X-ray Literature Review

https://www.govinfo.gov/content/pkg/CFR-2022-title21-vol8/pdf/CFR-2022-title21-vol8-sec1000-50.pdf

21 CFR § 1000.50 - Recommendation for the use of specific area gonad shielding on patients during medical diagnostic x-ray procedures.

Title 21 - Food and Drugs
Chapter I - FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)
Subchapter J - RADIOLOGICAL HEALTH
Part 1000 - GENERAL
Subpart C - Radiation Protection Recommendations
Section § 1000.50 - Recommendation for the use of specific area gonad shielding on patients during medical diagnostic x-ray procedures.

Hall EJ, Gaccia AJ. Radiobiology for the Radiologist. 7th ed. Philadelphia, PA: Lippincott Williams and Wilkins; 2011

Ionizing radiation may interact directly with target tissues or indirectly through the production of free radicals from its interaction with water molecules. Effects of radiation on cells differ depending on the cell's rate of division and with the level of cell differentiation. Tissue sensitivity to radiation varies from highest to lowest as follows: lymphocytes, erythroblasts, spermatogonia, epidermal stem cells, and gastrointestinal stem cells. Other types of cells (muscle, bone, and nerve cells) are less sensitive to the effects of radiation. DNA appears to be the principal target for biological effects of radiation, including cell death, mutation, and carcinogenesis. If cells are irradiated with ionizing radiation, single-strand or double-strand DNA breaks or other DNA changes may occur. This can be followed by error-free DNA repair, but if the repair is incorrect, it can result in cell death, chromosomal instability, mutation, and/or carcinogenesis.

Sensakovic WF, O'Dell MC, Letter H, Kohler N, Rop B, Cook J, Logsdon G, Varich L. Image quality and dose differences caused by vendor-specific image processing of neonatal radiographs. Pediatr Radiol. 2016 Oct;46(11):1606-13. doi: 10.1007/s00247-016-3663-2. Epub 2016 Aug 3. PMID: 27488507.

Ma H, Elbakri IA, Reed M. Estimation of organ and effective doses from newborn radiography of the chest and abdomen. Radiat Prot Dosimetry. 2013 Sep;156(2):160-7. doi: 10.1093/rpd/nct050. Epub 2013 Mar 21. PMID: 23520199.

https://ncrponline.org/wp-content/themes/ncrp/PDFs/Statement13.pdf

NCRP Recommendations for Ending Routine Gonadal Shielding During Abdominal and Pelvic Radiography

National Council of Radiation Protection and Measurements

NCRP Statement No. 13, January 12, 2021 Executive Summary

NCRP now recommends that GS not be used routinely during abdominal and pelvic radiography, and that federal, state, and local regulations and guidance should be revised to remove any actual or implied requirement for routine GS. GS use may remain appropriate in some limited circumstances. The recommendations in this Statement are limited to patient GS during abdominal and pelvic radiography. NCRP recognizes that adoption of these new recommendations requires addressing the impact of this substantial change on ingrained medical practice.

Situations in Which Gonadal Shielding May Be Used

Radiologic technologists should be supported as they carry out their professional responsibilities and tasks, including their interactions with patients (Marsh and Silosky 2019). This includes establishing procedures for circumstances where a patient, parent or caregiver requests that GS be used. Such requests for use of GS should be discussed to facilitate informed and mutual decision making, providing information that will help to answer the patient's questions and understand the risks and benefits. GS may be permissible when it will not interfere with the purpose of the examination. If consent for the examination cannot be obtained without use of GS, GS use should adhere to institutional or practice guidelines or policies that minimize or eliminate the negative impact on diagnostic potential.

ASRT Update on Gonadal and Fetal Shielding

American Society of Radiologic Technologists

ASRT Update on Gonadal and Fetal Shielding

Jan 15, 2021

On Jan. 12, 2021, the ASRT Board of Directors released a statement supporting the discontinuation of the use of gonadal and fetal shielding specifically during abdominal and pelvic radiography.

Significant advances in technology have resulted in reduced patient radiation dose during radiographic procedures, opening the door to this change in clinical practice. However, the radiation protection methods implemented by registered and certified radiologic technologists remain an essential component of high-quality and safe medical imaging procedures. While shielding placed outside of the exposed field may offer only limited additional reductions to patient exposure, this low-risk practice is an important component of our comprehensive efforts to reduce excess radiation dose during our procedures.

The ASRT Board supports the continued use of lead shielding during radiographic procedures where shield placement is appropriate and aligned with minimizing patient radiation exposure. For example, the placement of a lap shield during a radiographic extremity procedure carries little-to-no risk of exam interference or error, but may significantly increase patient comfort and confidence, thus helping to reaffirm our profession's commitment to maximizing safety. The elimination of all patient shielding from standard practice could exacerbate the radiophobia that exists among the public and our patients due to widespread media coverage of the published risks associated with medical radiation exposure.

Before considering the elimination of all patient shielding as a standard practice during radiographic procedures, it is essential that we educate our patients and health care colleagues on the recent advances in technology that have dramatically reduced patient radiation dose, as well as the indispensable role that radiologic technologists serve in the provision of safe and high-quality medical imaging procedures.

The ASRT will explore partnering with key stakeholders to collaboratively develop and disseminate educational materials to inform the public about the safety of our procedures.

Surjit Damon Jeetoo, MBChB, DA(SA), FC Rad Diag(SA), Johan Smith, MBChB, MMed (Paed), PhD, FC Paed, and Richard Denys Pitcher, MBChB, FC Rad Diag (SA), PhD. Radiological Studies in Very Low Birth Weight and Extremely Low Birth Weight Neonates: 'ALARA' Revisited. Journal of Tropical Pediatrics, 2020, 66, 403–411 doi: 10.1093/tropej/fmz080 Advance Access Publication Date: 31 December 2019.

This article discusses advances in neonatal care, concerning a dramatic increase in the survival of premature infants born at 23–24 weeks. Survival generally requires highly specialized care. Diagnostic imaging plays a central role with conventional radiography most used, playing a pivotal role in the diagnosis. Ionizing radiation is hazardous, with well documented deterministic and stochastic effects. Deterministic effects are dose-related and, thus, relatively predictable, causing direct injury, such as radiation burns. However, stochastic effects are less predictable and include later cancer induction. It is known that children are more sensitive to the harmful effects of ionizing radiation, demonstrating a 2–3 times higher risk of cancer induction per unit dose than the average population. Neonates are particularly susceptible.

The effective dose (ED) of ionizing radiation, which is cumulative, and measured in Sieverts (Sv), is acknowledged as the best predictor of cancer induction. Thus, two similar radiographic examinations have twice the ED of a single examination, while doubling the potential stochastic effect.

Despite striking advances in neonatal care in the past three decades, with associated changes in neonatal imaging, few studies have assessed both radiographic practice and ED in preterm neonates. This article discusses the very low birth weight and extremely low birth weight neonates concerning ALARA. AAPM Position Statements, Policies and Procedures - Details

American Association of Physicists in Medicine

April 2-3, 2019 Board of Directors Meeting Minutes

Policy text

Patient gonadal and fetal shielding during X-ray based diagnostic imaging should be discontinued as routine practice. Patient shielding may jeopardize the benefits of undergoing radiological imaging. Use of these shields during X-ray based diagnostic imaging may obscure anatomic information or interfere with the automatic exposure control of the imaging system. These effects can compromise the diagnostic efficacy of the exam, or actually result in an increase in the patient's radiation dose. Because of these risks and the minimal to nonexistent benefit associated with fetal and gonadal shielding, AAPM recommends that the use of such shielding should be discontinued.

For patients or guardians experiencing fear and anxiety about radiation exposure, the use of gonadal or fetal shielding may calm and comfort the patient enough to improve the exam outcome (1). This may be considered when developing shielding policies and procedures. However, blanket statements requiring the use of such shielding are not supported by current evidence (2-4). Additionally, the AAPM recommends that radiologic technologist educational programs (including patient outreach efforts) provide information about the limited utility and potential drawbacks of gonadal and fetal shielding.

Rationale for policy: Gonadal and fetal shielding in X-ray imaging has for decades been considered consistent with the ALARA principle and therefore good practice. Given advances in technology and current evidence of radiation exposure risks, the AAPM has reconsidered the effectiveness of gonadal and fetal shielding.

Gonadal and fetal shielding provide negligible, or no, benefit to patients' health.

1) Radiation doses used in diagnostic imaging are not associated with measurable harm to the gonads or fetus. The main concern with radiation exposure to the reproductive organs has been an increased risk of hereditary effects. However, according to the 2007 Publication 103 of the International Commission on Radiological Protection (ICRP), "no human studies provide direct evidence of a radiation-associated excess of heritable disease" (5). Similarly, the American College of Obstetricians and Gynecologists (ACOG) Guidelines, with endorsement from the American College of Radiology (ACR), states that "with few exceptions, radiation exposure through radiography, computed tomography scan, or nuclear medicine imaging techniques is at a dose much lower than the exposure associated with fetal harm" (6).

2) Patient shielding is ineffective in reducing internal scatter. In medical x-ray imaging, the main source of radiation dose to internal organs that are outside the imaging field of view is x-rays that scatter inside the body. However, surface shielding covering these organs has no impact on this scatter.

The use of gonadal and fetal shielding can negatively affect the efficacy of the exam.

1) Shielding can obscure anatomy, resulting in a repeated exam or compromised diagnostic information. Shielding placed inside the imaging field of view, or shielding that moves into the imaging field of view, can obscure important anatomy or pathology, or introduce artifacts. In such cases, if the procedure is not repeated the interpreting physician may lack important diagnostic information; if it is repeated, there will be a substantial increase in dose. Evidence shows that this is a more common problem than usually assumed (7-9).

2) Shielding can negatively affect automatic exposure control and image quality. All modern X-ray imaging systems use automatic exposure control, and the presence of shielding in the imaging field of view can drastically increase X-ray output, increasing patient radiation dose and degrading image quality (10).

FAQs Patient Shielding v8.0 FINAL (aapm.org)

American Association of Physicists in Medicine

This document offers discussion points within the FAQs. There are conflicting points.

Patient Gonadal and Fetal Shielding in Diagnostic Imaging Frequently Asked Questions

The committee recommends that facilities that choose to limit the routine use of patient fetal and gonadal shielding use this document, in part or in whole, to help establish a guideline or policy that meets the needs of their individual practice. Such guidelines or policies are critically important so that any changes in practice are adopted in a consistent manner; inconsistency in the use of shields can imply to patients that not using a shield is a lapse of proper care when they have other exams where shields are used.

A8. Should I continue to wear a lead (radioprotective) apron at work? Absolutely.

Gislason-Lee AJ. Patient X-ray exposure and ALARA in the neonatal intensive care unit: Global patterns. Pediatr Neonatol. 2021 Jan;62(1):3-10. doi: 10.1016/j.pedneo.2020.10.009. Epub 2020 Nov 18. PMID: 33349597.

This is a recent literature review of 25 studies from around the world. The number of X-rays a patient underwent during a NICU stay ranged from 0 to 159. Younger, lower birth weight patients consistently had the greatest number of X-rays per stay. The findings indicate a disparity

in the response to neonatal X-ray dose concerns on a global scale, posing a public health risk to this particular neonatal population.

Su, Yu-Tsun & Chen, Yu-Shen & Yeh, Lee-Ren & Chen, Shu-Wen & Tsai, Yu-Cheng & Wu, Chien-Yi & Yang, Yung-Ning & Tey, Shu-Leei & Lin, Chyi-Her. (2022). Unnecessary radiation exposure during diagnostic radiography in infants in a neonatal intensive care unit: a retrospective cohort study. European Journal of Pediatrics. 182. 3. 10.1007/s00431-022-04695-2.

This was a localized, very small retrospective cohort study. Requests and radiographs taken at a tertiary NICU between September and November 2018 were analyzed. There was a rate of discordance between requests and images taken and unnecessary radiation exposure in irrelevant regions during radiography. The rates between very low-birth-weight (VLBW, birth weight<1500 g) infants and non-VLBW infants were compared. A total of 306 radiographs from 88 infants were taken. Each infant underwent an average of 3.5 radiographs. However, the smaller the baby (very low birth weight-VLBW), the more x-rays were taken.

Yu CC. Radiation safety in the neonatal intensive care unit: too little or too much concern? Pediatr Neonatol. 2010 Dec;51(6):311-9. doi: 10.1016/S1875-9572(10)60061-7. PMID: 21146794.

Defined International Commission on Radiologic Protection, ICRP, is an advisory body established to provide recommendations and guidance regarding protection against ionizing radiation. Recommendations by the ICRP for the general public ionizing radiation is 1mSv per year with an average annual dose of 20mSv over 5 years and a maximum dose of 50mSv in a single year. For a child-bearing woman, the recommended dose limit is 1mSv during the 9 months of pregnancy. This study provided mSv doses for neonates.

This data was from a large series of newborns (n = 2408) who were admitted to a NICU in Japan; Ono et al, in 2002, analyzed the relationship between the frequency of radiographic examinations to birth weight and gestational age. They reported that lower birth weights, gestational ages, and longer stays in the NICU were associated with a greater number of total X-rays. In this series, the average number of X-rays performed on infants weighing less than 750g at birth was 26 as compared to 2.6 on infants with birth weights more than 2500 grams.

Kammer B, Schneider KO, Dell'Agnolo E, Seidenbusch MC. Organ doses in preterm and full-term neonates and infants - a retrospective study on 1,064 chest radiographs. Pediatr Radiol. 2022 Jul;52(8):1437-1445. doi: 10.1007/s00247-022-05324-8. Epub 2022 Mar 18. PMID: 35303134; PMCID: PMC9271106

In this retrospective study, 1,064 chest radiographs of 136 preterm and 305 full-term babies were evaluated with respect to field size and centering. The entrance dose was calculated from the dose-area product. Individual organ doses of the thyroid, the breast, the liver and active bone marrow for each chest radiograph was calculated. This study omitted gonadal exposure, however, provides support for number of radiographs taken.

Akshaya Vachharajani, MD,* Neeta A. Vachharajani, BS,† Tasnim Najaf, MD*.Neonatal Radiation Exposure. NeoReviews Vol.14 No.4 April 2013. American Academy of Pediatrics.

This article describes units used to describe doses of radiation, the effects of radiation, and authors experience with diagnostic radiographic procedures in neonates of all gestational ages. The article describes attempts at reducing radiation exposure include proper radiograph beam collimation that will limit radiation to only the requested area and avoid unnecessary organ exposure; shielding genitals in infants; and avoid repeating radiographic studies due to poor initial film quality.

Summary: radiographic evaluations are essential for diagnosis and treatment of neonates. Radiographs and other radiographic procedures impart ionizing radiation. The harmful effects of ionizing radiation are known in adults but not well understood in neonates.

Priyantha Edison,1 Pi Sun Chang,2 Guan Hong Toh,3 Li Na Lee,3 Sarat Kumar Sanamandra,3 Varsha Atul Shah1. Reducing radiation hazard opportunities in neonatal unit: quality improvement in radiation safety practices. BMJ Open Quality 2017;6:e000128. doi:10.1136/ bmjoq-2017-000128

Abstract
Aim Guided by the ALARA - "As Low As Reasonably Achievable" principle in radiation safety, a quality improvement project to optimise the bedside diagnostic imaging process to the best standards of care was conducted over a six month period. The goal was too reduce the radiation hazard opportunities in the neonatal intensive care unit by at least 75% from the existing level at Q2/2015, within 6 months.

Methods The existing bedside imaging process was critically analysed and the following quality improvement initiatives were implemented namely , mandatory lead protective gear to healthcare staff, gonadal shield for neonates, guidelines for optimal collimation of X-ray beam and optimal positioning of neonates. Radiation dosimetry results, regular staff awareness sessions and strong collaboration between neonatologists, radiologists, radiographers and neonatal nurses helped to ensure compliance to the revised imaging process. Radiation hazard opportunities were measured by analysing all radiographs done during the period under baby exposure and healthcare staff exposure categories.

Summary of results Radiation hazard opportunities were reduced by 100% to healthcare staff and 75% to neonates, and the overall reduction was 83%. The rate of discordance between radiograph request forms and images taken was measured as a surrogate marker for compliance

to the project initiatives and it declined by 77%. Mandatory orientation of staff to the revised policy on the standardized diagnostic imaging process, regular radiation awareness talks and staff feedback sessions are among several measures taken to sustain the project.

X-ray shields going by the wayside: What you and your patients need to know | AAP News | American Academy of Pediatrics

X-ray shields going by the wayside: What you and your patients need to know :
March 31, 2020

Donald Frush, M.D., FACR, FAAP; Janet Reid, M.D., FRCPC, FAAP

In April 2019, the American Association of Physicists in Medicine published a position statement that recommends limiting the routine use of patient gonadal and fetal shielding during X-ray-based diagnostic imaging (http://bit.ly/2PoIE0s). The statement was endorsed by numerous organizations, including the American College of Radiology, the Image Gently Alliance, the Health Physics Society, the Canadian Organization of Medical Physics and the Canadian Association of Radiologists.

Exceptions can be made if a parent/caregiver requests a shield and it is of psychological benefit. In these situations, the radiology practice should have guidelines and communication strategies to enable the requesting caregiver to understand the benefits and disadvantages of shielding. For example, the parent/caregiver should be made aware that using a shield outside the area to be X-rayed provides no benefit since shields do not prevent the small amount of internal scatter.

Changing from routine to exception-based gonadal shielding during pediatric X-ray studies will be challenging due to expectations of those who place shields and those who get shields. This change will require education of all members of the imaging team, including health care providers in intensive care units, newborn nurseries and outpatient settings. In addition, medical professionals must recognize that other imaging professionals such as dentists may have different practices, sometimes guided by different requirements.

Image Gently Document

What can I do as a Parent? - Image Gently