Children's
of Alabama®

January 25, 2022

Dear Referring Provider,

The American Association of Physicists in Medicine (AAPM), the American College of Radiology (ACR) and the National Council on Radiation Protection and Measurements (NCRP) have made recent advancements in best practices for patient safety in X-ray imaging. Please review the attached materials, which detail the changes being made and provide information to be shared with patient families.

Due to the advances in Radiology equipment, the change in practice will be to no longer provide lead shielding to patients receiving an X-ray exam.

Reasons for eliminating shielding:

- Can hide important anatomy that the physician needs to see.
- Can lead to repeat exams that result in unnecessary radiation.
- Increases patient radiation when detected by the X-ray equipment sensors.
- Provides no tangible benefits to patient safety other than easing anxiety about radiation.

This change may be challenging for parents and caregivers. We ask that you help us communicate this information when possible. A FAQ sheet is attached as a resource as well.

If parents have questions and you need additional information, please call X-ray at McWane at 205-638-6217 or X-ray at Children's South at 205-638-4744.

Sincerely,

Yoginder Vaid, MD

Yoginder Vaid, MD
Medical Director, Radiologist-in-Chief
Clinical Professor
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Chief Executive Officer

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May 30, 2019

Cynthia H. McCollough, PhD, FAAPM, FACR, FAIMBE
President
AAPM
1631 Prince Street
Alexandria, VA 22314

Dear Dr. McCollough,

I am pleased to inform you that the Executive Committee of the American College of Radiology (ACR) Board of Chancellors has voted to endorse The American Association of Physicists in Medicine (AAPM) **AAPM Position Statement on the Use of Patient Gonadal and Fetal Shielding.**

This endorsement implies permissions for the AAPM to officially list our organization as an endorser of this guideline and reprint our logo in the introductory section of the guideline document.

Thank you again for seeking our endorsement.

Sincerely,

William T. Thorwarth, Jr., MD, FACR
Chief Executive Officer

AAPM Advances Best Practices for Patient Safety in X-ray Imaging

Leads international educational efforts through its CARES Committee

ALEXANDRIA, VA, JANUARY 13, 2021 — Since April 2019, the American Association of Physicists in Medicine (AAPM) has championed a critical way to make X-ray imaging safer and more effective by discontinuing the long-standing practice of placing leaded shields over patient gonads.

Today, the National Council on Radiation Protection and Measurements (NCRP) released a statement recommending the discontinuation of routine shielding of patient gonads during X-ray imaging exams and AAPM stands ready to help imaging providers, patients and caregivers to understand and adopt these new best practices – practices that will ensure safer and higher-quality X-ray exams.

Discontinuing the routine shielding of patient gonads is a major shift in how X-ray exams are performed. To foster cohesive change, AAPM created a committee with representatives from the international imaging community. The CARES committee is an engaged community of stakeholders committed to ***C****ommunicating* ***A****dvances in* ***R****adiation* ***E****ducation for* ***S****hielding* (**CARES**). It includes members from more than a dozen professional organizations representing medical and health physicists, radiologic technologists, radiologic technologist educators, radiologists and other physicians, and state regulators.

"The NCRP statement is a national consensus document that provides the foundation on which changes in clinical practice and educational requirements can be built," said Sarah McKenney, PhD, DABR, lead medical physicist, Stanford University's Lucile Packard Children's Hospital. "It affirms the collaborative efforts of the AAPM CARES committee, where X-ray imaging stakeholders are working together to identify potential challenges in the implementation of these new best practices and develop practical solutions."

AAPM's 2019 position statement outlines the reasons for discontinuing the routine use of fetal and gonadal shielding in medical imaging. The CARES committee was formed shortly after adoption of the position statement to provide answers to frequently asked questions for health care professionals and patients.

In 2021, as part of its mission to improve the care of every patient, AAPM will release six continuing education modules developed and approved by the CARES committee. These educational materials will be made freely available to the entire imaging community.

Dr. Donald Frush, professor of radiology at Duke University who served as the chair of the NCRP subcommittee on gonadal shielding, noted, "As the Chair and on behalf of the SC4-11 Committee that prepared the Statement, I am thankful for the ongoing collaboration with and invaluable expertise of the AAPM as we all as an imaging community address this important topic for our medical professionals, our patients and the public."

About the American Association of Physicists in Medicine (AAPM)

AAPM is the premier organization in medical physics, a scientific and professional discipline that uses physics principles to address a wide range of biological and medical needs. The mission of AAPM is to advance medicine through excellence in the science, education, and professional practice of medical physics. Currently, AAPM represents over 9,000 medical physicists in over 96 countries.

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Patient Gonadal and Fetal Shielding in Diagnostic Imaging
Frequently Asked Questions

Introduction

In April of 2019, the American Association of Physicists in Medicine (AAPM) released a position statement outlining reasons for limiting the routine use of fetal and gonadal shielding in medical imaging[1]. This position statement has since been endorsed by the American College of Radiology (ACR)[2], the Canadian Organization of Medical Physics (COMP)[3], the Health Physics Society (HPS)[4], the Canadian Association of Radiologists (CAR)[5], the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM)[6], and the Image Gently Alliance[7]. Recognizing that removing patient shielding from routine use is a substantial shift in existing clinical practice, AAPM formed a committee to bring together stakeholders to discuss potential changes in the use of patient shielding. The committee includes representatives from many different societies and organizations with specialization in medical imaging and patient safety. The frequently asked questions (FAQs) and answers given in this document are the first part of this effort - Communicating Advances in Radiation Education for Shielding (CARES).

This document contains three sections, each with a different target audience. The first addresses questions and concerns of healthcare professionals, including, but not limited to, radiologic technologists, physicians, advanced practice providers, medical physicists, radiation safety officers, and nurses. This section also includes some suggested wording that can be used when discussing patient shielding with patients and parents or other caregivers of pediatric patients. The second section addresses common concerns among patients and is best suited for adult patient populations. The third section is intended for parents and other caregivers of pediatric patients.

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.

This document was developed by AAPM's Committee on Education and Implementation Efforts for Discontinuing the Use of Patient Gonadal and Fetal Shielding, which is a collaborative effort involving many different stakeholder organizations and individuals. The CARES committee would specifically like to recognize and thank the following contributors:

American Association of Physicists in Medicine
American College of Radiology, represented by Darcy Wolfman, M.D.
American Society of Radiologic Technologists
Association of Educators in Imaging and Radiological Sciences, represented by Nina Kowalczyk, Ph.D.
Canadian Organization of Medical Physicists
Conference of Radiation Control Program Directors
Health Physics Society
Image Gently
Image Wisely
Radiological Society of North America

Frequently Asked Questions
Target Audience: Healthcare Professionals

A1. Shouldn't we shield the gonads, especially for children, to minimize the risk of genetic damage to future generations?
Gonadal shielding was introduced into clinical practice over 70 years ago, when it was believed that exposing the gonads to radiation could damage reproductive cells such as sperm-producing cells and eggs, causing damage to patients' future offspring.[8] However, these genetic effects have not been observed in humans, even 3 to 4 generations after the atomic bombings.[9] International radiation protection organizations have lowered the risk weighting to the gonads in every successive revision of their tissue risk weighting factors since such factors were introduced in 1977.[10,11]

Suggested Talking Point:
There is no evidence that radiation from medical imaging damages reproductive cells such as eggs or those that produce sperm.

A2. Shouldn't we continue to shield the gonads so that we don't increase the risk of infertility?
The amount of radiation required to cause infertility is more than 100 times the dose from a medical imaging exam.[11] For example, the gonadal dose to an X-ray of the pelvis is less than 0.8 mGy for a teenage boy and less than 0.3 mGy for a teenage girl. Gonadal doses for newborns receiving medical imaging is about 90% lower than this.[12] In comparison, male fertility is not affected below an acute dose of 150 mGy. Permanent sterility does not occur in males below 3500 mGy. Female fertility is not affected below 2500 mGy.[11]

Suggested Talking Point:
The dose required to cause infertility is much higher than that used during a medical imaging exam.

A3. Why should we no longer shield patients routinely?
Any intended decrease in radiation exposure from shielding is negligible compared to the dose from radiation that is scattered within the patient's body. Shields do little or nothing to benefit the patient.[13-17] As with other areas of medicine, the use of patient shielding should be evaluated from a risk-benefit perspective. For example, any time a shield is used, there is a risk that it will cover and obscure anatomy that is important for an accurate diagnosis.[12,18-30] Since shielding can introduce these risks and provides little or no benefit to the patient, we should discontinue using shields as part of routine practice.

Suggested Talking Point:
Shields may cover up parts of your body that your doctor needs to be able to see. If this happens, we may have to repeat your image.

A4. Why are we doing this now?
Advances in medical imaging technology, such as better detectors, have greatly reduced the amount of radiation required to create a quality image. However, some of the features of modern imaging equipment (such as automatic exposure control) do not perform as intended when lead shielding is in the path of the beam.[31] As the medical imaging community continues to deepen its understanding about how radiation affects the body, we are recognizing that the risk for the majority of imaging exams is either too small to be determined or may even be zero. These advances have made patient shielding a practice that introduces more risk than benefit.

Suggested Talking Point:
The change in practice is due to improvements in imaging technology and a better understanding of how radiation might affect the body.

A5. Should we still shield pediatric or pregnant patients?
Fetal and gonadal shielding should not be used by default, regardless of the patient's age, sex, or pregnancy status. While shielding should not be used routinely, in very limited circumstances, it may be in the best interest of an extremely anxious patient to use shielding. (Please see FAQ A6 for more information.)

A6. Patients, and especially parents of pediatric patients, expect us to use shielding. Shouldn't we keep shielding because it makes people feel safer?
Clinical practice should be based on the best and most recent scientific evidence. Although patients expect to be shielded because it has been common practice for many decades, we should explain to the patient the benefits from shielding are negligible and thus there is no value to continuing this practice. Further, there is a small risk of compromising the exam if the shield enters the imaging field.

There are situations, however, that may require special consideration. For example, if a pregnant patient with a suspected pulmonary embolism refuses to have imaging done without shielding, then the benefit of getting a timely diagnosis outweighs the risk posed by using shielding. Similarly, for the parent of a critically ill pediatric patient, the psychological benefit to anxious parents or caregivers may exceed the risk posed by shielding.

In most situations, it is appropriate for the technologist and/or physician to explain why shielding is not recommended. If the patient or parent continues to insist that shielding be used, shields may be used at the discretion of the technologist, provided that careful attention is given to ensuring that image quality is not compromised and overall dose is not increased. While we propose some general rules for stopping the use of gonadal or fetal shielding, it is important to recognize that there will be situations that require professional judgement based on the individual patient and circumstances.

A7. What about pregnant women? Can't even a very small amount of radiation harm a fetus?
The American College of Obstetricians and Gynecologists (ACOG) has a guideline that states: "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."[32] This is true even for a CT scan of the abdomen and pelvis. If the fetus is outside of the imaging field of view, the dose to the fetus is below 1 mGy[33], which is about the same as the dose a fetus gets from background radiation during gestation. This is the case for a CT scan of the mother's chest.

Suggested Talking Point:
In almost all cases, the amount of radiation used in medical imaging is much lower than what is known to cause any harm to an unborn baby. Shields will not reduce the amount of radiation to your unborn baby but may cover up parts of your body that your doctor needs to be able to see.

A8. Should I continue to wear a lead (radioprotective) apron at work?
Absolutely. If you are working in an area with potential exposure to radiation (such as in an imaging exam room) occupational safety standards and regulations require that radiation workers take appropriate action to limit their occupational exposures. These actions include minimizing the time you are exposed to a radiation source, maximizing the distance between you and the radiation source, and placing shielding between yourself and the radiation source. The shielding can be the leaded window or wall of the control area or personal protective devices such as leaded aprons. These universally accepted methods to control occupational radiation exposures are not impacted in any way by recommendations to discontinue the use of shielding on patients.

A9. Even if the dose from one X-ray is small, what about patients who have many X-rays over their lifetime?
Healthy cells have repair mechanisms to help protect them against small doses of radiation.[34] We take advantage of these repair mechanisms in radiation therapy, where treatments are set up so that there are multiple treatment sessions. For example, radiation therapy for breast cancer may consist of 20 sessions with 2000 mGy delivered during each session, rather than a single session that delivered 40,000 mGy. This is done because delivering the dose in smaller amounts over a longer period of time, instead of all at once, allows more healthy tissue to recover, while killing cancer cells. Thus, there is evidence that the risk from multiple exams is not cumulative.

A10. On some X-ray images patient anatomy outside of the collimated view is still visible. Does that mean it is still being irradiated?
Often, a faint signal can be seen outside of the collimated field of view. This is from radiation that exposes anatomy within the collimated field of view and is then scattered within the patient, before reaching parts of the detector that are outside of the field of view. It is important to note that the dose to tissues outside of the collimated field of view is very small - hundreds to thousands of times smaller than the dose to anatomy within the field of view. We can see these regions on images only because modern X-ray detectors are very sensitive to small amounts of radiation. This very small amount of radiation outside the field of view is not justification for shielding patients.

A11. Do lead shields "trap" the radiation in the patient?
No. Lead, and lead-equivalent materials used in "lead" aprons, are very good at absorbing radiation. A very small amount can be reflected back towards the patient, but this dose is very small (less than 0.001 mGy - or a few hours of background radiation in the US)[35].

Suggested Talking Point: *Lead is very good at absorbing X-rays. Although a very small number of X-rays can be reflected back toward the patient, the dose from this effect is negligible.*

Frequently Asked Questions
Target Audience: Patients

B1. Why do you not shield patients anymore?
Patient shielding has been used for more than 70 years. We have better equipment that uses much less radiation and operates differently. We also know more about how radiation affects the human body and that some parts of the body - like the testicles and ovaries - are less sensitive to radiation than we used to think.

Most modern X-ray, fluoroscopy, and CT machines can automatically determine how much radiation to use based on the part of the body being imaged. If a shield gets in the way, it could mean an increase in radiation dose.

Since we have equipment that can give us better information using less radiation than in the past, patient shields are no longer beneficial.

B2. Doesn't shielding make me safer?
The amount of radiation used in most imaging exams is so small that the risk to you is either very small or zero. Shields provide negligible protection.

B3. But what's the harm in shielding?
When the reproductive organs are far away from the part of your body being imaged, there is no benefit from using shielding. When the part of your body receiving X-rays is close to your reproductive organs, a shield may cover up parts of your body that your doctor needs to be able to see. If this happens, we may have to repeat your exam.

B4. Won't radiation exposure to my sperm or ovaries harm my future children?
Since the 1950s, people were concerned that radiation might damage sperm or eggs and that this damage would be passed down to your future children. However, this has never been seen in humans even after many generations (years) of studying it closely. This is true even for people who have been exposed to much larger amounts of radiation than what is used in medical imaging.

B5. What if I'm pregnant?
We have equipment that can give us better information than ever before and can get good images using much less radiation than in the past. However, placing shielding over your belly can reduce the quality of the exam if it gets into the image and in some cases can increase the overall dose from the exam. Since shielding your belly provides no benefit to your baby, it is better to not do it.

B6. Will you still shield me if I want you to?
We do not recommend using lead shielding during imaging exams. Some exams can never be done using a shield because the shield would cover up parts of the body we need to see. But, if you insist that we use a shield, we will honor your request if it is possible to do so without compromising the exam you are having.

Frequently Asked Questions
Target Audience: Parents and Guardians

C1. Why is my child not shielded now?
Shields have been used in the past, but we know more about radiation now and have imaging equipment that uses much less radiation than in the past. We have also seen that shields can cover up parts of your child's body that are important for your doctor to see.

C2. Why is my child not shielded if I am required to wear a lead apron while I am in the room with them?
Your child's doctor wants an image so that he or she can better see what is going on inside your child's body. This exposes your child to a little bit of radiation. Your doctor has thought about the benefits and risks to your child. He or she has decided that the benefit from having the information from the image is much higher than the risk from the radiation, which is very small or zero. Because you aren't being imaged, there is no need for you to get any radiation and so we give you an apron to wear to make sure that you don't get any dose.

C3. My child previously had an imaging exam where shielding was used, why the change in practice?
Patient shields have been used for more than 70 years. A lot has changed since then. We have better machines that use much less radiation. We also know more about how radiation affects the human body. Some parts of the body - like the testicles and ovaries - are much less sensitive to radiation than we used to think, thus there is no benefit from placing shields on your child.

C4. Can I ask for a shield for my child?
We do not recommend using lead shielding during imaging exams. Some exams can never be done using a shield because it would always cover parts of the body we need to see. But, if you insist that we use a shield, we will honor your request if it is possible to do so without compromising the exam your child is having.

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NEW GUIDELINES FOR X-RAY EXAMS

When your child is having an X-ray exam, you may ask:

1. Why are you not shielding my child?
Research has shown that using a shield can cause the patient to receive more radiation than not using a shield.

2. Why are you wearing a shield, but my child is not?
The patient is intentionally getting X-rays for their exam, the technologist could assist with several exams each day and receive unnecessary scatter radiation each time.

3. Why did this change?
Over the years, we have learned more about radiation and X-ray equipment has changed eliminating the need for shielding.

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American Association of Physicists in Medicine (AAPM)
https://www.aapm.org/

American Board of Radiology (ABR)
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American Society of Radiologic Technologists (ASRT)
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Image Gently ®
https://www.imagegently.org/

Society for Pediatric Radiology (SPR)
https://www.pedrad.org/

ADDITIONAL RESOURCES:

The American Association of Physicists in Medicine:
Communicating Advances in Radiation Education for Shielding (CARES)
https://www.aapm.org/CARES/

British Institute of Radiology
https://www.bir.org.uk/

If you have any questions or concerns about your imaging exam, please talk to your radiologic technologist or doctor.

Information about NCRP Statement No. 13: *NCRP Recommendations for Ending Routine Gonadal Shielding During Pelvic and Abdominal Radiography*

https://ncrponline.org/publications/statements/

WHERE'S THE LEAD APRON?

WHY REPRODUCTIVE ORGAN SHIELDING IS NO LONGER RECOMMENDED

You may notice that we no longer shield patients' reproductive organs during imaging exams.

Based on over 70 years of research, medical experts now know that the best way to keep patients safe during imaging exams is to not use shields. This is true at any age, including for those who plan to have children in the future. We know this is different from how things have been done for a long time. This pamphlet talks about why this change was made.

National Council on Radiation Protection and Measurements

https://ncrponline.org/

BACKGROUND

In the 1950s, medical experts had less knowledge about how the x-ray radiation used in medical imaging affected our bodies.

One concern was that the radiation might damage cells that could be passed along to future generations. Because of this concern, lead shields were often placed over patients' reproductive organs during medical imaging exams.

We now know that the best way to safely image you is to not use shields.

Pelvic x ray

The amount of radiation used in medical imaging has decreased over 95% since the 1950s. Better technology means that today's medical imaging equipment can make high quality images using only very small amounts of radiation.

Scientists found that the gonads are much less sensitive to radiation than previously thought. This is true for everyone, including children and adults who plan to have children in the future.

Shields can cover up parts of the body that your doctor needs to see. If this happens, then the exam may need to be repeated.

Shields can interfere with other dose-saving features. X-ray equipment includes technology that makes sure just the right amount of radiation is used for the exam. Sometimes a shield can interfere with this technology, which can actually increase the amount of radiation from the exam.

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

NCRP Statement No. 13, January 12, 2021

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

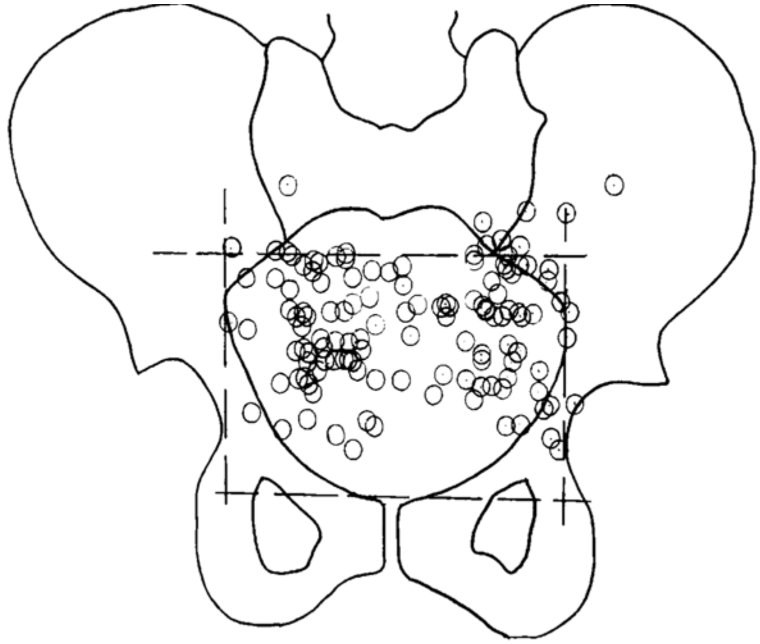

Fig. 1. The estimated position of 128 ovaries in pelvis in 70 adult patients using ultrasound. The variation in position demonstrates the challenge of locating and shielding the gonads without imaging assistance (Featherstone et al. 1999).

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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