National Council on Radiation Protection and Measurements
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NCRP Recommendations for Ending Routine Gonadal Shielding During Abdominal and Pelvic Radiography

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Executive Summary

The purpose of radiological protection, including recommendations for shielding, is to reduce the likelihood of possible harm. For medical exposures, the goal is to keep exposures as low as reasonably achievable while simultaneously ensuring that the needed information is obtained. Gonadal shielding (GS) was introduced and widely recommended in the 1950s with the intent of minimizing the potential for heritable genetic effects from medical exposures. Scientific evidence has led the National Council on Radiation Protection and Measurements (NCRP) to reconsider the recommendation for GS. Several factors contribute to NCRP's new recommendation.

- The risks of heritable genetic effects are now considered to be much less than previously estimated.
- Improvements in technology since the 1950s have resulted in up to a 95 % reduction in the absorbed dose to pelvic organs from radiography.
- GS can interfere with the use of automatic exposure control (AEC) and thereby cause an increase in dose to other pelvic and abdominal organs that may be more radiosensitive.
- GS obscures portions of pelvic anatomy and may obscure important findings on radiographs. This limits the practical dimensions and area of the shield.
- Despite adherence to practice guidelines by technologists, GS may not completely shield the gonads in the majority of patients due to the limited area of the shield and the normal variations in patient anatomy.
- A substantial portion of gonadal dose to the ovaries is delivered by scattered x rays that are not attenuated by GS.

As a result, NCRP has concluded that in most circumstances GS use does not contribute significantly to reducing risks from exposure and may have the unintended consequences of increased exposure and loss of valuable diagnostic information, and therefore use of GS is not justified as a routine part of radiological protection.

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.

Introduction

Medical imaging frequently uses ionizing radiation to provide information necessary for patient care. The goal of radiation protection in medical settings is to manage the radiation dose to the patient to be commensurate with the medical purpose. Scientific understanding in the 1950s included the possibility of radiation-induced heritable effects. Consequently, the use of radioprotective shields placed over the expected location of the gonads was recommended or required in guidelines and regulatory standards. This Statement reevaluates the effectiveness of GS in light of technological advancements in medical imaging and current scientific evidence, including gonadal radiosensitivity, in order to provide updated recommendations regarding GS.

Historical Rationale for the Use of Gonadal Shielding

The widespread practice of radioprotective (more familiarly "lead") shielding of the male and female gonads from the primary x-ray beam began in the 1950s (Magnusson 1952; ICRP 1955; Ardran and Kemp

1957; Abram et al. 1958), with evidence of a reduction in male gonadal dose of up to 98 % (Ardran and Kemp 1957; Feldman et al. 1958). In 1976, the U.S. Food and Drug Administration (FDA) introduced a recommendation in the U.S. Code of Federal Regulations (FDA 2019) that shielding should be used to protect the gonads from radiation exposure that may have genetic effects through mutations in germ cells (FDA 1976). The FDA recommendation was based on then-current scientific understanding that "exposure to ionizing radiation causes mutations in germinal tissue, which may adversely affect future generations," and the assumption that GS substantially limited the amount of ionizing radiation reaching the gonads during radiography (FDA 1976). Current U.S. state regulations vary but are most often derived from the 1976 FDA recommendation. This includes a requirement for GS during abdominal and pelvic radiography, with the exception that GS need not be used for cases in which it would obscure anatomy of interest in the diagnostic examination.

Reduction of Patient Doses During Radiography

In the first half of the 1950s, when beam filtration was typically <2.5 mm aluminum equivalence (Stanford and Vance 1955), the entrance air kerma for an anterior-posterior radiograph of the abdomen and pelvis was 11 to 12 mGy for an adult patient (Handloser and Love 1951) and 1.4 mGy for an infant (Billings et al. 1957). This corresponded to estimated gonadal doses for unshielded patients of 10 to 11 mGy and 4 mGy for adult males and females, respectively (Somasundaram et al. 2020). Three developments since the 1950s have dramatically reduced patient dose during diagnostic radiographic examinations (Huda et al. 2008): increased x-ray beam filtration (Ardran 1956; Nickoloff and Berman 1993), improvements in x-ray generators (Sobol 2002; Matsumoto et al. 1991), and faster image receptors (Rossi et al. 1976; Haus and Cullinan 1989). These advances have reduced current typical gonadal dose delivered by up to 95 % as compared to the doses delivered in the 1950s (Jeukens et al. 2020).

Factors Impacting the Radiation-Reduction from Gonadal Shielding

"Ideal" GS follows manually centered shields placed between the gonads and the x-ray source. Levels of gonadal radiation dose reductions can differ when comparing ovaries and testes and can be substantial with ideal shielding. However, shield placement is seldom ideal and can increase the radiation dose when used in conjunction with AEC.

Estimations of radiation dose to the testes and ovaries based on ideal shielding are listed in Table 1 (Somasundaram et al. 2020). Monte Carlo simulations for standardized adult, 5 y old, and newborn anthropomorphic phantoms with and without the use of GS were conducted. The simulations included clinically appropriate shield sizes, positioning, and collimation. AEC was not used. The percent reduction in absorbed dose to the testes and ovaries with GS compared to no shielding was 85 to 90 % and 57 to 72 %, respectively, with the highest percent reductions occurring for the youngest, smallest patients.

Impact of Primary and Scattered X Rays

Prior to interaction with the patient, the x-ray beam consists only of primary x rays (assuming negligible interactions with air). As the x-ray beam travels through the patient's body, attenuation removes some primary x rays and creates scattered x rays. As a result, the scatter-to-primary ratio (SPR) (the ratio of the number of scattered x rays to the number of primary x rays) increases with depth of penetration in the body. The SPR is low near the surface of the body where the x-ray beam enters (*e.g.*, at the expected location of the testes), intermediate at the depth of the ovaries, and maximum where the x-ray beam exits the body (Table 1). SPR also increases with an increase in patient size.

A 0.5 mm lead equivalent GS attenuates more than 99 % of the incident Bremsstrahlung x-ray energy (NCRP 2004) from a typical diagnostic x-ray beam (85 kV and a minimum of 2.5 mm aluminum filtration). Provided the shield covers the gonads completely, GS spares the gonads from essentially the entire radiation dose from primary x rays. As shown in the Table, for the unshielded case, the SPR is substantially <1 for the testes regardless of patient size. Since the dose to the testes is due principally to primary x rays as relatively few scattered x rays are present at the depth of the testes, ideal GS effectively reduces the radiation dose to the testes.

At the depth of the ovaries in an unshielded patient, scattered x rays substantially outnumber primary x rays. The SPR of the ovaries is >1 for the adult and 5 y old and ~1 for the newborn (Table 1). A primary x ray with the most prevalent energy in the Bremsstrahlung beam that has undergone a single 60 degree scattering event retains more than 97 % of its original energy (Bushberg et al. 2012), so the dose to the ovaries from a single scattered x ray is similar to the dose from one primary x ray. Since more scattered x rays are present at

TABLE 1—*Organ doses with and without ideal GS, percent dose reduction, and SPR for abdominopelvic radiographs obtained using standard filtration (Somasundaram et al. 2020).*[a]

Location	Adult			5 y Old			Newborn		
	Testes	Ovaries	Exit	Testes	Ovaries	Exit	Testes	Ovaries	Exit
No GS (mGy)	1.81	0.54		0.45	0.16		0.16	0.090	
With GS (mGy)	0.28	0.23		0.044	0.055		0.016	0.025	
Percent reduction[b]	85	57		90	66		90	72	
SPR	0.68	1.47	6.86	0.71	1.61	1.78	0.52	0.92	1.03

[a]Validation of Monte-Carlo calculations results in an accuracy of the estimated doses of ±8 %
[b]Gonadal dose reduction did not occur with misalignments of the shield and gonads of 4 cm horizontal displacement or more, with the exception of the testes in the adult phantom, where GS did not become totally ineffective until the misalignment was ≥6 cm.

the ovaries than primary x rays (SPR > 1), the ovarian dose from scattered x rays is substantially greater than ovarian dose from primary x rays. Since ideal GS reduces primary x rays present in the shadow of the shield, GS reduces the ovarian dose delivered by those blocked primary x rays as well as the associated dose that would have been delivered by x rays scattered from the blocked primary radiation. GS does not, however, remove the substantial amount of scattered x rays from the unshielded imaged regions.

Impact of Automatic Exposure Control

While AEC is a standard of care to ensure consistent image quality, it can lead to an increased dose to the gonads and surrounding region if shielding covers the AEC detectors. AEC detectors between the patient and the imaging receptor monitor the radiation transmitted through the patient. When the dose measured by the detectors reaches a designated level, the exposure ends. In adults and larger children, AEC is the standard of care, as it prevents errors that may result from use of manual techniques. AEC is usually not used in small children with an anterior-posterior thickness <12 cm [average age 3 y old (Kleinman et al. 2010), average weight 14 kg (CDC 2010)] because a small child's body may not adequately cover the AEC detector, resulting in an incorrect exposure.

If GS is used with AEC, to have the desired effect the AEC detectors must remain completely uncovered by the shield in the primary x-ray beam. If the AEC detector is partially or completely covered by GS, the AEC system will extend the exposure time, increasing radiation dose to the remainder of the anatomy within the imaged area. One phantom study showed that a covered AEC detector increased the dose to the unshielded organs surrounding the gonads by up to 51 % and 100 % in phantoms of a 5 y old and adult, respectively (Kaplan et al. 2018). Another study demonstrated a dose increase to unshielded surrounding organs of 25 % when an AEC detector was covered (Kaplan et al. 2020). Importantly, some of the surrounding abdominal organs receiving increased doses are more sensitive to the carcinogenic potential of radiation than are the gonads (ICRP 2007).

A number of professional organizations, including the American Association of Physicists in Medicine (AAPM 2019), the Image Gently® Alliance (Goske et al. 2011), the Health Physics Society (Goldin 2020), the American Society of Radiologic Technologists (DeMaio et al. 2019), the American College of Radiology (ACR 2019), and the Canadian Organization of Medical Physicists (COMP 2019) recommend against the use of GS in conjunction with AEC.

Difficulty with Gonadal Shielding Accounting for Normal Variation in Gonadal Location

The location of the gonads within the body varies considerably among patients. Shielding the ovaries is challenging because the ovaries are not visible and may be located anywhere in a large area within (Featherston et al. 1999; Bardo et al. 2009) (Figure 1) and occasionally outside of the pelvis (Featherston et al. 1999). Fawcett and colleagues evaluated 306 female patients and concluded that a GS positioned appropriately based on practice guidelines, including using external landmarks, will not protect the ovaries in more than one-third of children (Fawcett et al. 2012). Given the typical location of the testes within the scrotum, it is reasonable to assume that accurate positioning of GS should occur substantially more frequently for males than for females. However, difficulties in gonadal coverage are more frequent in younger than older males due to the relatively high location of the testes in the smaller prepubertal scrotum as well as the occurrence of

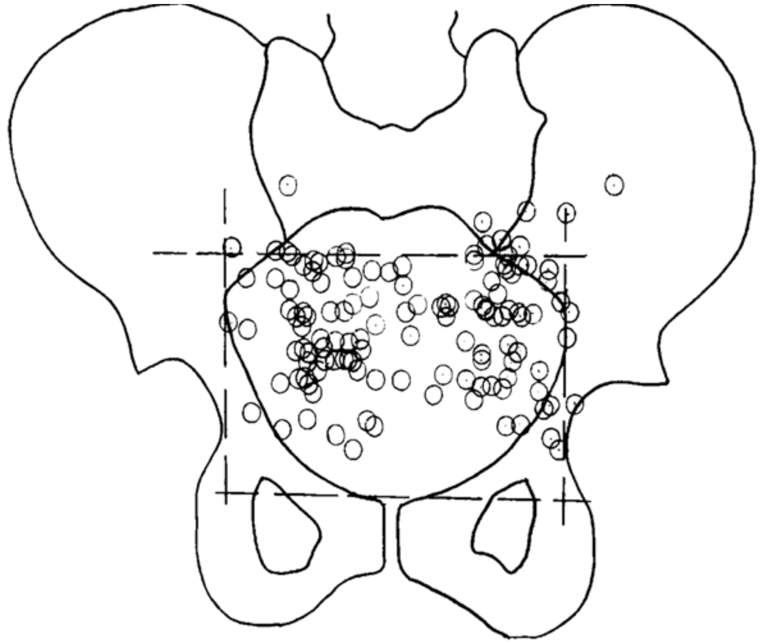

Fig. 1. The estimated position of 128 ovaries in pelvis in 70 adult patients using ultrasound. The variation in position demonstrates the challenge of locating and shielding the gonads without imaging assistance (Featherstone et al. 1999).

retractile, inguinal testes and undescended testes; these conditions are often unrecognized. In addition, active children are more likely to move and displace the GS between placement and exposure (Fawcett and Barter 2009). A meta-analysis of 18 studies provides an overall summary that GS failed to fully cover the gonads 52 % of the time for males and 85 % of the time for females (Karami et al. 2017). Monte Carlo simulations demonstrate the progressive ineffectiveness of inaccurately placed shielding (Somasundaram et al. 2020).

Summary of the Radiation-Reduction Impact of Gonadal Shielding

Ideal GS effectively attenuates primary, unscattered x rays. While GS prevents attenuated primary x rays from generating scattered x rays in the shadow region underneath the shield, it does not attenuate scattered x rays generated by x-ray interactions outside the shadow of the shielded area. Since primary x rays deliver the majority of dose to the testes, ideal GS substantially reduces the dose to testes. Since a substantial portion of ovarian dose is delivered by scattered x rays created by x-ray interactions outside the shadow region of the shield, ideal GS is less effective at reducing ovarian dose when compared to the reduction in testicular dose. Ideal GS is often not achievable for either male or, more commonly, female patients despite accurate placement relative to surface landmarks of the patient. While the scrotum is visible, anatomic differences in younger males make testes location difficult. Also, GS may be displaced due to patient movement. If GS partially or completely blocks the AEC detector, the radiation dose to all abdominal organs in the primary x-ray beam may increase by up to 25 % (Kaplan et al. 2020). This negates any dose reduction provided by GS and also increases the radiation dose to the remainder of the imaged portion of the abdomen and pelvis.

Current Understanding of Gonadal Radiosensitivity

The discovery in the early twentieth century that x rays could rearrange and damage the heritable genetic material of the cell in the fruit fly and mouse raised concerns about the possible consequences of x-ray exposure on reproduction in the human population (NA/NRC 2006). The potential heritable effects of radiation on the gene pool of the population from widespread use of human-made radiation became an even more urgent and serious concern after the detonation of atomic bombs in World War II and subsequent aboveground atmospheric testing of nuclear weapons (NA/NRC 2006). Historically, GS was believed to be a method of protecting the gonads and thus reduce the likelihood of any heritable genetic damage occurring among the offspring of patients undergoing medical x-ray examinations.

The current scientific understanding of gonadal radiosensitivity no longer supports the use of GS in most circumstances (NCRP 2013, 2018). First, the heritable effects observed in progeny induced by radiation are now recognized to be induced by other causes — they are not specific to radiation. In addition, the number of radiation-induced gene mutations and chromosomal aberrations in cells is linearly related to absorbed dose with no evidence of a threshold when doses are low to moderate in magnitude (ICRP 2007). After the initial x-ray interaction event and damage, various biological processes become active, which may repair the damage, eliminate the cell from viability, etc. Such mechanisms are highly effective in eliminating damage but may not completely eliminate the damage in all cases. For doses delivered to multiple generations of insects and mice that are well in excess of those from all diagnostic uses of x rays, there is a statistically significant occurrence of heritable radiation-induced genetic effects. While heritable genetic effects have been observed in experimental studies of fruit flies and mice, there is little to no convincing or consistent evidence for heritable genetic effects in humans. Furthermore, the use of radiation in medicine has occurred for many years although human epidemiology studies of exposures have been for only one or two generations. Studies of human descendants of individuals exposed to high levels of radiation (*e.g.*, atomic bomb survivors and individuals exposed to therapeutic medical radiation) have not demonstrated with statistical significance the occurrence of heritable genetic effects (Schull et al. 1981; NA/NRC 2006). Current evidence continues to indicate the possibility of genetic effects, but not at the magnitude that was previously estimated.

Many patients are concerned about the potential heritable genetic effects from medical radiation. When compared to the frequency of heritable genetic effects occurring naturally in the population, heritable genetic effects from exposures to human-made radiation have never been observed in large-scale and comprehensive human epidemiologic studies. Available evidence suggests strongly that any potential for a detriment induced by medical radiography is exceedingly remote and insignificant when compared with the health benefits derived from a justified examination.

Managing potential detriment from radiation exposure includes managing both the risk of potential heritable genetic effects and the risk of radiation-induced cancer. Both of these risks are included in the concept of health detriment. The relative health detriment of an organ or tissue resulting from uniform irradiation of the body is indicated by its tissue weighting factor (w_T), with greater detriment indicated by a greater w_T. Current understanding has resulted in a substantial decrease in the assigned detriment to the gonads from ionizing radiation from 0.20 to 0.08, while the assigned detriment to other abdominal and pelvic organs has remained essentially unchanged or minimally decreased (ICRP 2007). The gonads currently have a lower assigned w_T than the bone marrow, colon, lung, or stomach, (0.12). A shielding practice that may spare a less sensitive organ a fraction of its unshielded dose is generally not appropriate from a risk perspective.

Obscured Anatomy from Gonadal Shielding

When GS is used, it inherently hides a portion of the pelvic anatomy. The impact of this undesirable outcome depends on the nature of the clinical question. For example, shielding of the ovaries may not affect the ability to identify the location of a nasogastric tube in a patient, but the potential exists that a contributory or unexpected finding may be missed due to obscured anatomy. The status of the obscured portions of the anatomy remains unknown unless a second image is completed without GS that essentially doubles the dose to the abdomen-pelvis. These concerns limit the clinically acceptable shield size; the shielded area is smaller than the area in which the ovaries commonly occur (Somasundaram et al. 2020). GS may also be displaced due to movement of patients, especially in young children, obscuring anatomy that was originally intended to be visible. Depending upon the reasons for examination, a decision must be made about whether GS may reduce or impede the diagnostic yield of the examination.

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.

Recent Regulatory Changes in Recommendations Regarding Gonadal Shielding

In April 2019, FDA proposed amending its regulations to repeal 21 Code of Federal Regulations (CFR) 1000.50 in its entirety (FDA 2019). This included removal of the recommendation that shielding should be used to protect the gonads during abdominal and pelvic radiography. The Conference of Radiation Control Program Directors provides Suggested State Regulations for Radiation Control Programs within each state to consider to promote and foster uniformity of radiation control laws and regulations. The requirement for routine use of GS during abdominal and pelvic radiography, present in the 2009 Suggested State Regulations, was removed from the 2015 revision (CRCPD 2015). In 2019, The American Association of Physicists in Medicine stated that GS provides negligible or no benefit to patients' health, and may be detrimental under certain circumstances (AAPM 2019).

NCRP Recommendations for Gonadal Shielding During Abdominopelvic Radiography

- State and local regulations and guidance should be revised guided by NCRP recommendations for routine GS of patients during abdominal and pelvic radiography.
- Medical facilities should develop policies and procedures that address specific situations in which GS may be indicated.
- Professional societies and other pertinent organizations should assist in the development of model policies and procedures for GS.
- Professional organizations should review and, as necessary, modify their guidelines, requirements, bylaws, certification requirements, statements and other sanctioned communications, and training to be consistent with current recommended practice for GS of patients.
- Implementation of these recommendations by healthcare facilities should include providing pertinent educational materials to relevant medical practitioners, especially radiologic technologists.
- Discussion of GS should be part of an open dialogue with the patient, etc., responding to any question in a transparent manner, that also strives to foster a clear understanding of the implications of the shield and promotes informed and mutual decision making.
- In conjunction with medical physicists, health physicists and technologists, imaging practitioners should provide information explaining changes to GS protocols to referring healthcare providers, especially pediatric healthcare practitioners. This may include guidance on how best to discuss these recommendations with patients and caregivers.
- GS may be permissible when it will not interfere with the purpose of the examination. If consent for the examination cannot be obtained without its use, GS should adhere to institutional or practice guidelines or policies that minimize or eliminate the negative impact on diagnostic potential.
- AEC should not be used in conjunction with GS if the GS is within the x-ray field-of-view.

Important Considerations in Adoption of NCRP Recommendations

For several decades, GS has been a fundamental and familiar component of medical imaging practice with an expectation by patients, caregivers, the public and medical practitioners that it will be used routinely. Any change in this embedded clinical practice requires effective communication with these and other groups before and during the implementation process as well as intermittently once practice changes are made (Marsh and Silosky 2019; BIR 2020). A separate document on strategies for communication of changes in practice for GS during radiography is available at:

https://ncrponline.org/wp-content/themes/ncrp/PDFs/Stat13_Companion_Comm.pdf.

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