
- Identify low dose (<10 mGy) and high dose (> 10 mGy) imaging procedures,
- Provide fetal risk assessments, if requested.

4.8. Pregnant or Unsure Pregnancy – Approval to Proceed with Examination

In case a patient is pregnant, or unsure of pregnancy status, it is the responsibility of the referring physician and/or radiologist to communicate fetal risk to the patient. The exam may proceed if approved by the patient, and referring physician/radiologist. The patient's decision to proceed must be respected, as per the mandatory DAP Standard DPC 3.2.5.

4.9. Compliance

Compliance audits will be performed by VCH regional staff (Quality Coordinators, Regional Practice Leads or other designates). Site directors will be notified of non-compliance among staff.

References

Fetal Dose Estimates For VCH

Health Canada Safety Code 35

College of Physicians and Surgeons of BC, Diagnostic Accreditation Standards

Regional Guideline – Acoustic Output Levels in Obstetric Ultrasound Scans

Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, Interim Edition.

Protection of Pregnancy Patients During Diagnostic Medical Exposures to Ionizing Radiation, Health Protection Agency, RCE-9, 2009.

ACR Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation, 2008, Resolution 26.

Breastfeeding recommendations for Patients Undergoing Nuclear Medicine Procedures, VCH Protocol, 2008.

Definitions

HCSC35 - Health Canada Safety Code 35

DAP – College of Physicians and Surgeons of BC, Diagnostic Accreditation Standards

IAEA - International Atomic Energy Agency

ICRP - International Commission on Radiological Protection

RIS - Radiology Information System

LMP - Last Menstrual Period

ALARA - As Low As Reasonably Achievable

ACR – American College of Radiology

ACOG – American College of Obstetricians and Gynecologists

Appendix A - Modality Based Patient Screening Flowchart

As a general rule the radiation received by a fetus from a single diagnostic examination is unlikely to result in fetal death, malformation, growth retardation or impairment of mental development. The ACR and ACOG have stated that doses below 50 mGy are considered to have negligible impact on fetal risk. However, in keeping with the ALARA principles, VCH strives to mitigate future fetal risk by implementing an effective screening process. This screening program balances: fetal risk, patient risk, and impact on clinical management.

Examinations are deemed as either a low dose procedure (<10 mGy) or a high dose procedure (> 10 mGy). Estimated fetal dose for various medical imaging examinations are available in the fetal dose educational document located on the MI Quality Teamsite and MI intranet.

Global Requirements – Patient Electronic Record

GM7.2.11	Mandatory	Comprehensive examination details recorded in the medical record include the patient pregnancy status, as required by the facility's policies.
GM7.2.12	Mandatory	Comprehensive examination details are recorded in the medical record that include: date of Last Menstrual Period (LMP) for examinations involving any radiation to the abdomen or pelvis, or administration of radiopharmaceuticals, to women of childbearing age (11 to 55 years).

Global requirements GM7.2.11 and GM7.2.12 promulgate to all radiation or magnetism imaging systems. Pregnancy screening for specific modalities is based on a best practice approach (GM7.2.12). This approach balances the clinical need for the examination with risk to the fetus. In addition to global requirements, each modality may have specific standards associated with pregnancy screening or breast feeding (i.e. nuclear medicine). Modality specific requirements are incorporated into their respective screening algorithm and are stated at the beginning of each modality screening algorithm.

"No Chance Pregnancy" Response

In some circumstances a potentially pregnant patient may respond as "No Chance Pregnancy" due to duress (i.e. in the presence of a parent/guardian/partner) or misunderstanding the question. In this situation, to mitigate fetal risk, LMMI encourages the technologist to use their professional judgment. This may include: clarifying the response in a private setting, using the "uncertain" segment of the screening policy for the specific modality or treat the response as no chance pregnancy.

Known or Possible Pregnancy – Patient Informs Staff

If a patient notifies the technologist or physician/radiologist that they are pregnant, or there is a possibility of pregnancy, staff should perform the following:

1. If a high dose radiation exam consult the referring physician or radiologist,
2. For a low dose exam where screening is deemed necessary (e.g. abdomen radiograph), consult a physician or radiologist,
3. For a low dose exam, where screening is not deemed necessary (e.g. extremity radiograph), technologist to provide risk information to patient,
4. For MRI, follow MRI guidelines in "A.1 DAP Requirements for MRI Examinations."

Magnetic Resonance Imaging (MRI) and Ultrasound

A.1 DAP Requirements for MRI Examinations

MRI involves the deposition of RF energy into the fetus and exposure of the fetus to high magnetic field strengths.

- Currently no known fetus risk has been established from MRI examinations.
- Imaging during the first trimester should be avoided. This is accomplished by asking for pregnancy status only (LMP is not required) as per GM7.2.11.
- Studies without contrast may proceed if the patient is not pregnant or outside the first trimester of pregnancy.
- A radiologist must be consulted prior to studies involving pregnant patient studies during the first trimester or studies in the second or third trimester that involve contrast.

A.2 DAP Requirements for Ultrasound Examinations

Ultrasound or Ultra-Sonography involves the use of sound waves to obtain images. Currently the DAP does not mandate screening for pregnant patients.

- There have been no reports of adverse fetal effects of Ultrasound in Humans, including Doppler, Power Doppler and harmonic imaging; however use of Doppler in fetal imaging must follow provincial guidelines. Please see the document "Regional Guideline – Acoustic Output Levels in Obstetric Ultrasound Scans" located on the VCH intranet for more guidance regarding conditions for use of Doppler during pregnancy.
- There are no contraindications for the use of ultrasound during pregnancy.
- Although GM7.2.11 requires screening for the medical record, pregnancy screening for ultrasound exams is not required by federal regulations or international bodies.
- Pregnancy screening for Ultrasound examinations is not mandatory.

Mammography and Radiography

A.3 DAP Requirements for Mammography Examinations

No specific *diagnostic* mammography accreditation requirements for pregnancy screening. See below for screening mammography program requirements.

A.4 DAP Requirements for Radiography Examinations

RS2.2		Procedures are in place to protect female patients of childbearing age. *Intent: Only essential investigations are taken in the case of pregnant or suspected pregnant women. Care is taken to protect the fetus from radiation when the X-ray examination of a pregnant woman is unavoidable. This includes keeping the exposure to the absolute minimum, the use of shielding of the abdominal area and the use of a well collimated X-ray beam.*
RS2.2.2	Mandatory	If an examination is requested on a pregnant or potentially pregnant patient, there are documented procedures on how to proceed with the examination request. *Guidance: The procedures should speak to who is responsible for discussing the patients' options for imaging such as the risk versus benefit of proceeding with or declining an examination, and how to proceed if the patient has questions regarding their care. The individuals involved in discussing the patient's concerns may encompass the referring physician, radiologist, medical physicist, and imaging technologist.*

- Radiation received to the fetus for all Mammography and Radiography examinations is considered low (Dose <10 mGy) and a single examination is deemed safe for the fetus. For the purpose of screening, hip examinations are considered part of the pelvis.
- Patient screening must follow Chart 1; *screening is not required* for patients undergoing radiographic examinations *outside the abdomen and pelvis region* or diagnostic mammography exams.
- Protective equipment is not required for imaging exams unless requested by the patient, caregiver or guardian.
- Due to the asymptomatic nature of patients undergoing SMP examinations, mammographic screening of confirmed pregnant patients should be delayed until after breast feeding. Uncertain pregnancies should be delayed until after the next menstrual cycle or confirmed pregnancy.

Recommendations for Radiography of Known Pregnant Patients

- High kVp, low mAs technical factors should be selected, consistent with adequate diagnosis,
- Use High speed screen/film combination (where applicable),
- Use DR imaging technology, if available, or dual CR imaging plate technology, if available,
- Imaging of the maternal abdomen/ pelvis should be taken PA rather than AP, if possible,
- Avoid sitting patient with knees under the imaging table/ plate during extremity views, Where applicable, limit the views to PA and Lateral

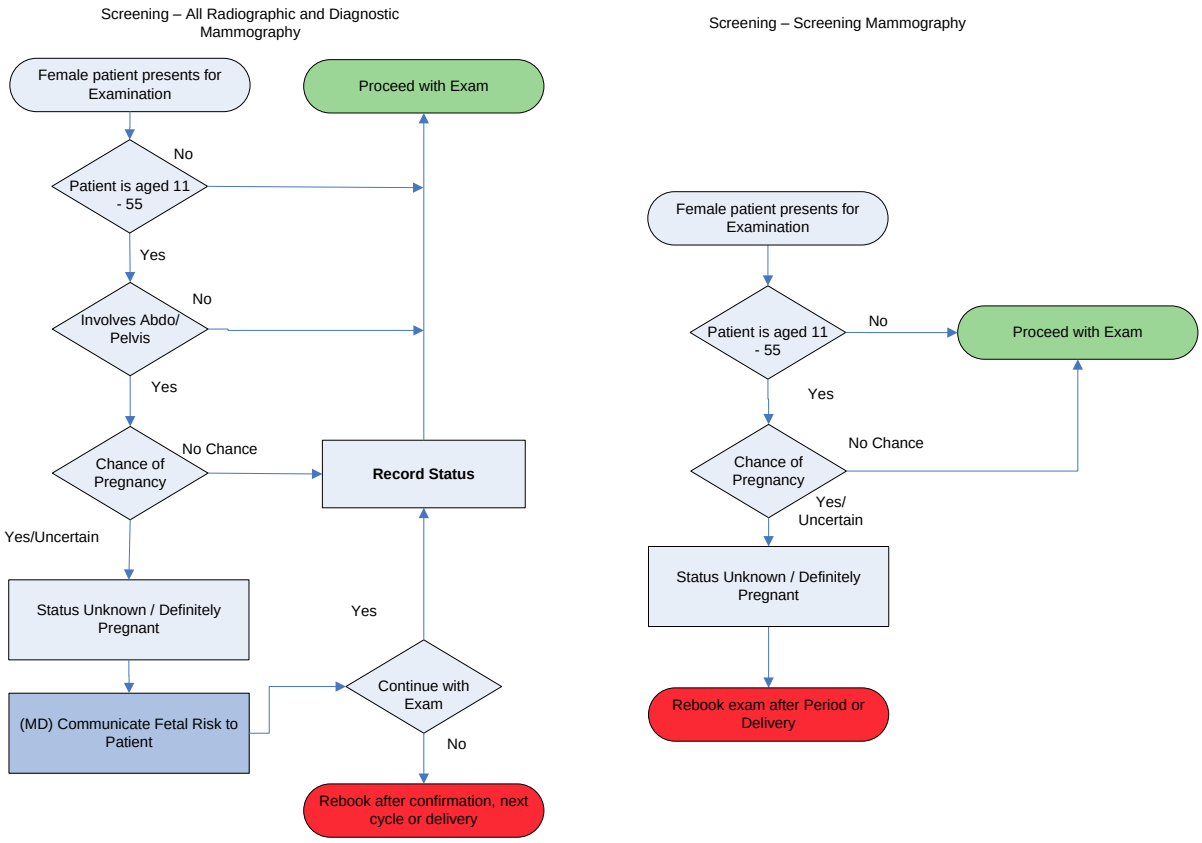

Chart 1 – Flow Chart for all mammography and radiography examinations.

Radioscopy (Fluoroscopy/Angiography)

A.5 DAP Requirements for Radioscopy Examinations

RS2.2 Procedures are in place to protect female patients of childbearing age.

Intent: Only essential investigations are taken in the case of pregnant or suspected pregnant women. Care is taken to protect the fetus from radiation when the X-ray examination of a pregnant woman is unavoidable. This includes keeping the exposure to the absolute minimum, the use of shielding of the abdominal area and the use of a well collimated X-ray beam.

RS2.2.2 Mandatory If an examination is requested on a pregnant or potentially pregnant patient, there are documented procedures on how to proceed with the examination request.

Guidance: The procedures should speak to who is responsible for discussing the patients' options for imaging such as the risk versus benefit of proceeding with or declining an examination, and how to proceed if the patient has questions regarding their care. The individuals involved in discussing the patient's concerns may encompass the referring physician, radiologist, medical physicist, and imaging technologist.

When radiological examinations of the pelvic area or abdomen are required:

Due to the nature of these procedures, possible complications may result in longer procedures times, uncertain radiation to the fetus and the administration of contrast and/or pharmaceuticals during the procedure. Therefore, LMP and/or pregnancy confirmation may be required as a necessary step to establish the appropriate clinical management pathway when the patient is uncertain of pregnancy status during abdomen and pelvis exams.

- All uncertain cases involving the abdomen/pelvis area of a women of childbearing age (ages: 11-55) must request LMP as part of pregnancy screening.
- Technologists must follow the screening steps outlined in Chart 2.

Confirmation of pregnancy can be achieved by:

- In-hospital blood or urine tests for changes in human chorionic gonadotropin (hCG),
    - Requested when: 1) emergency case, and 2) ward exam requisition
    - Blood tests are more accurate and may detect pregnancy 7-12 days after conception compared with urine tests at 14 days (some urine tests have improved sensitivity)
- Wait until next cycle and rebook exam or use a take home "off the shelf" test (patient independently confirms their pregnancy status),
    - Outpatient or other non-emergent cases.

Patients undergoing Hysterosalpingograms (HSG) must be confirmed for pregnancy.

Recommendations for Radioscopy of Known Pregnant Patients

- Use low dose mode, if available,
- Minimize fluoroscopy time,
- Use pulse fluoroscopy (decrease pulse rate),
- Use "Last Image Hold" as opposed to producing a radiographic exposure,
- Decrease DSA frame rate,
- Use Roadmap/ Fluoro Overlay techniques to decrease procedure time,
- Employ virtual coning,

- Use collimation,
- Use digital zoom (as opposed to magnification), check with physics whether a dose penalty will occur with zooming or review physics annual testing report,
- Imaging of the maternal abdomen/ pelvis should be taken PA rather than AP, if possible,
- Neonates should be screened for hypothyroidism,
- Contrast should be used if deemed absolutely necessary, if required, must be a non-ionic contrast media,

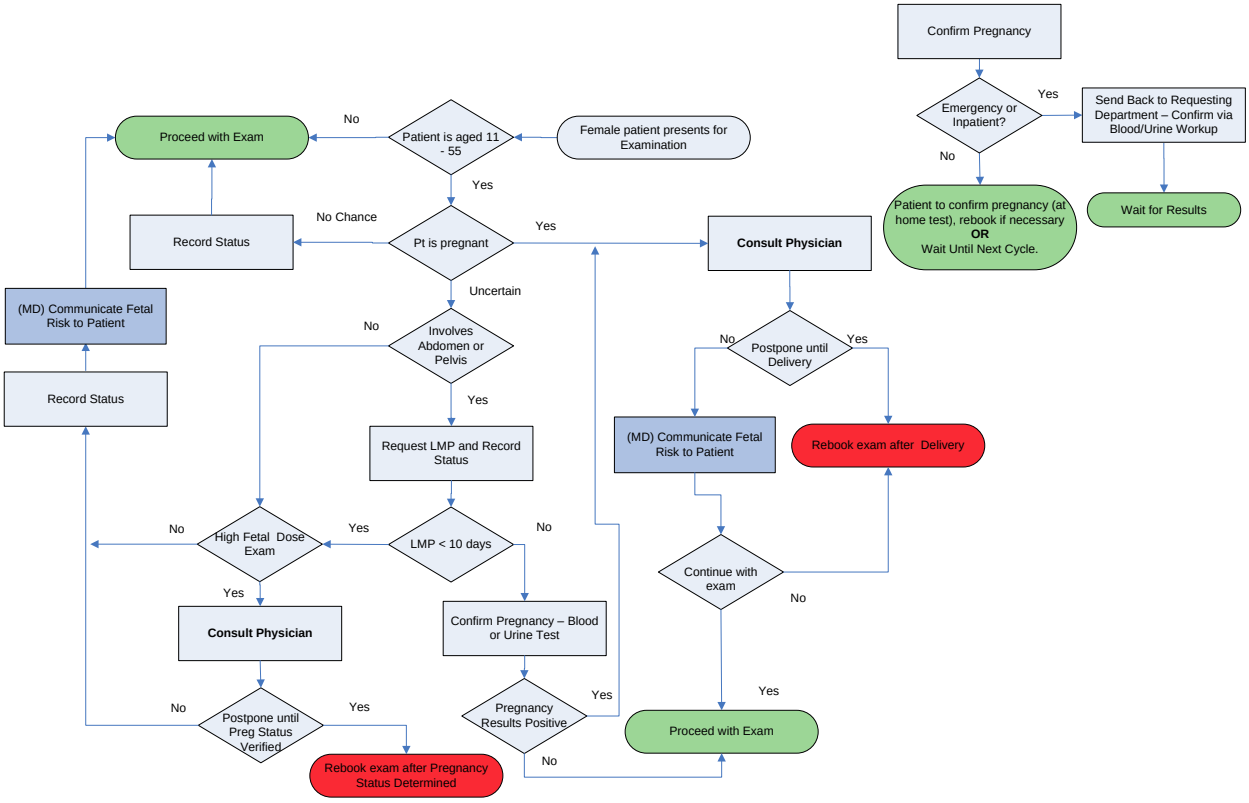

Chart 2 – Flow chart for all radioscopic (fluoroscopy/angiography) examinations.

Computed Tomography

A.6 DAP Requirements for Computed Tomography Examinations

The DAP standards do not state specific standards for pregnancy screening of CT examinations, thus global standards GM7.2.11 (pregnancy status is established) and GM7.2.12 (date of LMP for abdo/pelvis exams) apply.
The VCH implementation is a best practice approach, balancing the need for the exam with risk to the fetus.

Specific requirements of the CT pregnancy screening program:

- Computed Tomography examinations that include the abdomen/pelvis area of the patient may result in a fetal dose > 10 mGy and are considered high fetal dose examinations.
- Screening must be performed to ensure pregnancy status is confirmed prior to imaging if the abdomen/pelvis is included in the examination. LMP is required if pregnancy status is uncertain.
- Helical scans of the chest incorporate over/under scanning, which may increase fetal dose. This is influenced by scanner technology and beam collimation. Chest CT must be screened for pregnancy status. LMP is required, if pregnancy status is uncertain, to establish whether fetal risk must be conveyed to the patient (not required if LMP < 10 days).
- CT exams of the head, neck or extremity do not require LMP.
- Fetal risk must be conveyed by a physician and/or radiologist, if required,
- Technologists must follow the screening steps outlined in Chart 3.

In Chart 3, confirmation of pregnancy is required when:

- A female patient is between 11-55 years old, and
- Pregnancy is uncertain, and
- The examination incorporates the abdomen or pelvis (or chest with LMP > 10 days)

Confirmation of pregnancy can be achieved by:

- In-hospital blood or urine tests for changes in human chorionic gonadotropin (hCG),
    - Requested when: 1) emergency case, and 2) ward exam requisition
    - Blood tests are more accurate and may detect pregnancy 7-12 days after conception compared with urine tests at 14 days (some urine tests have improved sensitivity)
- Wait until next cycle and rebook exam or use a take home “off the shelf” test (patient independently confirms their pregnancy status),
    - Outpatient or other non-emergent cases.

Recommendations for Computed Tomography of Known Pregnant Patients

- Use Peripheral Dose Reduction Technology, if available,
- Use Lower kVp, adjust mAs to ensure appropriate image noise,
- The iodine content has the potential to produce neonatal hypothyroidism after the direct instillation of ionic contrast into the amniotic cavity during amniofetography,
- Neonates should be screened for hypothyroidism,
- Contrast should be used if deemed absolutely necessary, if required, must be a non-ionic contrast media,

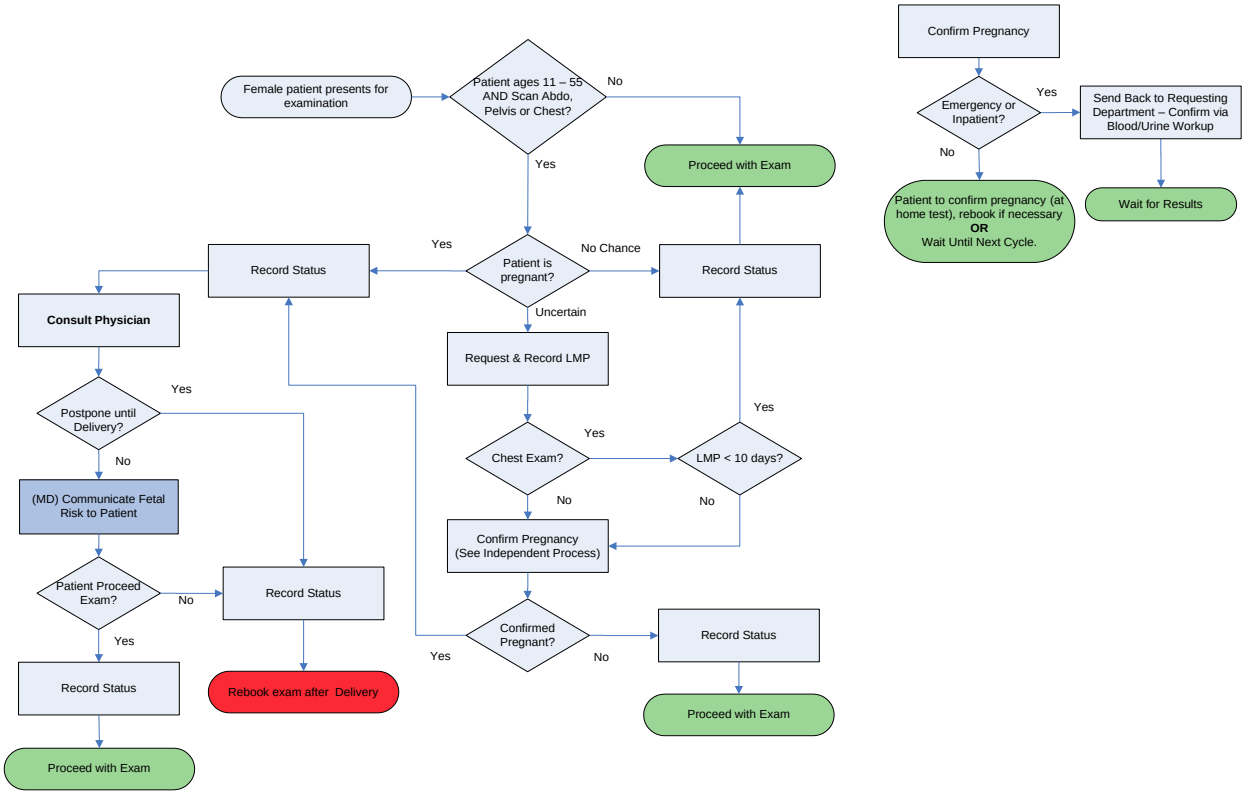

Chart 3 – Flow chart for all computed tomography examinations. LMP is necessary for Chest CT exams if the patient is uncertain of her status. Method of confirmation based on exam urgency and requesting department/physician. See guidelines to establish correct method of pregnancy confirmation.

Nuclear Medicine

A.7 DAP Requirements for Nuclear Medicine Examinations

NM2.2.1	Mandatory	Contraindications are identified (e.g. pregnancy, breastfeeding, medications, allergies, etc.) and documented.
NM7.2.1	Mandatory	Comprehensive examination details are recorded in the medical record that includes breast feeding status.

- Examinations with large administered activities can result in a fetal dose > 10 mGy,
- It is critical to avoid administration of radiopharmaceuticals that can cross the placenta (i.e. Iodine and Gallium); these procedures are considered high dose procedures,
- Precautions must also be taken for patients whom are breastfeeding or in close contact with infants,
- Pregnancy screening procedures for nuclear medicine exams are outlined in Chart 4,
- Screening procedures for breastfeeding patients and patients having close contact with infants or small children are outlined in Chart 5, definitions are provided in the VCH Breast Feeding Guidelines.

The majority of nuclear medicine exams are considered "low dose" and from a fetal risk perspective could proceed if a physician was available to provide risk assessment. However, unlike x-ray examinations a successful nuclear medicine examination must incorporate time-dependent processes (administration of radiopharmaceuticals and image acquisition). Due to workflow and availability of risk communication by a physician, studies deemed "non-urgent" for patients with an "Uncertain" pregnancy status should be rebooked. A list of urgent exams is provided below.

Urgent Exams:
Ventilation/Perfusion (V/Q)
Myocardial Perfusion Imaging (MPI)
Gastrointestinal (GI) Bleed
Bone Scan/White Blood Cell for Infection
Bone scan for metastatic survey

Additional information regarding clinical management of breast feeding patients is provided in the supplemental educational document.

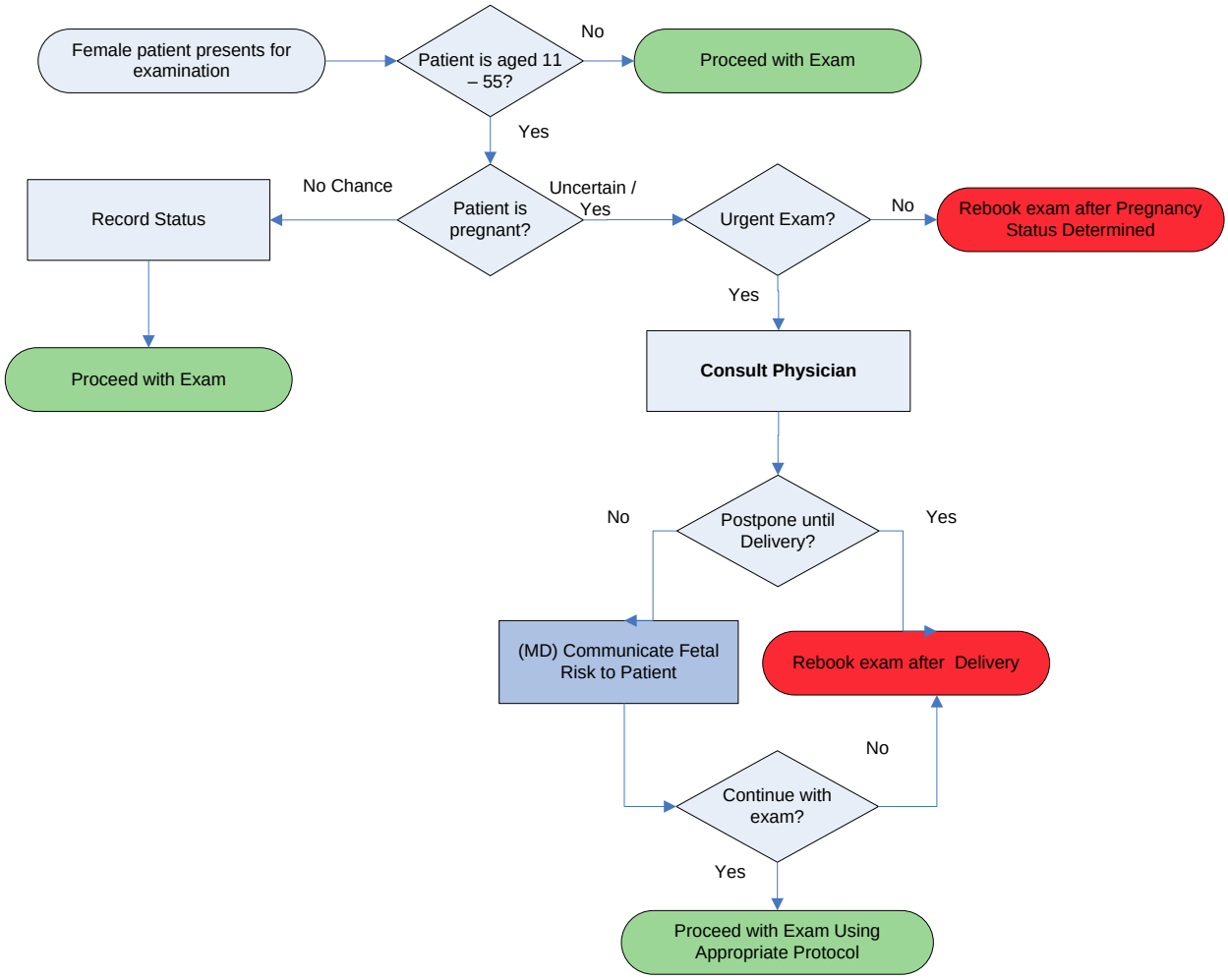

Chart 4 – Flow chart for pregnancy screening for all nuclear medicine examinations.

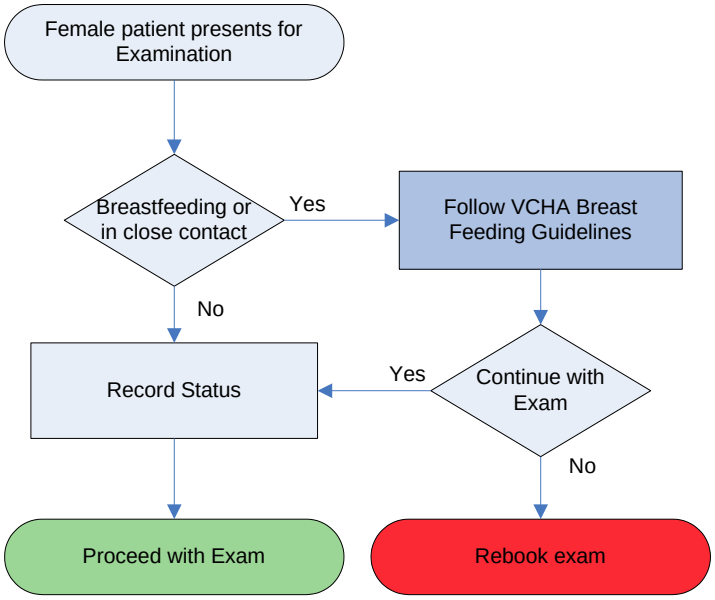

Chart 5 – Flow chart for nuclear medicine examinations in the case of patients who are breastfeeding or have close contact with an infant or small child.

Bone Densitometry

A.8 DAP Requirements for Bone Densitometry Examinations

BD7.2.1	Mandatory	Comprehensive examination details are recorded in the medical record that includes menopausal status. *Guidance: Further information may include menopause date or date of last menstrual period (LMP) when known by the patient, date of surgical menopause.*

Radiation received to the fetus for all Bone Density examinations is considered low (Dose <10 mGy) and a single examination is deemed safe for the fetus, from a radiation safety perspective. However, pregnancy maybe a contraindication for Bone Density examinations, thus LMP is required to establish the correct clinical management pathway.

Scientific evidence suggests bone density decreases during lactation amenorrhea (breast feeding). Diagnostic information may be improved if bone densitometry exams are performed 6 months after cessation of breast feeding. This is recommended, but not required practice.

When requesting menopausal status, record all information relevant to the exam, included menopause date or date of surgical menopause. Patient screening must follow Chart 6.

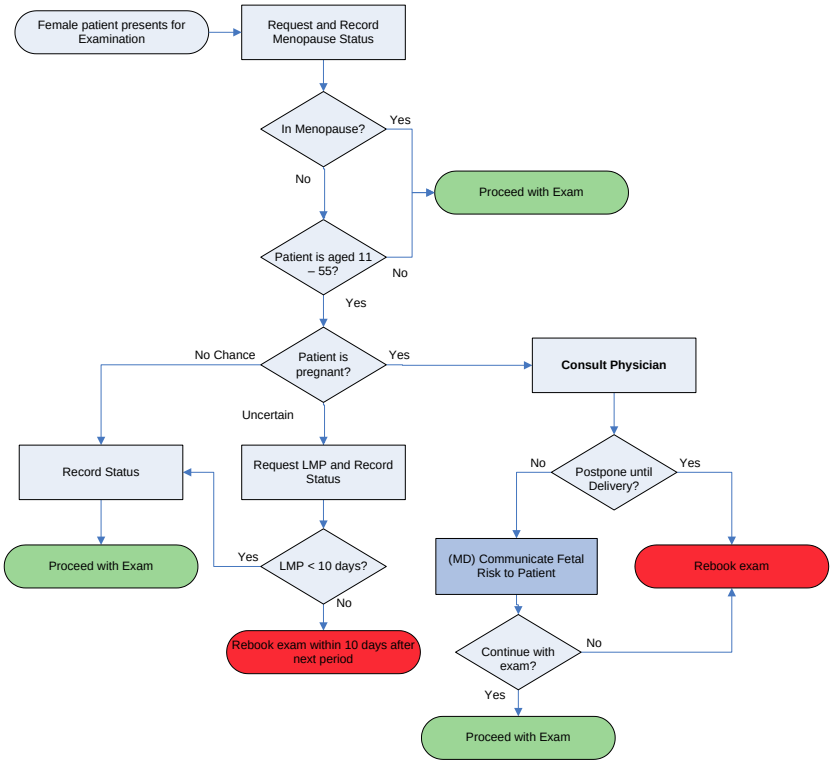

Chart 6 – Flow Chart for all bone densitometry examinations.

Appendix B – VCH Review History

Date (dd/mm/year)	Review Body	Comments
25/02/2015	General Radiology PPWG	
26/03/2015	Nuclear Medicine PPWG	BD flow chart changed to reflect concerns regarding rebooking Added reference to 2008 VCH breast feeding guidelines
08/04/2015	Mammography PPWG	
27/04/2015	MRI PPWG	Sites currently follow these guidelines, BC CH screens at 12 instead of 11. Site overall to change screening age (all modalities)
13/05/2015	General Rad PPWG	Second Review
27/05/2015	NA - ythakur	Added: patients who inform tech prior to screening.
09/06/2015	MI Directors	Add Hysterosalpingiogram to fluoroscopy as a must
20/08/2015	MI EXEC and MPL	Circulated by L. Jongedijk to MI EC and MPL's – feedback by Sept 3rd
18/09/2015	NA	Comments received by J Clement (08/20) and C. Yong-Hing (09/02) added, New LMMI header/footer added.
08/10/2015	US PPWG	No changes suggested
14/10/2015	MIEC	Approved for trial at a selected site
06/01/2016	Dr. Stephan Ho (MPL – Interv.) & Dr. Charlotte Yong-Hing	Modified angio/fluoro algorithm as requested by Dr. Ho, feedback and review requested for Jan 11th.
09/03/2016	Discussion with Dr. Sexsmith – NM lead FHA	Modified algorithm for NM, modified to "urgent" vs. "non-urgent" cases. List of urgent cases provided by Dr. Sexsmith and included in document. Timing very important for NM exam… too much time to obtain physician risk discussion. For screening… discussion regarding "close contact" with children
22/03/2016	Adjusted flow chart 4 after discussion with Dr. Sexsmith	Minor change to flow chart
18/02/2017	Kevin E and Yogesh	Adjusted wording in CT section to accurately reflect need for LMP
09/28/2022	Yogesh	Updated document to reflect changes in DAP standard, revised wording accordingly.