
INVITED PAPER

IMAGE GENTLY CAMPAIGN: MAKING A WORLD OF DIFFERENCE

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Abstract—Focused care that addresses the needs of the pediatric patient during imaging should improve diagnosis and reduce radiation doses. This requires trained staff correctly operating appropriately configured imaging equipment. This is one of the objectives of the Image Gently Campaign (IGC) by the Alliance for Radiation Safety in Pediatric Imaging (IGA). This article features a description of IGA's campaigns, an explanation of the methods used to develop and disseminate its message, and a description of the IGA's current and future goals. The concept and model of IGA, along with the provision of the citations of the majority of its published resources, is provided to the international medical physics community so that they might be used for local pediatric applications worldwide. A brief summary of the fundamentals of medical physics that should be applied during pediatric imaging concludes this discussion. The ultimate goal is imaging with the appropriate amount of radiation required to provide adequate image quality and imaging guidance. The reduction in the x-ray flux during pediatric imaging provides the opportunity for the medical physicist to recommend different x-ray tube voltages/added filtration, reduced pulse widths, or focal spot sizes that either improve image quality, reduce patient dose, or both. The medical physicist needs to ensure that the desired acquisition parameter changes for pediatric imaging are incorporated into the configuration of the installed imaging device.

Keywords—Image Gently, pediatrics, radiation dose, image quality

I. INTRODUCTION

While most state-of-the-art imaging equipment provides reasonable image quality on teenagers using the manufacturer's recommended configurations for adults, excessive radiation dose levels and less than optimum image quality may result when imaging smaller children. [1,2] This deficiency during imaging may be more acute when using imaging equipment manufactured prior to 2010. Focused care, which addresses the needs of the patient during pediatric imaging may improve diagnosis and reduce pediatric radiation doses. This is achieved

when appropriately trained staff members operate properly configured imaging equipment. [3]

This paper has two main goals. First, the formation of the Image Gently Campaign (IGC) by the Alliance for Radiation Safety in Pediatric Imaging [Image Gently Alliance (IGA)] is described. [4,5] This is followed by a review of its campaigns, an explanation of the methods used to develop and disseminate its message, and a description of the IGA's current and future goals. The concept and model of the IGC, along with the provision of the citations of the majority of its published resources, are shared with the international medical physics community so that they might be used for local applications worldwide. One of the objectives of the IGC is to assist radiologists and radiologic technologists in improving imaging performance in children.

The second goal is a brief summary of the fundamentals of medical physics that should be applied to imaging devices that will be used to image children. The ultimate goal is to perform necessary imaging "with the least amount of radiation required to provide adequate image quality and imaging guidance." [6] Section IV of this paper stresses the importance of teamwork and the important role of the medical physicist. The fundamental differences between small children and adults are briefly discussed. The fundamental reduction in the x-ray flux emitted by the x-ray tube during pediatric imaging provides the opportunity for the medical physicist to recommend different x-ray tube voltages/added filtration, reduced pulse widths, or focal spot sizes that either improve image quality, reduce patient dose, or both. The medical physicist needs to ensure that the desired acquisition parameter changes for pediatric imaging are incorporated into the configuration of the installed imaging device.

II. THE IMAGE GENTLY ALLIANZ

A. RATIONALE

The Alliance for Radiation Safety in Pediatric Imaging (imagegently.org) was officially announced in 2007, after nearly a year of developing the concept. The organization was formed by members of the Society for Pediatric Radiology (SPR) from a shared sense that what was a long-standing commitment to safe and effective imaging in children needed to find a broader audience including patients, parents and other caregivers, our colleagues who cared for children including pediatricians and family practitioners, and the public. This need was partly a result of a growing visibility in both the healthcare and public sector of the issue of potential cancer induction due to radiation from diagnostic imaging, especially due to the relatively higher doses from computed tomography (CT). While the cautious use of radiation is particularly relevant in the pediatric population and was familiar to the pediatric radiology community, other unique considerations in the care of children may have received less attention. These included the need for dedicated time for informed conversations with parents and caregivers, the need for technical adjustments across the wide range of sizes when imaging children, and strategies that can be different between adult and pediatric populations (i.e. ultrasonography is much more frequently employed in children with possible appendicitis versus the overwhelming use of CT in the adult population in the United States). These differences resonate in the introduction to the CT campaign on the IG website: "One size does not fit all...when CT is the right thing to do, child-size the mA and kVp, one scan (single phase) is often enough, [and] scan only the indicated area".

The four founding, and still the masthead organizations for the Alliance were the Society for Pediatric Radiology, American Association of Physicists in Medicine (AAPM), American College of Radiology (ACR), and American Society of Radiologic Technologist (ASRT). One fundamental consideration for organizational success of the Alliance was inclusion of major stakeholders in pediatric imaging: medical physicists, radiologists, and radiologic technologists, through the parent U.S. organizations. These groups contributed, then, to the development of the mission statement, organizational structure and strategic priorities. The leadership also felt it was important to design an Alliance structure that would partner with other relevant professional societies and organizations, in part to share resource and expertise. These groups included imaging organizations such as the Radiological Society of North America (RSNA) as well as signature pediatric health care societies, such as the American Academy of Pediatrics (AAP). The initial efforts were anticipated to be directed at a North American, and

mostly U.S. market, however, interest in and affiliation with international organizations began almost immediately. In the first few years, the number of affiliated organizations grew from 13, and now comprises nearly 100, representing over 1,000,000 professional members, which include scientists (e.g. medical and health physicists), radiologists, dentists and dental surgeons, radiologic and dental technologists, pediatric surgeons, and pediatricians. The number of international alliance members based outside North America currently totals 35.

Leadership of the Alliance began with a steering committee of approximately 15 individuals, headed by Marilyn Goske, M.D. The initial committee represented (predominantly academic) pediatric radiologists, radiologic technologists, medical physicists, and individuals with media, marketing, or administrative/executive experience. More recently the steering committee has added individuals with adult radiology expertise, dental expertise, community radiology practice, and patient advocacy representation. The initial and expanded constituencies were considered critical in assuring a representative voice in Image Gently efforts. Marilyn Goske served as a chair from 2007-14, and co-chair 2014-15 together with Donald Frush, M.D., an original steering committee member who then assumed the chair position in July 2015. Keith Strauss, MS, a diagnostic medical physicist, also an original steering committee member, now serves as vice chair.

The initial organizational structure consisted of arenas that included research, finance, international affiliations, and modality-based campaign elements. This structure was recently re-engineered in the spring of 2015 to resonate with a strategic plan with formalized major goals: (1) advocacy and awareness, [7] (2) education [8,9], (3) research, and (4) assurance of long term Alliance stability. This organizational structure now consists of committees under these goals consisting of at least one steering committee member with additional membership for direct activities such as international and other organizational partnerships (goals 1 and 2), campaigns (goal 2), and document review (e.g., from The Joint Commission, proposed regulations to states by Conference of Radiation Control Program Directors (CRCPD), Food and Drug Administration, Nuclear Regulatory Commission, etc.—goal 1). The mission statement that was also recently distilled to capture a simple and evocative sense of purpose is "... through advocacy, to improve safe and effective imaging care of children worldwide". This modification was in part due to rapidly growing international presence and recognition. In addition, there was a carefully considered and crafted operational approach, with the fundamental principles which will be described below, fortified through substantive content, a consistent investment by

the Image Gently Alliance. Part of this content is through the campaigns, which will be subsequently discussed.

B. SCOPE OF CAMPAIGNS TO COVER MODALITIES USING IONIZING RADIATION

Each of the six campaigns below address a different imaging modality. Educational material for each campaign provides helpful information for parent/guardians, radiologists, radiologic technologists, and medical physicists. In some instances information is provided for referring physicians. Published resources written by Alliance members that cover the modality in general are listed immediately after the ‘slogan’ associated with each modality. If a more focused paper was also published, the reference to that paper is listed in the description for the modality. An image of the poster used to illustrate each campaign is provided.

1. CT: “One Size Does Not Fit All” [10-15]

this campaign was initiated, basic recommendations were posted on the IG website to assist end-users in reducing their CT techniques (mAs) to ensure that any size patient’s CT radiation dose was similar to that of the facility’s standard sized adult. In 2014, these recommendations were modified, improved, and expanded. Now the end-user has three choices of reduction of patient dose, i.e. smallest patients receive 100%, 75%, or 50% of the adult radiation dose at a given facility. Two additional publications were created to help end-users and medical physicists use these recommended protocols. [17,18]

2. Interventional radiology: “Step Lightly” [19-22]

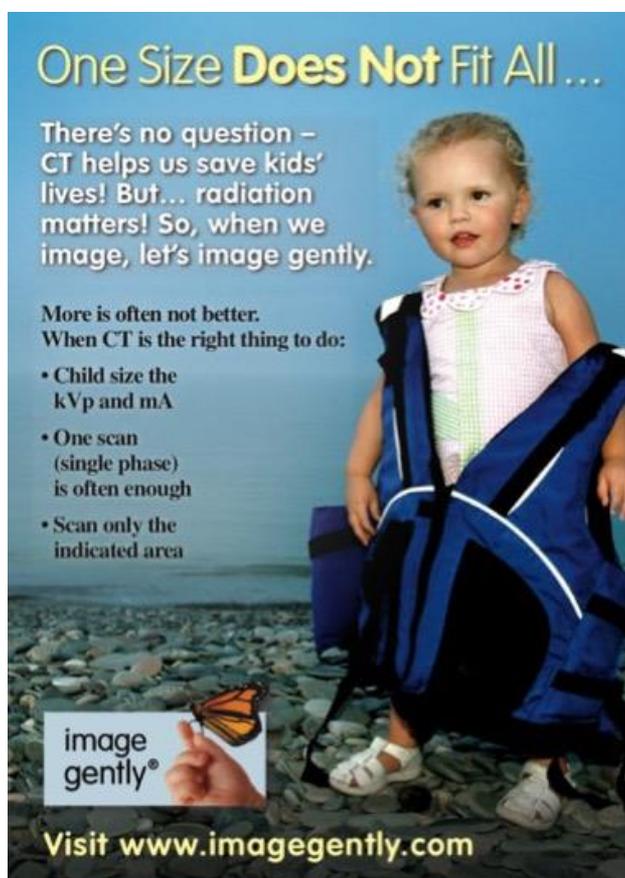


Fig. 1 “One Size Does Not Fit All”

This first campaign of the Alliance in 2008, increased awareness that $CTDI_{vol}$ is not a patient dose and underestimates CT radiation doses to the smallest pediatric patients up to three-fold.[16] As

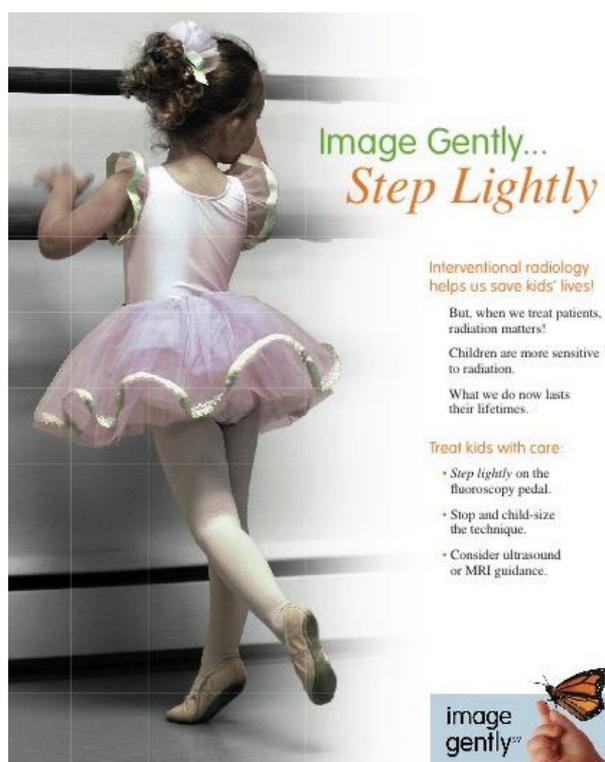


Fig. 2 “Step Lightly”

This campaign encourages the operator of an interventional fluoroscope to make sure that appropriate acquisition parameters designed for the specific size of the patient are appropriately selected. The operator is encouraged to limit the amount of fluoroscopic exposure time during the procedure. Three links are provided on the IG website to provide access to three educational modules for radiologists and radiologic technologists. The three modules are entitled ‘Enhancing radiation protection in pediatric fluoroscopy: prior to, during, and after the fluoroscopic procedure.’ These modules apply to either interventional or general fluoroscopy.

3. General fluoroscopy: "Pause and Pulse" [23,24]

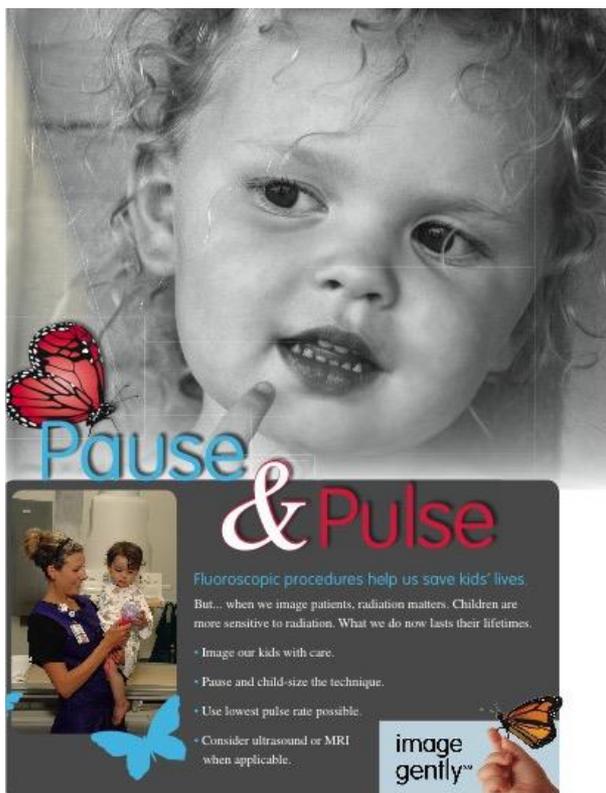


Fig. 3 "Pause and Pulse"



Fig. 4 "Back to the Basics"

The operator is reminded of steps that can be taken to reduce patient dose during general fluoroscopic studies: tightly collimate, minimize the use of electronic magnification, minimize fluoroscopic time, substitute fluoroscopic images for fluorography images where appropriate, select pulsed fluoroscopy as opposed to continuous fluoroscopy if both modes are available.

4. Digital Radiography: "Back to the Basics" [25-29]

The IG website contains links to multiple power point presentations on various aspects of digital radiography. This campaign helped lead to the adoption of the EI dose index on digital radiographic images developed by Task Group 116 of the AAPM as the standard for dose indices for digital radiography. [30]

5. Nuclear Medicine: "Go with the Guidelines" [31,32]



Fig. 5 "Go with the Guidelines"

The cornerstone of this campaign is the 'North American Guidelines for Pediatric Nuclear Medicine' for High Quality Images at low Radiation Dose that have been converted more recently to an international scope. This document

is used as a guide to standardize the radiation dose received by pediatric patients from the radionuclides injected for nuclear medicine studies. [31]

6. Dental: "Image Gently Campaign in Dentistry" [33,34]



Fig. 6 "Image Gently . . . in Dentistry"

The most recent campaign of IG stresses that cone beam CT should be used only when necessary and standard dental x-rays should be acquired based on an individual patient's need as opposed to routine. Two helpful presentations are linked to the IG website, one for parents and one for medical physicists. *C. METHODS*

As previously discussed, the formation of the IGA was based on careful consideration of what was originally an implied set of principles (in essence a constitution) which has been consistently adhered to; the success of the organization can easily be defended as due in large part to this constitution. In developing this constitution, the values of the IGA were *safety, effectiveness, consensus, advocacy, and accessibility*. The goals of these values are to have IG be strong, stable and strategic. To accomplish these values, the blueprint was based on the following fundamental elements: the message, the messengers, and the messaging.

The *message* is fundamental. Each IG campaign message was embedded by the short, simple, memorable phrase, one that resonated effectively – be gentle with our children. This was easily understood and difficult to not support (at least publicly). Critical in this age of alarmist messages both from within and outside of the Radiology profession, [35,36] is IG's positive message, about improvement (rather than current or past failure). This position of advocacy has been consistent and clear throughout the educational products, website content, campaign materials, and publications and presentations. While other voices espousing the negative perspective that we are doing harm to children have often captured the public attention, [35] the enduring stance of the steering committee, the founding organizations, and the nearly 100 affiliates (through pledging to the IG position) has been that a balanced approach of radiation safety through improved delivery while creating quality imaging, (a perspective of assurance) should and will prevail. The phrase "image gently" was crafted by Jennifer Boylan, the executive director of the SPR, in 2007, and was immediately recognized as the embodiment of the mission of the Alliance. In addition to this taproot of the Alliance, other messages are found in the publications, presentations, educational modules, and other website material.

The *messengers* are also critical in IG's success. In keeping with the values of consensus efforts, the Alliance needed to have *engaged* representation from the major stakeholders, but with equal voice *despite what might be unequal contribution of resources such as personnel, time, or financial support*. Alienation of any group would potentially undermine the value of that group and the ability to conscript these professionals in Alliance efforts, as all Alliance member groups are messengers. These groups, in their partnership in the Alliance would agree to help with appropriate educational and other informational content (e.g., meeting assistance including speakers, manuscript preparation, email blasts from their membership lists during campaign roll outs). No financial contribution was requested or accepted from the Alliance members that joined following the formation of the organization. Industry or individual practices or university programs were not considered for Alliance membership to facilitate independence and to maintain partnership along professional denominations. The message and messengers then could not be construed as serving purposes other than advocacy for children. The strength of the messenger, a responsibility of the Alliance partners, was through a bidirectional flow to have amplification in messaging to members through the affiliate organizations as well as to provide expertise and guidance to the Alliance when relevant. Other messengers consisted of content experts. Image Gently content experts were carefully selected (see below). An additional important messenger was the website. A

recent presentation at RSNA [37] notes that there were substantial increases in website activity following the CR/DR and dental campaigns, as well as the publication relating childhood CT to the development of cancer. [38] In addition, a website revision in January, 2014, resulted in notable and sustained increased activity.

Messaging was also a critical element in the Alliance success. The model of the IG Alliance is social marketing. In social marketing, behavior/perspective is influenced by information primarily through educational campaigns to benefit those targeted by this information, not to the benefit of the organizations responsible for the educational campaigns. [8] As introduced previously, there was a core group of speakers identified who were provided IG materials with consistent messages. Relevant materials often from a pool created and reviewed by members of the steering committee were made available. Messaging has included 39 peer review publications (most including IG steering committee authorship) specifically titled as addressing IG efforts up through the end of 2014. [15] In addition, conferences including manufacturer summits for CT in 2008, CR/DR in 2010, as well as multispecialty conferences organized by the IG steering committee and based on the IG ALARA theme 2014. Messaging includes cooperation with groups in document review such as the Food and Drug Agency (FDA), the Environmental Protection Agency (EPA), and The Joint Commission (TJC) providing content expertise and guidance related to medical imaging in children.

Part of messaging is control of branding. The hallmark IG butterfly logo, Fig. 7, was not provided to groups and there was no cobranding with groups such as insurance companies, radiology benefit managers, or radiology practices wishing to promote that they supported and/or practiced safe imaging for children. Not that this proclamation was inconsistent with the Alliance, but it would be impossible to assure that representation of the IG brand was always harmonious with IG principles. While such cobranding would probably have had an initial expanded visibility, this would likely not be enduring and could be detrimental depending on unforeseen motives. This would be impossible to predict given resources and virtually impossible to police. It was strongly believed that this brand control would best assure that Image Gently would be recognized, and the message not diluted or misrepresented.

Early in Alliance conception, it was universally recognized that appropriate messaging was important for multiple stakeholders with different levels of understanding, and different magnitudes of interest (discussed in more detail in III.B.). These include radiologic technologists, radiologists, medical physicists, pediatric clinical care providers, patients, parents and other caregivers, as well as the public, administrators, and guidance, regulatory, or governmental organizations as

well. For example, there is information for parents and caregivers for many of the campaigns. All efforts, including messaging, are volunteer except for a portion of administrative support. Success is maintained with volunteers' heads (content), hands (i.e., crafting information through presentation, for example), and hearts (Image Gently serves a need and it is the right way to serve this need).



Fig. 7 Image Gently Logo

There has been some grant support obtained by steering committee members. There are no private donations accepted and no industry support with the exception of an initial unrestricted educational grant by General Electric at the concept and development stages, before the Alliance was official. The adult imaging community embraced the mission of the Image Gently Alliance with the creation of Image Wisely for adults. The Alliance organization and use of social marketing methods for advocacy and education were pioneering and some elements were used as a template for subsequent important global initiatives such as EuroSafe and AfroSafe.

D. ADDITIONAL PUBLICATIONS

In addition to its website, publications in peer reviewed journals provide additional information for the end-user conducting pediatric imaging. A few additional published manuscripts published by individuals associated with the Alliance are cited here. [39-43] These articles respectively discuss:

1. Importance of Alliance partnerships
2. Lessons from the past applied to the present
3. Child-sizing radiation doses to children
4. ACR Dose Index Registry and Diagnostic reference ranges
5. ACR sponsored CT training website

III. GOALS OF THE ALLIANZ

The Alliance currently has a number of goals in progress.

A. *CREATE A TEMPLATE FOR SUCCESS FOR OTHER ALLIANCES WITH A DIFFERENT FOCUS*

The IGC has achieved success by using a social marketing model and associated organizational structure as previously discussed in Section II.B. For example, a similar Alliance, Image Wisely, was created in the United States a couple of years after the formation of the IGC to address adult imaging concerns. While the regulatory environment in countries outside the United States may be considerably different, social marketing should also be successful in other countries.

B. *PROVIDE INFORMATION RELEVANT TO RADIATION DOSE MANAGEMENT (ALONG WITH IMAGE QUALITY MANAGEMENT) FOR PEDIATRIC IMAGING PROCEDURES*

1. Provide parents/caregivers with information before performing imaging procedures of their children

Parents/caregivers need information about their children's imaging procedures. The Alliance has developed multiple, informative pamphlets for caregivers which have been translated into multiple languages. These pamphlets, posted on the IG website, assist caregivers in asking questions and making more informed decisions about their child's medical care. [5,44-47]

2. Healthcare providers

Referring physicians and other healthcare professionals in the United States provide the primary medical care for patients in the United States. These individuals select or request their patients' diagnostic studies, or in the case of dental care both determine the need for and perform imaging examinations. These individuals need to know the strengths and weaknesses (including the relative radiation dose) of each type of diagnostic imaging exam available with respect to answering the clinical question at hand. IGC's website contains information to help the referring physician sort through these differences.

4. Imaging experts

In the United States it is estimated that approximately 15% of all pediatric imaging [48,49] is conducted within dedicated pediatric hospitals or focused sections of pediatric imaging within an adult hospital. Therefore, the vast majority of pediatric imaging occurs primarily within adult focused departments where pediatric imaging is the minority of completed studies. As discussed in

Section IV below, pediatric patients cannot simply be treated as if they are small adults. Radiologists and radiologic technologists with limited experience conducting pediatric imaging studies and their pediatric patients should benefit from additional information on pediatric imaging.

End-users of imaging equipment may assume that the manufacturer's representative or application specialist fully understands the correct application of the imaging product purchased. On many occasions, this is true for adult imaging. However, if the manufacturer of the imaging device has not previously installed one of their units in a dedicated pediatric hospital with sound medical physics support, the manufacturer may not have had the opportunity to develop operational configurations of their equipment specifically designed to image small children.

C. *ENHANCE EDUCATION AND USER SUPPORT DURING PEDIATRIC IMAGING*

The Alliance has developed numerous presentations and other educational resources for pediatric imaging procedures. Due to rapid advances in technology, end-users of imaging equipment need continual training to understand how to leverage a particular piece of equipment's design features to properly manage radiation dose and image quality. The Alliance has assisted the International Atomic Energy Agency by editing some of its pediatric curriculum for medical physicists. Numerous web-based modules have been created and placed on the IG website on "Enhancing Radiation Protection in Computed Tomography for Children", one for each major equipment manufacturer in 2010. [50-53] In 2013, a three part training web module for radiologists and physicians sponsored by a competitive grant from the US Food and Drug Administration entitled "Image Gently: Enhancing Radiation Protection and Fluoroscopy for Children" was developed. [54]

D. *FOSTER THE TAILORING OF IMAGING EQUIPMENT TO THE UNIQUE NEEDS OF PEDIATRIC IMAGING PROCEDURES INCLUDING DEVELOPMENT AND USE OF PEDIATRIC DOSE INDICES.*

For the reasons explained in Section IV, imaging equipment tailored to the unique needs of pediatric patients should produce equal or better image quality with the same or less radiation dose to the child. This level of configuration of the imaging equipment is achieved by consultation with the imaging equipment manufacturer's representatives,

physicians who will use the imaging device, and radiologists who will assist the physicians. If available, a medical physicist can help identify potential solutions to specific pediatric imaging needs by serving as an interpreter between clinicians and equipment manufacturer's representatives. [55]

To date, The Alliance has sponsored three summits, two in CT (2008, and 2014) and one in digital radiography, which included equipment design engineers and educators from industry. The summit on digital radiography resulted in the adoption of a standardized Exposure Index (EI) designed to allow radiologic technologists to estimate the radiation dose to the patient. [56] The three CT-based meetings [16,57,58] raised the awareness of the need for a better pediatric patient dose index during CT. In response, the AAPM developed the Size Specific Dose Estimate (SSDE), [59] that estimates the radiation dose to the patient instead of the radiation dose to a phantom ($CTDI_{vol}$). Currently, medical physicists are working with the International Electro-technical Commission (IEC) on behalf of the IGC to develop a new IEC standard that will require the manufacturers to calculate and display SSDE on all their new CT scanners in the future.

E. PROVIDE GUIDANCE TO REGULATORY OR ADVISORY AGENCIES RESPONSIBLE TO MAINTAIN/ IMPROVE PEDIATRIC IMAGING AND/OR RADIATION PROTECTION

The medical physicist must understand the specific role of the various agencies within their country that regulate the use of ionizing radiation on pediatric patients and should obtain copies of applicable regulations. Advisory agencies develop recommendations. These advisory recommendations, necessary to establish 'a standard of good practice', are optional. However, if a regulatory agency adopts a suggestion from an advisory agency and promulgates it into a regulation, the regulation becomes mandatory. Individuals involved with the IGC have had the opportunity to offer expert advice and provide suggestions for pediatric specific information into some of these agency's publications of the regulatory/advisory agencies listed below.

1. Examples of advisory agencies

- a. *National Council of Radiation Protection and Measurements (NCRP)*

A nonprofit corporation chartered by the United States Congress to collect, analyze, develop, and disseminate information and recommendations

about radiation protection, radiation measurements, quantities, and units. [60]

- b. *International Council on Radiological Protection and Units (ICRU)*

This advisory agency has a scope similar to the NCRP. However, its international membership includes a larger variety of perspectives on radiation health issues. [61]

- c. *International Atomic Energy Agency (IAEA)*

Despite its name, this international advisory agency, located in Vienna, Austria, publishes advisory documents on management of pediatric imaging. For example, in 2014, "Dosimetry in Diagnostic Radiology for Pediatric Patients" was published. [62]

- d. *Accrediting Agencies*

Professional organizations may provide accreditation services to end-users of imaging equipment in the United States. The American College of Radiology and The Joint Commission are two accreditation bodies typically with quality standards that a facility must meet to implement and maintain accreditation status. The accrediting agency is not a regulatory agency. However, quality control elements developed by the Accrediting Agency may be adopted as regulations by a given state or may become mandatory if a hospital or site wishes to receive payment for their services from a third party insurance payer. While the accrediting agency has no regulatory authority, if a regulatory body or insurance payer requires a facility to be accredited, the accreditation body's quality control programs must be performed to maintain the accreditation. One member of the IGC was requested by a United States accreditation body to assist in developing quality control elements of their program; as a result, pediatric considerations were added to the program. [63]

2. Examples of regulatory agencies

- a. *Conference on Radiation Control Program Directors (CRCPD)*

The CRCPD develops Suggested State Regulations (SSRs) that individual state regulatory programs within the United States can adopt to control the use of ionizing radiation by end-users. Regulatory control is contained within each of the 50 states; a state may adopt or modify the SSRs as written by the CRCPD when promulgating its rules. [64]

- b. *Nuclear Regulatory Commission (NRC)*

This United States regulatory agency promulgates regulations that control the use of radioisotopes used for nuclear medicine procedures by end-users.

c. *United States Food and Drug Administration (FDA)*

This body is a national regulatory agency that controls the design and capability of all x-ray producing machines sold within the United States. A manufacturer of imaging equipment must have the design of a given unit approved by the FDA before that type of imaging equipment can be sold in the United States market. A competitive grant was awarded to the IGC by the FDA in 2012, to write guidelines for manufacturers of imaging equipment to be used for pediatric imaging. [65]

d. *International Electro-technical Commission (IEC)*

The IEC develops regulations that control the design and features found on imaging equipment that use ionizing radiation. A manufacturer, which desires to sell its products worldwide, must meet all the stipulations included in applicable IEC standards. One author within the IGC is currently assisting draft of IEC 62B/PT 62985 'Size Specific Dose Estimate (SSDE) on Computed Tomography Units', an IEC standard which will require the calculation and display of SSDE in the future on all CT scanners if approved and adopted when completed.

F. *DEVELOP AND IMPLEMENT QUALITY CONTROL PROCEDURES SPECIFICALLY FOR PEDIATRIC PATIENTS*

1. Improve existing accreditation programs by including pediatric quality control tests

Accreditation programs are designed to evaluate the quality of imaging at a given clinic or hospital. The more comprehensive programs are designed to evaluate both image quality and the radiation dose required to achieve a specified level of image quality. Sample images and the radiation doses used to produce those samples are typically submitted periodically to the accrediting body for evaluation. To be granted accreditation, the site must achieve pre-determined levels of image quality and radiation dose. Steering committee members of the Alliance have had the opportunity to introduce testing methods specifically designed for pediatric patients on CT scanners in the United States. [63]

2. Provide resources related to diagnostic reference levels for pediatric imaging

Diagnostic Reference Levels (DRLs) establish patient dose levels for various diagnostic imaging exams based on surveys of actual patient doses in multiple facilities typically within a single or region. If the patient's radiation dose exceeds the DRL, the imaging department is strongly encouraged to carefully investigate and identify steps that can be taken to reduce patient radiation doses during subsequent imaging studies. While many European countries have well-established DRLs for most adult and some pediatric examinations, the United States and some third world countries need to develop more complete DRLs. While the pediatric imaging community has made some progress with this goal in abdominal CT [13] and interventional fluoroscopy, [66] much work remains to be done. Hopefully, the further development of a national dose database provided by the American College of Radiology will soon expand its scope beyond CT scans and provide the data necessary to meet this goal.

G. *EFFECTIVE AND EFFICIENT ORGANIZATIONAL OPERATIONS*

The IGC continually strives to improve its operations. Additional campaigns may be developed in the future. The Alliance operates by consensus representation and voice to ensure the appropriateness of its proposals. As discussed in greater detail above, it is important for the Alliance to maintain its independence from other select interests, e.g. industry and its desire to sell its products, or organizations with for-profit agendas. At the same time, the Alliance needs to form appropriate alignments with existing resources that aid the dissemination of the Alliance's message, e.g. Radiology info.org, Image Wisely, and international alliances with similar goals.

H. *ASSESS CLINICAL IMPACT OF CAMPAIGN*

A real measure of clinical effectiveness of the IGC is just as important as the rollout of numerous campaigns. While some analysis has been completed [32,67,68], it is limited due to the difficulty of establishing quantitative measures that can be accurately determined.

I. *POSSIBLE FUTURE GOALS*

1. Smaller, focused topic campaigns that impact more than one pediatric imaging modality will likely be addressed, e.g. appropriate use of gonadal shielding during pediatric imaging, etc.

2. Campaigns with other imaging groups, such as pediatric cardiologists, or orthopedists who use ionizing radiation equipment.
3. Clearer delineation, especially on an international scale, of organizational expertise and responsibility. Given limited resources, duplicate efforts are wasteful. Further discussions between international organizations can help define areas of authority and improved allocation of resources as well as consistent messaging.
4. Constant reassessment of the Alliance's mission and strategic plan with adoption of necessary organizational shifts that continue to provide the greatest opportunity to manage efforts in meeting its mission.

IV. FUNDAMENTAL MEDICAL PHYSICS OF PEDIATRIC IMAGING

A. TEAM APPROACH TO THE IMPROVEMENT OF PEDIATRIC IMAGING

Two independent, yet inter-related approaches are recommended to achieve properly managed patient doses and image quality. First, the design features of the imaging equipment should be

configured to reduce radiation dose rates during fluoroscopy and during recording of images (fluorography) left side of Fig. 8. Second, correct operation of the fluoroscope by properly trained operators should reduce fluoroscopy time; the number of fluoroscopic images created. The experienced operator also reduces the number of recorded images, which properly documents the results of the study and allows for correct diagnosis, right side of Fig. 8.

A variety of individuals should work as a team to achieve diagnostic quality images at properly managed radiation doses. End-users should explain their clinical needs to the manufacturer while the manufacturer matches components of their product line and their configuration to these needs. The recommended environment that allows optimum performance of the selected imaging device should be created. [69] After installation of the equipment and completion of agreed upon pediatric modifications/configurations of the unit, a qualified medical physicist should perform extensive functional testing of the imaging device to verify that all technical imaging parameters that affect patient dose are performing in an acceptable manner prior to first clinical use. [70-75] These activities address the left side of Fig. 8.

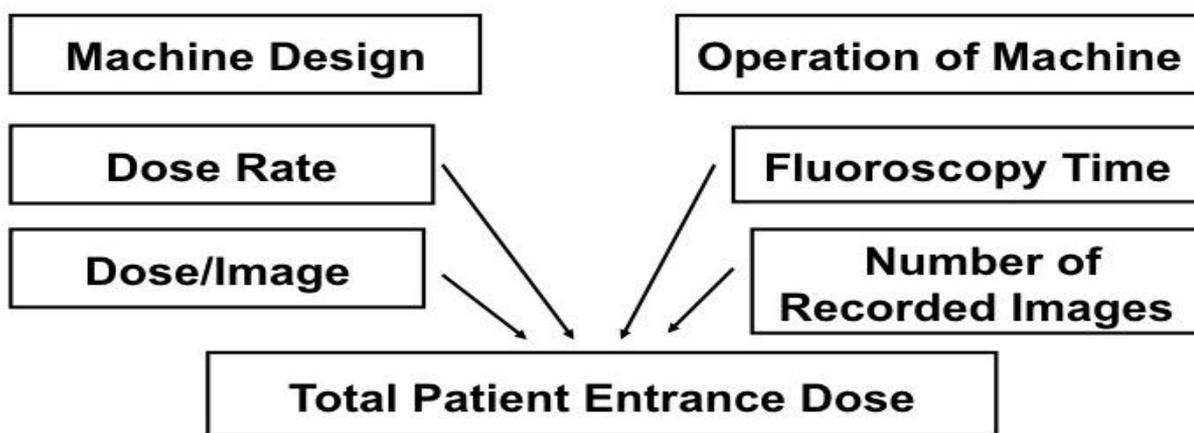


Fig. 8: Total patient entrance dose from a fluoroscope depends on the dose rate during fluoroscopy and dose per recorded image, both factors dependent on the fluoroscope's design and configuration. Total patient entrance dose is also directly related to fluoroscopy time (number of fluoroscopic images) and number of recorded images, which are more dependent on the training and experience of the operator than on the fluoroscope's design and configuration.

Clinical staff in addition to the operator may be involved in ensuring the proper operation of the imaging equipment, right hand side of Fig. 8. [2,76] First, the clinical need and justification of the imaging study involving ionizing radiation should be evaluated. Will the results of the study realistically answer the original clinical question? Should an alternative

imaging modality without ionizing radiation be considered first? Answering the clinical question without using ionizing radiation is the most effective method of reducing radiation dose to the patient.

In addition to an understanding of basic physics principles of fluoroscopy, the operator should complete operational training ("buttonology") on every

aspect of fluoroscopic equipment operation. End-users require an ongoing, close, working relationship with their chosen manufacturer. Free exchange of all necessary information is necessary. Positive changes in practice occur when the four groups of individuals in Fig. 9 work effectively together. The manufacturer may need to make design engineers (in addition to product specialists and application specialists) available to communicate to the customer the operational design capabilities of the fluoroscope that can be harnessed to meet clinical objectives. An available qualified medical physicist with experience in pediatric imaging can, through interpretation, help the flow of information between the clinic and industry. This shared knowledge leads to a properly modified and configured fluoroscope for pediatric imaging. The ultimate goal is to perform necessary imaging “with the least amount of radiation required to provide adequate image quality and imaging guidance. Images that are inadequate for diagnosis or for guiding interventions introduce the risk of catastrophic complications.” [6]

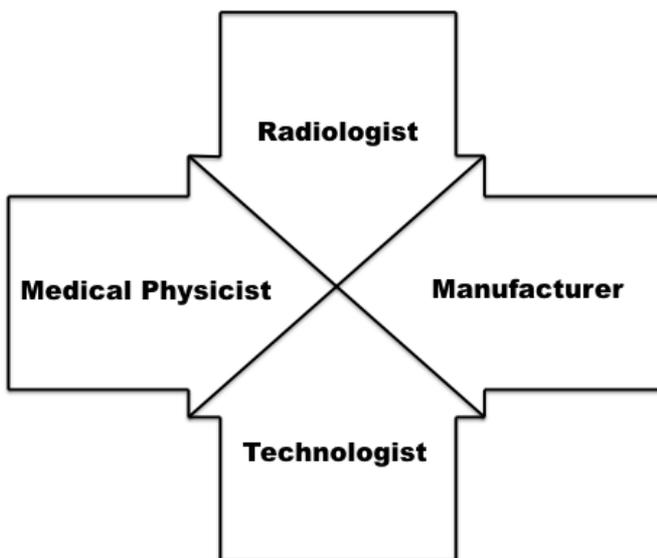


Fig. 9 Pediatric imaging is best optimized when the four groups of individuals shown work effectively together.

B. IMAGE QUALITY, PATIENT DOSE, AND PEDIATRIC CONSIDERATIONS

Children are not small adults. First, their disease states differ from those of adults, which may lead to multiple interventions in the imaging room. For example, neonates and infants may present with a large variety of congenital heart and/or vascular defects or diseases [77] as opposed to coronary artery disease common in adults. These complex pediatric conditions

may require as many as ten cardiac catheterizations to manage the disease prior to the patient reaching adulthood[77], which underscores the necessity to manage the radiation dose from each examination. Second, small children may not be able to cooperate during their x-ray examination. The majority of small children are fearful of unfamiliar surroundings, patient staff, the possibility of additional pain, and large pieces of imaging equipment.

1. Radio-sensitivity of Children

Since a child has the majority of their life span ahead of them, the small possibility of a stochastic radiation injury expressed later in the child’s life (e.g., radiation induced cancer) is more probable than a deterministic radiation injury (e.g., skin damage). The deterministic injury seldom occurs in a child due to the smaller size of their body, which reduces their entrance skin dose relative to that of an adult. [60]

2. Implications of Patient Size on Radiographic Techniques

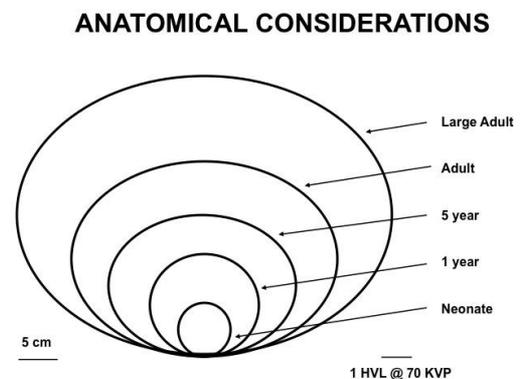


Fig.10 The LAT diameter through the patient’s thorax ranges from 5 – 45 cm as a function of age. This range in size (pediatric imaging) requires a change in the required number of x-rays by more than a factor of 8,000 to maintain the same dose to the image receptor provided the voltage used to produce the x-rays remains unchanged.

The small size of a neonate or infant relative to an adult demands a large dynamic range of radiologic technique factors. A neonate has a posterior-anterior [77,78] dimension of approximately 5 cm, while a large adult can have a PA dimension up to 33 cm or more [79,80] as illustrated in Fig.10. The range of tissue path length in the lateral direction is even greater, 5 – 45 cm. If the Half Value Layer (HVL) of tissue is assumed to be approximately 3 cm at 70 kV for fluoroscopic imaging equipment with standard total filtration, this range of patient sizes exceeds 13 HVLs. This requires a dynamic range of radiation per pulse of

greater than 8,000 to minimize the increase in Voltage and reduction of image contrast from the smallest to largest patient!

When imaging the largest adults, producing a sufficient patient entrance flux of radiation to deliver the necessary flux of x-rays at the image receptor is a primary design consideration. When imaging smaller pediatric patients, the need of high radiation flux is dramatically reduced. *This provides the opportunity to select desired x-ray tube voltages/added filtration, reduced pulse widths, or smaller focal spot sizes that either improve image quality, reduce patient dose, or both.* The range of patient sizes depicted in Figure 3 represents the range of patient size within the pediatric population, typically defined as neonates to 21 years of age. If equipment is designed to image children, it is designed for all patients, not just small to large adults. Many imaging units can be altered to reduce patient dose with little or no degradation in clinical image quality. The results of this exercise can be more dramatic than anticipated with the appropriate configuration. [81,82]

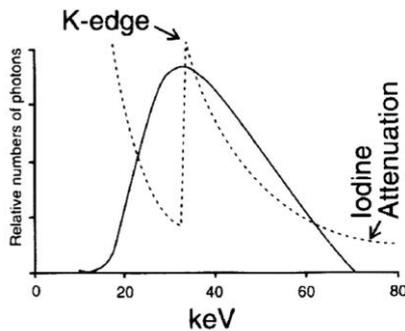


Fig. 11. Iodine Attenuation compared to the effective energy of a 70 kV X-ray Beam Spectrum with 3 mm aluminum total filtration. The effective energy of the x-ray beam spectrum, ~ 30 keV, is well matched to the 33 keV k-edge of iodine. This matching increases the radiopacity of an iodine-filled vessel. Reprinted with permission. [83]

3. Pediatric image quality

Image quality should be tightly controlled in infants and small children to ensure clinically useful images. Small patients have small body parts. For

example, the tiny clenched fist of the newborn baby illustrates the size of the patient's tiny heart that the pediatric cardiologist must examine and repair. A sharp image of the patient's anatomy and the smaller devices and hardware used by the pediatric cardiologist or radiologist is extremely important. This requires that sources of unsharpness in the image introduced by the finite size of the focal spot, design of the image receptor, motion of the patient, or geometry of the patient with respect to the location of the image receptor and focal spot must be carefully controlled.

A sharp clinical image must also provide adequate contrast to be clinically useful. Inherent subject contrast of soft tissue structures is limited by the magnitude of the mismatch of the k-shell binding energy of soft tissue (~ 0.5 keV) and the effective energy of the x-ray beam (~ 30 keV), which is necessary to penetrate through the patient's body at a reasonable patient dose. (The effective energy of the x-ray beam, determined by the x-ray tube voltage and added thickness of filter in the beam, should match the k-edge of the contrast media as illustrated in Fig 11.) The limited natural subject contrast is improved by the injection of contrast media (with a k shell binding energy similar to 33 keV [iodine]) into the patient's vascular. Subject contrast created by iodine is a function of the concentration of the iodine in the vessel and the diameter of the vessel [84]. The smaller diameters of the child's vessels require higher concentrations of contrast media to achieve the same subject contrast created by the larger vessels of adults. However, the total volume of injected iodine per patient is limited due to the toxicity of the contrast agent (4 - 6 cm³/kg of 320 - 350 mg/cc iodine) [77].

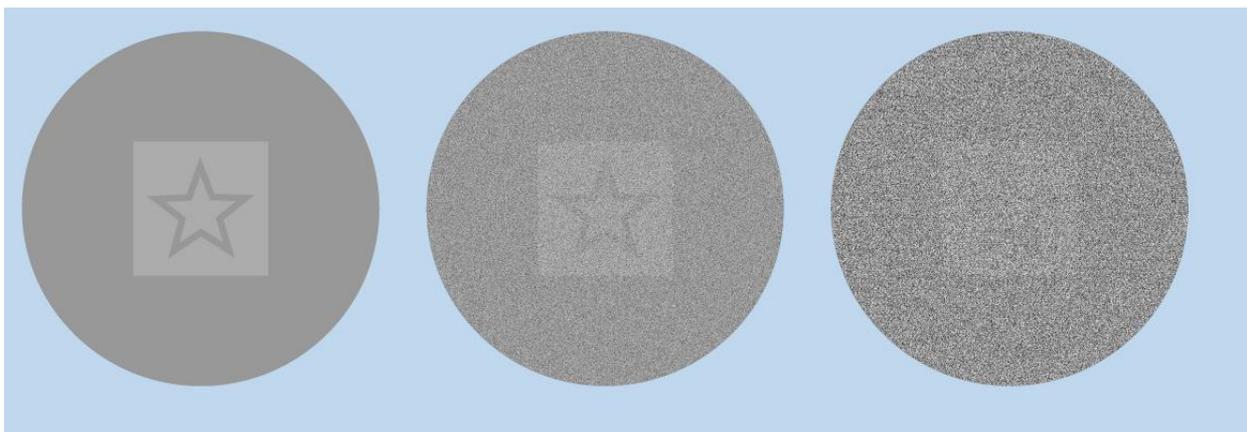


Fig. 12: The image on the left is produced with a radiation dose to the patient more than an order of magnitude greater than the image on the right. The central image is the correct configuration: diagnostic image quality at a properly managed radiation dose

Good low contrast sensitivity in the image is also necessary to distinguish between soft tissue structures within the body. Soft tissue structures are masked by the presence of scatter radiation, which should be controlled with an effective grid. Soft tissue structures are also masked by the quantum mottle in the image as illustrated in Fig 12. As one scans from left to right in the figure, the quantum mottle increases as x-ray flux to the image receptor decreases by more than an order of magnitude. The dose reduction of the right-most image in Fig. 12 is desirable for pediatric imaging, but this large reduction is not clinically acceptable. The elevated quantum mottle in the image would probably prevent an accurate diagnosis; it would probably result in the request for a repeat image. Acceptable pediatric patient doses should be tailored to the imaging task, not an arbitrary dose level. Significant dose reduction may be possible during some high contrast studies where more quantum mottle may be tolerable, but not during low contrast studies. Examples of high contrast studies are a VCUG using iodine or lower GI study using barium contrast agents. Performing angiography of small vessels using iodine is an example of a low contrast study. Reducing radiation dose while ignoring associated degradation of image quality is a relatively simple task, but clinically unacceptable. The correct challenge is to reduce the patient's radiation dose while maintaining diagnostic image quality.

V. CONCLUSIONS

Improving the medical care of pediatric patients by properly managing when examinations using ionizing radiation are performed, by properly managing the quality of the clinical images, and by properly managing the associated radiation dose to patients to produce each image is not trivial. Quality pediatric imaging requires attention to detail and effort. Appropriately trained staff members need properly configured imaging equipment to achieve this goal.

Fig. 13 is a recent photograph of the same child on the same beach with the same life jacket in Fig. 1 approximately 8 years earlier. The child has grown to be a pre-teenager instead of a toddler. Image Gently, its methods and programs, described here have also expanded and matured over this time period. Hopefully, medical physicists in all countries striving to improve the care of children locally by developing educational and clinical support activities designed to assist radiologists, radiologic technologists, and representatives of the imaging equipment manufacturer will find these Image Gently programs and resources helpful.



Fig. 13 Same scene, same life jacket and child 8 years after the photograph in Fig. 1

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