NCRP SC 4-11 DRAFT Statement on Routine Gonadal Shielding of Patients
During Abdominal and Pelvic Radiography

Executive Summary

Gonadal shielding (GS) was widely introduced in the 1950s with the intent of minimizing the potential for heritable genetic effects. However, heritable genetic effects in humans have never been demonstrated with any statistical significance; due to improvements in technology, the absorbed dose to pelvic organs has been reduced by 95% compared to the 1950s; use of GS can interfere with the use of automatic exposure control (AEC) and thereby cause an increase in dose to other pelvic and abdominal organs; GS obscures portions of pelvic anatomy, and its use may obscure important findings on radiographs, which limits the practical dimensions and area of the shield; despite adherence to practice guidelines by technologists, GS does 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. The National Council on Radiation Protection and Measurements (NCRP) now recommends that GS not be used routinely during abdominal and pelvic radiography, and that State and local regulations and guidance should be revised to remove the requirement for routine gonadal shielding of patients during abdominal and pelvic radiography. The recommendations in this Statement are limited to patient GS during abdominal and pelvic radiography. NCRP recognizes that adherence to these recommendations requires addressing the impact of this substantial change on an ingrained medical practice.

Introduction

Medical imaging uses ionizing radiation to provide information necessary for patient care. The goal of radiation protection 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 radio-protective 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 technical advancements in medical imaging and current scientific evidence, including gonadal radiosensitivity, in order to provide updated recommendations regarding GS.

History 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 (1–4), with evidence of a reduction in male gonadal dose of up to 98 % (2, 5). In 1976, the U.S. Food and Drug Administration (FDA) introduced a recommendation in the U.S. Code of Federal Regulations (21 CFR Part 1000.50) that shielding should be used to protect the gonads from radiation exposure that may cause genetic mutations (6). 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. 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 less than 2.5 mm Al equivalence (7), the entrance air kerma for an anterior-posterior (AP) radiograph of the abdomen and pelvis (“KUB”) was approximately 11 to 12 mGy for an adult patient (8) and 1.4 mGy for an infant (9). This corresponded to estimated gonadal doses for unshielded patients of 10 to 11 mGy and 4 mGy for adult males and females, respectively (10). Three developments since the 1950s have dramatically reduced patient dose during diagnostic radiographic studies (11): increased x-ray beam filtration (12, 13), improvements in x-ray generators (14, 15), and faster image receptors (16, 17). These advances have reduced current gonadal doses without GS by 95 % compared to the doses delivered in the 1950s (18).
Estimated Gonadal Dose Reduction Using “Ideal” Gonadal Shielding

“Ideal” GS implies centered shields above the location of the gonads using a manual radiographic technique. Estimations of radiation dose to the testes and ovaries with these stipulations are listed in Table 1 (10). Monte Carlo simulations for standardized adult, 5 y old, and newborn anthropomorphic phantoms with and without the use of GS were completed. 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 from the direct beam with GS use is 85 to 90 % and 57 to 72 %, respectively, with the highest percent reductions occurring for the youngest, smallest patients. These levels of gonadal dose reductions are substantial, but ideal shield placement is seldom achieved in practice as explained below.

Factors that Affect the Effectiveness of Gonadal Shielding:

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 (at the level 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 (19) from a typical diagnostic x-ray beam (85 kV and a minimum of 2.5 mm Al 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 Table 1, for the unshielded case, the SPR is substantially less than 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 greater than 1 for the adult and 5 y old and approximately 1 for the newborn (Table 1). A primary x ray that has undergone a single scattering event retains more than 97% of its original energy (20), 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 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 (AEC)**

Consistent image quality can be difficult to achieve using operator-selected manual techniques. AEC is a feature of x-ray units that provides consistent image quality by properly managing the radiation dose to the irradiated portion of the patient being imaged, regardless of patient size, by designating a dose to the detector that corresponds to the desired image quality. Sensors between the patient and the imaging receptor monitor the radiation transmitted through the patient. When the dose measured by the sensors reaches a designated level, the exposure ends. In adults and larger children, AEC is the typical 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 less than 12 cm [average age 3 y old (21), average weight 14 kg (22)] because a small child’s body may not adequately cover the AEC sensor, resulting in an incorrect exposure.
If GS is used with AEC, the AEC sensors must remain completely uncovered by the lead equivalent shield in the primary x-ray beam. If the AEC sensor 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 sensor 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 (23). During x-ray examinations of patients with AEC, another study demonstrated a dose increase to unshielded surrounding organs of 25 % when an AEC sensor was covered (24). Importantly, some of the abdominal organs receiving increased doses are more radiosensitive than the gonads (25). A number of professional organizations, including the American Association of Physicists in Medicine (26), Image Gently Alliance (27), Health Physics Society (28), American Society of Radiologic Technologists (29), American College of Radiology (30), and Canadian Organization of Medical Physicists (31) have recommended against the use of gonadal shielding in conjunction with AEC.

Impact of GS Positioning and Gonad Location

The position 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 of the pelvis (Figure 1) (32). 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 (33). 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 retractile, inguinal testes and undescended testes; these conditions are often unrecognized. In addition, active children may move and displace the GS between placement and exposure. 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 (34). Monte Carlo simulations demonstrate the progressive ineffectiveness of inaccurately placed shielding (10).
Summary of the Radiation-Reduction Effects of Gonadal Shielding

Ideal GS effectively attenuates primary, unscattered x rays. While GS does not attenuate scattered x rays generated by x-ray interactions outside the shadow of the shielded area, it does prevent attenuated primary x rays from generating scattered x rays in the shadow region below the shield. 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 sensor, the radiation dose to all abdominal organs in the primary x-ray beam may increase by up to 100%. 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.

Radiosensitivity of the Gonads

The discovery that x rays could rearrange and damage the heritable genetic material of the cell raised many concerns about the consequences of x-ray exposure on reproduction in the human population (35). The potential heritable effects of radiation on the gene pool of the population from widespread use of man-made radiation became an urgent and serious concern after the detonation of atomic bombs in World War II (35). Historically, GS was believed to be a method of protecting the most radiosensitive organs in the body.

Current scientific understanding of gonadal radiosensitivity has undermined this rationale for GS. The heritable effects induced by radiation and observed in progeny can also be induced by other causes—they are not specific to radiation. 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 (25). 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. However, 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 (35, 36). Nearly all studies of progeny from human populations exposed to high levels of radiation (atomic-bomb survivors and individuals exposed to therapeutic medical radiation) demonstrate a slightly positive effect that is not statistically significant. That trend suggests that some low-frequency effects possibly occur in humans. (36)

Many patients are rightfully concerned about the potential heritable genetic effects from their medical radiation. However, the perceived risk to the gene pool is often greatly exaggerated when compared to reality. On an absolute scale, as well as when compared to the frequency of effects occurring naturally in the population, heritable genetic effects from exposures to man-made radiation have never been shown to exist with statistical significance. Available evidence suggests strongly that any potential for a detriment induced by medical radiography is exceedingly remote and insignificant when compared to the health benefits derived from a justified examination.

Managing potential detriment from radiation exposure includes managing both the risk of 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 (25). 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 not defensible when more sensitive organs may receive a higher dose.

Obscured Anatomy from GS

When GS is used, it inherently hides a portion of the pelvic anatomy. The impact of this undesirable effect 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 teenage girl. However, 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 (10). GS may also be displaced due to patient motion, especially in young children, obscuring anatomy that was originally intended to be visible.

In those cases where the potential impediment of GS is uncertain, a decision must be made about whether GS may reduce the diagnostic yield of the examination. The responsibility for making this decision is often not clearly defined and may fall to the technologist. If the decision to use GS is made by the technologist, and the resultant examination is felt by the interpreting provider to be inadequate, a repeat examination will result in an increased exposure to the areas that were and were not shielded.

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 (37). This includes establishing procedures for circumstances where a patient, parent or caregiver requests that GS be used. Such requests for GS use should be discouraged through informed discussion. GS use, when it will not interfere with the purpose of the examination, may be permissible. 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 Changes in Recommendations Regarding GS

In April 2019 FDA proposed amending its regulations to repeal 21 CFR Part 1000.50 in its entirety (38). This includes 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 (CRCPD) provides Suggested State Regulations (SSR) for Control of Radiation 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 version, was removed from the 2015 revision (39). 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 (26).

NCRP Recommendations for Gonadal Shielding During Radiography

1. State and local regulations and guidance should be revised to remove the requirement for routine gonadal shielding of patients during abdominal and pelvic radiography.

2. Medical facilities should develop policies and procedures that address specific situations in which gonadal shielding may be indicated, and professional societies and other pertinent organizations should assist in the development of model policies and procedures for gonadal shielding.

3. 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 gonadal shielding of patients.

4. Implementation of these recommendations by healthcare facilities should include providing pertinent educational materials to relevant medical practitioners, especially radiologic technologists.
5. In conjunction with medical physicists, health physicists and technologists, imaging practitioners should provide appropriate information to referring healthcare providers, especially pediatric healthcare practitioners. This may include guidance on how best to discuss these recommendations with patients and caregivers.

6. Gonadal shielding 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, gonadal shielding should adhere to institutional or practice guidelines or policies that minimize or eliminate the negative impact on diagnostic potential.

7. Automatic exposure control should not be used in conjunction with gonadal shielding.

**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 (37). A separate document on strategies for communication of changes in practice for gonadal shielding during radiography is available at [www.ncrponline.org/placeholderfornow](http://www.ncrponline.org/placeholderfornow).

**References**


Table 1—Organ doses with and without ideal* GS, percent dose reduction, and scatter/primary ratio (SPR) for abdominopelvic radiographs obtained using standard filtration (Somasundaram E. 2020)

<table>
<thead>
<tr>
<th>Location</th>
<th>Testes (mGy)</th>
<th>Ovaries (mGy)</th>
<th>Exit (mGy)</th>
<th>Percent reduction</th>
<th>SPR</th>
</tr>
</thead>
<tbody>
<tr>
<td>No GS</td>
<td>1.81</td>
<td>0.54</td>
<td>0.45</td>
<td>85</td>
<td>0.68</td>
</tr>
<tr>
<td>With GS</td>
<td>0.28</td>
<td>0.23</td>
<td>0.044</td>
<td>90</td>
<td>0.044</td>
</tr>
<tr>
<td>Percent reduction</td>
<td>57</td>
<td>66</td>
<td>72</td>
<td>0.52</td>
<td>0.92</td>
</tr>
</tbody>
</table>

GS = gonadal shielding
SPR = scatter-to-primary ratio

*Gonadal dose reduction did not occur with misalignments of the shield and gonads of 4 cm 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.

Fig. 1. The estimated position of 128 ovaries in the adult pelvis using ultrasound. The variation in position demonstrates the challenge of locating and shielding the gonads without imaging assistance (28) (Used with permission from...).