

Best Evidence Statement (BEST)

Date published/posted: December 3, 2010

Title: Among pregnant healthcare workers does prolonged exposure to the radioisotope Neurolite compared to no exposure increase teratogenic risks?

Clinical Question

P (population/problem)	<u>pregnant healthcare workers</u>
I (intervention)	<u>prolonged exposure (>2 to 6 hours) to the radioisotope Neurolite</u>
C (comparison)	<u>no exposure</u>
O (outcome)	<u>increased teratogenic risks</u>

Target Population: Pregnant healthcare workers

Recommendation

There is insufficient evidence and a lack of consensus to make a recommendation regarding the safety of prolonged exposure to the radioisotope Neurolite by pregnant healthcare workers, specifically related to exposure greater than two to six hours of direct contact.

Note: Evidence regarding exposure to less than two to six nursing contact hours per day would suggest pregnant healthcare workers exposed to low dose ionizing radiation exercise caution. (Mountford, & Steele, 1995 [4a], Russell, 1992 [5]).

Relevant CCHMC policies / procedures: A7 Neuroscience Unit Ictal SPECT Guidelines

Discussion/summary of evidence

It is known that large doses of radiation are harmful to a fetus, yet the risks of small doses can not be accurately determined because any small increase in cancers or inherited disease which might be related to occupational exposure can be masked by natural radiation exposures (Burks, Griffith, McCormick, & Miller, 1982 [4a], Fattibene, Mazzei, Nuccetelli, & Risica, 1999 [5], Harding, & Thomson, 2000 [5], Thompson, 2001[5]).

The reported evidence regarding the effects of radioisotope exposure on the fetus was estimated from exposure simulations (Phantom measurements of exposure to in-patients that have received a radioisotope for a diagnostic test) (Mountford, & Steele, 1995 [4a], Russell, 1992 [5]) and estimated exposures to atomic bomb survivors (Schull, & Otake, 1999 [5]).

Low level evidence was found which stated that exposure to the radioisotope Neurolite will expose a pregnant healthcare worker to very low levels of ionizing radiation; levels that are expected to be below the 1 mSv which is the government regulated maximum fetal exposure level for the duration of the declared pregnancy (Mountford, & Steele, 1995 [4a], Burks, et al., 1982 [4a], Bolus, 2008 [5]).

Note: a declaration of pregnancy must be made in writing by the pregnant worker to her supervisor. (Bolus, 2008 [5]).

There was no consistent evidence or published expert opinion that exposure during certain trimesters of gestational development is safe even to low dose radiation exposure (Bolus, 2008 [5], Fattibene, et al., 1999 [5], Harding, & Thomson, 2000 [5], Mountford, & Steele, 1995 [4a], Russell, 1992 [5]).

No evidence was found specifically referring to Healthcare workers being directly exposed to the radioisotope Neurolite for prolonged periods of time (greater than two to six nursing contact hours per day).

Two published articles referring to the Nurses role in the delivery of an Ictal injection did give special consideration to pregnant nurses. In Georgia, the pregnant nurse was not required to perform the duty of ictal SPECT injection nurse. They also issued a fetal monitoring badge (Huntington, 1999 [5]). In Canada, injections were contraindicated if the nurse or the patient is pregnant or if they are currently breast feeding. The pregnancy is confirmed with beta human chorionic gonadotropin testing in serum (Burneo, Vezina, Romsa, Smith, & McLachlan, 2007 [5]).

Local expert opinion was obtained from Dr. Gelfand, Nuclear Medicine Attending at CCHMC and Dr. Gardner, Good Samaritan OB/GYN group. Dr. Gelfand stated it is safe to handle Neurolite while pregnant. Dr. Gardner recommends no exposure to low dose ionizing radiation while you are pregnant.

Acceptable exposure levels for pregnant healthcare workers were not found in the literature, likely due to ethical considerations in this type of research. Therefore the evidence consists of exposure levels of phantom simulations and atomic bomb survivors, as well as exposure levels of patients post diagnostic testing with radioisotopes.

Health Benefits, Side Effects and Risks

Not applicable because there is no literature regarding prolonged exposure.

Descriptive studies support the safety of healthcare workers exposed to the radioisotope Neurolite for less than two to six nursing care contact hours per day (Mountford, & Steele, 1995 [4a], Burks, et al., 1982 [4a]). However, there is theoretical concern regarding teratogenic risks from ionizing radiation among published expert opinion (Bolus, 2008 [5], Fattibene, et al., 1999 [5], Harding, & Thomson, 2000 [5], Russell, 1992 [5]).

References/citations (evidence grade in []; see *Table of Evidence Levels following references*)

Bolus, N. (2008). Review of common occupational hazards and safety concerns for nuclear medicine technologists. *J Nucl Med Technol*, 36, 11. [Level 5]

Burks, J., Griffith, P., McCormick, K., & Miller, R. (1982). Radiation exposure to nursing personnel from patients receiving diagnostic radionuclides. *Heart & Lung*, 11(3), 217. [Level 4a]

Burneo, J., Vezina, W., Romsa, J., Smith, B., McLachlan, R. (2007). Evaluating the Development of a SPECT Protocol in a Canadian Epilepsy Unit. *The Canadian journal of Neurological sciences*, 34, 225-229. [Level 5]

Fattibene, P., Mazzei, F., Nuccetelli, C., & Risica, S. (1999). Prenatal exposure to ionizing radiation: Sources, effects and regulatory aspects. *Acta Paediatr*, 88, 693-702. [Level 5]

Harding, L. K., & Thomson, W. H. (2000). Radiation and pregnancy. *Quarterly Journal of Nuclear Medicine*, 44(4), 317-324. [Level 5]

Huntington, N. (1999). The Nurse’s Role in the Delivery of Radioisotope for Ictal SPECT scan. *American association of Neuroscience Nurse*, 31(4), 208-215. [Level 5]

Mountford, P. J., & Steele, H. R. (1995). Fetal dose estimates and the ICRP abdominal dose limit for occupational exposure of pregnant staff to technetium-99m and iodine-131 patients. *European Journal of Nuclear Medicine*, 22(10), 1173-1179. [Level 4a]

Russell, J. G. (1992). Pregnancy and Ionizing Radiation. *British Medical Journal*, 305(6863), 1172. [Level 5]

Schull, W. J., & Otake, M. (1999). Cognitive function and prenatal exposure to ionizing radiation. *Teratology*, 59, 222-226. [Level 5]

Thompson, M. (2001). Maintaining a proper perspective of risk associated with radiation exposure. *Nuclear Medicine Technology*, 29(3), 137. [Level 5]

Note: Full tables of evidence grading system available in separate document:

- [Table of Evidence Levels of Individual Studies by Domain, Study Design, & Quality](#) (abbreviated table below)
- [Grading a Body of Evidence to Answer a Clinical Question](#)
- [Judging the Strength of a Recommendation](#) (abbreviated table below)

Table of Evidence Levels (see note above)

Quality level	Definition
1a† or 1b†	Systematic review, meta-analysis, or meta-synthesis of multiple studies
2a or 2b	Best study design for domain
3a or 3b	Fair study design for domain
4a or 4b	Weak study design for domain
5	Other: General review, expert opinion, case report, consensus report, or guideline

†a = good quality study; b = lesser quality study

Table of Recommendation Strength (see note above)

Strength	Definition
“Strongly recommended”	There is consensus that benefits clearly outweigh risks and burdens (or visa-versa for negative recommendations).
“Recommended”	There is consensus that benefits are closely balanced with risks and burdens.
No recommendation made	There is lack of consensus to direct development of a recommendation.
<p>Dimensions: In determining the strength of a recommendation, the development group makes a considered judgment in a consensus process that incorporates critically appraised evidence, clinical experience, and other dimensions as listed below.</p> <ol style="list-style-type: none"> 1. Grade of the Body of Evidence (see note above) 2. Safety / Harm 3. Health benefit to patient (<i>direct benefit</i>) 4. Burden to patient of adherence to recommendation (<i>cost, hassle, discomfort, pain, motivation, ability to adhere, time</i>) 5. Cost-effectiveness to healthcare system (<i>balance of cost / savings of resources, staff time, and supplies based on published studies or onsite analysis</i>) 6. Directness (<i>the extent to which the body of evidence directly answers the clinical question [population/problem, intervention, comparison, outcome]</i>) 7. Impact on morbidity/mortality or quality of life 	

Supporting information

Introductory/background information

Since the development of the Epilepsy Surgery Program at Cincinnati Children’s in 2007, new diagnostic testing has been added for this patient population. One new diagnostic test that has potential safety implications for pregnant nurses or healthcare providers is the Ictal SPECT scan. In order to provide care, to the patient undergoing this scan the nurse is required to become certified in Radiation handling. This nurse then is able to administer the radioactive nuclide or radioisotope called Neurolite.

For an Ictal SPECT injection, the nurse is present at the patient’s bedside with a syringe of radioisotope for up to seven hours at a time, at very close range. The syringe is protected in a lead shield, and attached to the patient’s peripheral intravenous catheter secured to their arm.

Healthcare workers questioned the safety of handling the radioisotope Neurolite while pregnant, since they have no control over the time spent in contact with or distance from the radioisotope in the context of administering an Ictal SPECT injection.

Group/team members

Group/Team Leader

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Search strategy

DATABASES

- OVID MEDLINE
- OVID CINAHL
- OVID EBM Reviews (Cochrane)
- other - Scopus, Biomedical reference collection

SEARCH TERMS

Neurolite, Tc99m, Technetium Tc-99m Bicisate dihydrochloride, Radiopharmaceutical, Radioactive, Low dose ionizing radiation, Teratogenic, teratogens, Pregnancy, Reproduction, Reproductive health, Occupational exposure, Declared pregnant women, Fetus, Radionuclide procedures

Filters: English Language

Date Range Searched: Inclusive through March, 2010

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This Best Evidence Statement addresses only key points of care for the target population; it is not intended to be a comprehensive practice guideline. These recommendations result from review of literature and practices current at the time of their formulation. This Best Evidence Statement does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the recommendations to meet the specific and unique requirements of individual patients. Adherence to this Statement is voluntary. The clinician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.

Reviewed against quality criteria by 2 independent reviewers