Diagnostic X-ray and Fluoroscopy Policy and Procedure for Duke Primary Care and Other Duke-Affiliated Clinics: Pregnant or Potentially Pregnant Patients

PURPOSE: To establish a policy for the safe use of radiological exams that use ionizing radiation (radiography, CT, fluoroscopy/angiography) by technologists and responsible practitioners in a pregnant or potentially pregnant patient.

APPLIES TO: Duke Primary Care (DPC) clinics and other off-site facilities affiliated with the Duke University Health System, excluding Duke University Hospital, Durham Regional Hospital and Duke Raleigh Hospital.

EFFECTIVE DATE: 3 August 2010

REVISION DATE: 10 December 2015

(1) Some radiologic examinations expose the fetus/baby to radiation doses that are negligible, and pregnancy status should not affect the decision to proceed with a medically indicated and properly performed exam. Such studies are listed in Section A of Appendix I (When to Document Pregnancy Status and Obtain Signed, Informed Consent), and Appendix II (Categories of Radiation Risk of Fatal Childhood Cancer Following In-Utero Medical Radiation Exposure).

If a patient presents for one of these exams and is known to be pregnant, this information should be brought to the attention of the responsible on-site licensed practitioner*. The responsible practitioner should discuss with the patient that any risk to the unborn fetus/baby is minimal, since the radiation dose is considered negligible. This should be documented in the radiology report. Information about diagnostic radiation during pregnancy that may be helpful when talking to a pregnant or potentially pregnant patient can be found in Appendix III (Patient Information). When possible and desired (i.e., requested by the patient) lead-equivalent shielding to wrap the abdomen and pelvis should be provided during any examination where this area is not included in the imaging field (i.e. x-rays of the skull, chest, T-spine, mammograms).

(2) Otherwise, those radiology exams that deliver more than a negligible amount of radiation to the fetus/baby and/or involve direct exposure of the female pelvis to ionizing radiation require assessment of pregnancy status. Pregnancy status shall be determined in all girls and women between the ages of 12 and 50 years prior to performing the procedure. Such studies are listed in Appendix I, sections B and C, and Appendix II. The following process shall be employed:

   (a) Patients shall be questioned as to the possibility of pregnancy. This should be done as sensibly and unobtrusively as possible, in order to protect a woman’s privacy and dignity. Parents or guardians of minor children should not be present during the inquiry regarding the possibility of pregnancy. Guidance for interviewing patients to determine pregnancy status is provided in Appendix IV (Pre-Examination Pregnancy Interview Guidelines).

   (b) If there is the possibility that pregnancy is likely, the responsible practitioner shall be notified. After obtaining verbal consent from the patient, the practitioner may order a urine or blood test to rule out pregnancy.
(c) If it is determined that the patient is pregnant, the responsible practitioner will notify the patient of the positive results, in compliance with Duke Medicine policy*. The patient, referring physician, and responsible practitioner will then determine if the study is appropriate for the clinical indications, or may be deferred to a later date. Alternative procedures using nonionizing imaging such as ultrasound and magnetic resonance imaging (MRI) should be considered. The patient, practitioner, and referring physician will decide on the optimal test, while maintaining an optimized (especially minimized) radiation dose necessary for diagnostic quality.

(d) If the exam is deemed to be necessary while the patient is pregnant, the responsible practitioner is to inform the patient of the risks to the embryo/fetus that are associated with ionizing radiation. For information on the risks of x-rays during pregnancy, see Appendix III. The Duke Radiation Safety Division may be contacted at (919)684-2794 for consultation information.

(e) If the patient is pregnant and informed consent is appropriate (see Appendix I, Sections B and C, and Appendix II), the responsible practitioner is to be contacted to consent the patient (Consent form can be found as Appendix V). Helpful information when consenting a pregnant patient for a radiation exam can be found in Appendix III.

(f) If the patient consents to proceed with the x-ray examination, she should be shielded with 0.5 mm lead equivalent to minimize exposure to the embryo/fetus, if doing so would not interfere with the exam. If the x-ray field includes the abdominal/pelvic region, a modified x-ray examination should be performed. Modifications in technique may include optimizing the kVp, mAs, fluoroscopy time and CT protocol parameters to values consistent with obtaining the required diagnostic information. Appropriate modification of technique shall be done in consultation with the responsible practitioner or other qualified expert.

(3) If a patient has been exposed to significant radiation and is pregnant, but this was not known at the time of the exam, the Duke Radiation Safety Division staff, or other qualified expert, will be contacted to perform dose estimations, with follow-up with the patient and her responsible healthcare provider. This process will be documented.

*“Responsible on-site licensed practitioner” may be an on-site radiologist, non-radiology physician or any other licensed practitioner of the healing arts who is responsible for the operation of and medical care delivery at a clinic.

**As of 2/28/2014 the Duke Medicine policy regarding sharing of sensitive health information pertaining to minors in MyChart with parents/guardians is as follows:

<12 yrs.: Parents can access and read
12-<15 yrs.: Requires clinician approval for the parent to read
15 yrs. and over: Not accessible to parents (child can give them access).

RADIATION SAFETY OFFICER APPROVED: 10 December 2015