# Prioritizing Patient Radiation Safety Globally: A Narrative Review Evaluating Global Patient Radiation Safety Initiatives using a SWOT Approach

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#### **ABSTRACT**

The application of ionizing radiation for medical imaging has become an integrated aspect of modern medicine. As a result of the increased demand for these medical services, patient safety regarding radiation protection has emerged as a global priority. In 2012, the International Atomic Energy Agency held a conference cosponsored by the World Health Organization to address issues in medical radiation protection, resulting in the development of the *Bonn Call-for-Action*. These recommendations have guided the coordination and subsequent implementation of various global patient radiation safety initiatives throughout Europe, North America, South America, Africa, Asia, and the Middle East. This paper will review and emphasize the importance of these patient radiation safety initiatives and will explore and evaluate the independent progress, overall effectiveness, and unique priorities of each global initiative using a strengths, weaknesses, opportunities, and threats (SWOT) analytical approach.

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#### LIST OF ABBREVIATIONS

ALARA As Low As Reasonably Achievable

BCfA Bonn Call-for-Action

BEIR Biological Effects of Ionizing Radiation

BSS Basic Safety Standards

CT Computed Tomography

DRL Diagnostic Reference Level

IAEA International Atomic Energy Agency

ICRP International Commission on Radiation Protection

IR Ionizing Radiation

ISR International Society of Radiology

ISRQSA International Society of Radiology Quality and Safety Alliance

LNT Linear No-Threshold

MI Medical Imaging

MRI Magnetic Resonance Imaging

NCD Non-Communicable Disease

PET Positron Emission Tomography

SWOT Strengths Weaknesses Opportunities and Threats

UNSCEAR United Nations Scientific Committee on the Effects of Atomic Radiation

WHO World Health Organization

# CHAPTER 1: THE IMPORTANCE OF MEDICAL IMAGING IN MEDICINE Medical Imaging in Medicine

Medical imaging (MI) has become an extremely valuable tool across all fields of medicine. The World Health Organization (WHO) estimates that every year, hundreds of millions of people in a healthcare setting benefit from the variety of imaging modalities and processes used for diagnostic, interventional, and therapeutic purposes (WHO, 2014). Through the ubiquitous use of MI in current healthcare practice, disease diagnosis can be quickly and accurately confirmed while disease treatment, most commonly of cancers, can be easily assessed, monitored, and adapted (WHO, 2018a).

MI can utilize ionizing radiation (IR), which are characterized as high frequency and high-energy electromagnetic waves, or non-ionizing radiation from either an internal or external source (Gianfaldoni et al., 2017; WHO, 2016). The most readily used external source of IR in MI is conventional radiography, which produces an image of internal structures using x-ray electromagnetic radiation (WHO, 2018b). Wilhelm Conrad Röntgen first discovered the x-ray in 1895 and his subsequent work earned him the first Nobel Prize in 1901 (Bradley, 2008; Rafat, Ali, & Graves, 2015). In radiography, IR is externally produced and passed through the patient, penetrating soft tissues while denser materials absorb more radiation, and is captured by a film or, more commonly, a digital detector to produce a 'through and through' image (Bradley, 2008; WHO, 2018b). As such, this type of imaging modality is extremely effective in producing contrast images of internal structures that are used for clinical applications.

IR, in the form of x-rays, is also heavily used in other imaging modalities including fluoroscopy, angiography, and mammography. Fluoroscopy uses internal high contrast agents with continuous x-ray application to capture dynamic images in real-time (WHO, 2018c). Angiography is another imaging modality that uses contrast media injected into blood vessels to visualize arteries and veins, as well as the different heart chambers (WHO, 2018d). Like fluoroscopy, angiography captures real-time images, although many procedures now utilize magnetic resonance rather than x-ray radiation (WHO, 2018d). Mammography is a slightly unique imaging modality as it uses low energy x-ray radiation to image breast tissue for breast cancer screening purposes (WHO, 2018e).

MI modalities that utilize radiography have significantly advanced in the last 50 years with the integration of computerized technology, specifically with the inclusion of computed tomography (CT). CT uses x-ray radiation to produce images, which are then digitally reconstructed into either two or three-dimensional images (WHO, 2018f). These images can also be viewed in slices (tomography) to enable more effective diagnosis.

Where radiography utilizes IR from an external source, the field of Nuclear Medicine uses internally injected radioactive tracers, known as radiopharmaceuticals, to visualize internal structures (WHO, 2018g). As the radioactive tracer decays within the patients' body, gamma rays are emitted and subsequently detected resulting in a localized image (WHO, 2018g). Another imaging modality used within the field of Nuclear Medicine to visualize cancerous tumours is positron emission tomography (PET) imaging. With PET imaging, a positron-emitting radioactive isotope, most commonly fluorine (F-18), is incorporated into a glucose analog, which is readily taken

up by cancerous cells (Rafat et al., 2015). As the positron is emitted, it annihilates with a neighbouring electron causing a release of two 511 KEv photons in opposite directions (Bradley, 2008). The photon detector then localizes the internal source of emission, resulting in a PET scan (Bradley, 2008).

As previously mentioned, some MI modalities do not require the use of IR. These include ultrasound and magnetic resonance imaging (MRI). During an ultrasound, high-frequency sound waves are applied and tomographic images are produced depending on the density of the tissue reflecting the waves (Bradley, 2008). MRI uses magnetic radiation to produce real-time multi-planar images of internal structures in three-dimension (WHO, 2018h). This form of imaging orients the spin character of hydrogen molecules and provides efficient soft tissue contrast, and as such, is effective in visualizing the brain, spine, muscle, and joints (Bradley, 2008; WHO, 2018h).

The benefits of MI are widely recognized by both the public and healthcare professionals; however, it is argued that there are significant risks associated with repeated exposure to IR. As a result, patients should not be subject to unnecessary diagnostic examinations. With the rapid increase in demand for MI services across the globe, however, it is important that a balance is found to further the individual health of the patient while mitigating the risks of IR exposure.

#### The Risks of Patient Radiation Exposure

Given the increased demand for MI services involving IR within the last two decades, the risks associated with patient radiation exposure have become more prevalent in the literature and public media (O'Connor, 2017). Radiation dose can either

be measured as absorbed dose or effective dose, also referred to as the dose equivalent (Lin, 2010; WHO, 2016). The absorbed dose quantifies the radiation energy deposited per unit mass and is measured in grays (Gy) (Lin, 2010). However, the biological harm when using this measurement method is dependent on the type of radiation, as well as the sensitivity of the affected tissues and organs (Lin, 2010; WHO, 2016). As such, the effective dose, which is measured in in millisieverts (mSv), is more frequently used as it accounts for the type of radiation in addition to the tissue and organ sensitivity (Lin, 2010; WHO, 2016).

It is well understood that IR exposure at high effective doses (above 100 mSv) can result in detrimental long-term health outcomes (Averbeck et al., 2018; Hendee & O'Connor, 2012; O'Connor, 2017). However, the negative health impact of IR exposure at low effective doses (between 10 and 100 mSv), which is commonly seen with MI modalities, is still relatively uncertain (Averbeck et al., 2018; Lin, 2010). As a result, it is common practice, albeit controversial, to assume similar risks with low effective doses of IR (O'Connor, 2017).

Furthermore, IR has the potential to both directly and indirectly damage DNA.

Because of its high frequency and high-energy nature, IR can displace valence electrons (Goodman, 2010). These displaced electrons can then either directly damage DNA or create reactive oxygen species to further damage DNA (Goodman, 2010).

Although the body has innate repair systems designed to remedy radiation-induced DNA damage, disrepair can cause genetic mutations that negatively impacts cell function (Havas, 2017).

The detrimental biological effects from IR are categorized as either tissue reactions, also referred to as deterministic effects, or stochastic effects (Goodman, 2010; Lin, 2010). Tissue reactions, although uncommon with MI procedures, are threshold dependent, where the severity of the symptoms is relative to the effective dose received (Goodman, 2010; Rehani & Srimahachota, 2011). Examples of tissue reactions include injuries to the skin, cataracts, sterility, and radiation sickness (Goodman, 2010; Rehani & Srimahachota, 2011). Conversely, stochastic effects are believed to follow a linear no-threshold (LNT) hypothesis (Goodman, 2010; Lin, 2010). The LNT hypothesis states that adverse effects can occur at any effective dose, although the probability of damage increases linearly with increased exposure (Goodman, 2010; Lin, 2010). Cancer and other genetic disorders are examples of stochastic effects (Goodman, 2010; Lin, 2010).

The stochastic relationship between radiation exposure and cancer is difficult to quantify, as there is significant lag between exposure and disease onset. The committee on the Biological Effects of Ionizing Radiation (BEIR), however, uses the LNT hypothesis as a model to predict the carcinogenic effects of IR and to estimate the overall risk of radiation-induced cancer (Averbeck et al., 2018; Hendee & O'Connor, 2012; O'Connor, 2017). The BEIR VII report compiles large-scale epidemiological data evaluating four different exposure populations: 1) environmentally exposed groups, 2) medically exposed groups, 3) occupationally exposed groups, and 4) Japanese atomic bomb survivors (Averbeck et al., 2018; Hendee & O'Connor, 2012; O'Connor, 2017). Current evidence outlined within this report supports that high effective doses of IR (above 100 mSv) pose serious risks of radiation-induced cancer (Hendee & O'Connor,

2012; Lin, 2010; O'Connor, 2017). The data presented in the BEIR VII is widely accepted by national and international governing agencies and is often used to inform policy. However, many researchers question the validity of the LNT hypothesis in accurately depicting the carcinogenic effects of low effective doses (Hendee & O'Connor, 2012; O'Connor, 2017). As such, there is significant motivation to better understand the risks associated with low dose radiation exposure.

## **Patient Radiation Exposure Mitigation Strategies**

There is a global understanding and consensus amongst governing entities and healthcare professionals to minimize patient risk by reducing IR exposure in MI.

Consequently, many mitigation strategies have been developed and subsequently endorsed worldwide. The basis of these mitigation strategies is the assumption presented in the BEIR VII report that IR, regardless of the effective dose, has the potential to cause serious long-term harm to patients (Averbeck et al., 2018; Lin, 2010).

The International Commission of Radiation Protection (ICRP) outlines two key principles of patient radiation safety in MI: justification and optimization (Tomà, Cannatà, Genovese, Magistrelli & Granata, 2017). Justification, where the potential benefit of undergoing the MI procedure must exceed the understood harm, is encouraged through the global *Choosing Wisely* campaign (Levinson et al., 2015; Ross, Santhirapala, MacEwen, & Coulter, 2018; Tomà et al., 2017). *Choosing Wisely* began in the United States in 2012 and has since been adopted in 22 countries (Levinson et al., 2015; Ross et al., 2018). The overall goal of *Choosing Wisely* is to engage healthcare professionals and patients in an active benefit-risk dialogue in order to eliminate unnecessary patient exposure to IR (Levinson et al., 2015; Ross et al., 2018).

Optimization, on the other hand, refers to eliminating a significant proportion of the standard dose, often resulting in an increased signal-to-noise ratio, without compromising the diagnostic ability of the MI procedure (Tomà et al., 2017). In other words, it aims to balance the diagnostic value of the procedure without compromising patient health outcomes (Samei et al., 2018). The As Low As Reasonably Achievable (ALARA) principle also emphasizes optimization (Samei et al., 2018).

In addition to justification and optimization, there are many large-scale radiation exposure mitigation strategies that have been adopted globally. A key strategy includes the creation and global implementation of the Basic Safety Standards (BSS) from the International Atomic Energy Agency (IAEA). These standards aim to proactively protect individuals (workers, patients, and the general public) from the risks of IR exposure (European Commission, n.d.). The BSS have been endorsed by many global policymakers and have been enforced in jurisdictions worldwide (European Commission, n.d.). Another large-scale mitigation strategy is the development and adherence to diagnostic reference levels (DRLs). DRLs are used as an internal auditing tool to promote patient radiation safety (IAEA, 2017). They are not strictly enforced, but rather are guidelines used to identify unusually high effective doses in MI (IAEA, 2017).

In addition to precautions that healthcare professionals take when mitigating patient radiation exposure, patient safety has also been considered by developing criteria for medical radiation equipment. Regulatory requirements regarding patient safety with medical radiation equipment are crucial as equipment failures and tube leakages have resulted in patient harm (Gilley & Holmberg, 2013).

There are many mitigation strategies that are used to guide healthcare professionals when evaluating the necessity of MI procedures for patients. Specifically, the principles of justification and optimization (and their applications through the global *Choosing Wisely* campaign) in addition to the implementation of BSS, DRLs, and precautionary measures taken from medical equipment manufacturers are used. It is essential that collaborative and transparent partnerships between policymakers, manufacturers, and healthcare professionals continue to ensure patients are not needlessly subjected to IR.

## **Rationale and Purpose of Paper**

It is estimated that more than 3.6 billion MI procedures involving IR are performed annually worldwide (Mettler et al., 2009). Although the use if IR in MI has been seen to slightly decrease, there is still a significant demand for these services given the aging population, as well as the rapidly growing prevalence of non-communicable diseases (NCDs), specifically cancer (Hendee & O'Connor, 2012). As such, maximizing MI effectiveness while mitigating potential patient harm from IR exposure has emerged as a global healthcare priority.

This paper will first identify the key international policymakers and stakeholders responsible for global patient radiation safety. Then, the global patient radiation safety initiatives within the International Society of Radiology Quality and Safety Alliance (ISRQSA), specifically those that align with recommendations from IAEA and the WHO, will be analyzed using a strengths, weaknesses, opportunities, and threats (SWOT) approach.

The overall purpose of this paper is to assess the independent progress, overall effectiveness, and unique priorities of each global patient radiation safety initiative since the 2012 *Bonn Call-for-Action (BCfA)* guidelines were established. By evaluating each initiative independently, recommendations can be derived and presented to facilitate the success of future patient radiation safety initiatives.

### **CHAPTER 2: THE GLOBAL NEED FOR PATIENT RADIATION SAFETY**

## **Key Global Policymakers and Stakeholders**

Given the rising demand for MI services that utilize IR, patient radiation safety continues to emerge as a global healthcare priority. In order to ensure patient radiation safety, engagement and subsequent global action from key international policymakers and stakeholders, with the support and adherence from regional and national governing agencies, is essential. There are many important international policymakers and stakeholders who significantly support the reduction of patient IR exposure.

The IAEA is a global leader in patient and environmental radiation safety focused on contributing to "atomic energy peace, health, and prosperity around the world" (Deatsch-Kratochvil, Pascual, Kesner, Rosenblatt, & Chhem, 2013; IAEA, 2018). They establish standards and protocols for the safe use of IR in medicine and actively encourage regional, national, and international adherence and implementation by regulatory authorities and professional associations (Abdel-Wahab et al., 2011; Gilley & Holmberg, 2013; IAEA, 2018). Additionally, the IAEA provides a set of safety standards for the manufacturers of radiation equipment (Gilley & Holmberg, 2013).

The main focus of the ICRP is radioprotection, and they frequently collaborate with other international policymakers and stakeholders to promote the justification and optimization principles (Gianfaldoni et al., 2017; IRCP, 2018). They are also responsible for the creation and global implementation of the International System of Radiological Protection – the basis for all IR protection standards, legislation, guidelines, programs, and practices (ICRP, 2018). This system is informed by current scientific understanding

of the detrimental health outcomes from IR exposure, in addition to 'value judgements', including societal expectations, ethics, and first-hand experience (ICRP, 2018).

The International Society of Radiology (ISR) is a representative non-governmental organization closely associated with the WHO and IAEA that represents the interests of national radiological societies (Allen, 2018). Their goal is to further their member organization's global agenda while improving patient care and population health through the use of diagnostic imaging (Allen, 2018). In 2016, the ISR established the ISRQSA as an umbrella entity to coordinate the global alliance of patient radiation safety initiatives (Allen, 2018; Frija, 2017).

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) is another highly regarded international policymaker. They are mandated to evaluate and disseminate information regarding the effects of IR and have published dozens of reports assessing radiation risks, which have informed legislation in many countries regarding subsequent protective measures (UNSCEAR, 2018).

The WHO is a specialized agency within the United Nations that advocates for global public health. They are instrumental in bringing together stakeholders to encourage patient radiation safety initiatives, especially through their Global Initiative on Radiation Safety in Healthcare Settings (WHO, 2008). This initiative guides health authorities in maximizing the benefits of using IR in MI while minimizing the risk for patients and healthcare professionals (WHO, 2008).

These influential policymakers and stakeholders are responsible for evaluating the current status of global patient radiation safety and providing recommendations for

regulatory bodies. Collaboration between policymakers, international stakeholders, and the private sector is crucial if patient radiation safety is to continue as a global healthcare priority.

#### The Bonn Call-for-Action

The IAEA organizes many conferences in collaboration with other influential policymakers and stakeholders to promote comprehensive quality assurance and patient safety throughout all aspects of radiation medicine (Shortt, Davidsson, Hendry, Dondi, & Andreo, 2008). In 2012, the IAEA held a conference co-sponsored by the WHO in Bonn, Germany titled "International Conference on Radiation Protection in Medicine: Setting the Scene for the Next Decade" (WHO, 2014, p. 3). This conference brought together 536 participants representing 77 countries and 16 independent organizations to identify and address issues in medical radiation protection (WHO, 2014). During this conference, stakeholders discussed and developed priorities regarding radiation protection in medicine for the next decade. Afterwards, the IAEA and the WHO released a joint position statement summarizing the efforts, resulting in the *BCfA* (WHO, 2014).

The *BCfA* outlines recommendations that were identified by stakeholders as crucial for furthering radiation protection in medicine from 2012 to 2022. The overall goals of the *BCfA* are to:

- 1. Strengthen the radiation protection of patients and health workers overall;
- 2. Attain the highest benefit with the least possible risk to all patients by the safe and appropriate use of IR in medicine;

- 3. Aid the full integration of radiation protection into health care systems;
- 4. Help improve the benefit-risk dialogue with patients and the public; and
- 5. Enhance the safety and quality of radiological procedures in medicine (WHO, 2014, p. 3).

Specifically, the *BCfA* endorses ten action items, with related sub-actions, as essential for enhancing radiation protection in medicine. These action items are:

- 1. Enhance the implementation of the principle of justification;
- Enhance the implementation of the principle of optimization of protection and safety;
- 3. Strengthen manufacturers' role in contributing to the overall safety regime;
- 4. Strengthen radiation protection education and training of health professionals;
- Shape and promote a strategic research agenda for radiation protection in medicine;
- Increase availability of improved global information on medical exposures and occupational exposures in medicine;
- 7. Improve prevention of medical radiation incidents and accidents;
- 8. Strengthen radiation safety culture in health care;
- 9. Foster and improve radiation benefit-risk dialogue; and
- 10. Strengthen the implementation of safety requirements globally (WHO, 2014, p. 4–13).

The IAEA and the WHO encourage all stakeholders and member states to adopt these action items. To date, eight large-scale global initiatives, under the ISRQSA, have

been developed to align with the *BCfA* recommendations to improve radiation protection in medicine. These include AfroSafe, ArabSafe, Canada Safe Imaging, EuroSafe Imaging, Image Gently, Image Wisely, Japan Safe Imaging, and LatinSafe.

#### **CHAPTER 3: SWOT ANALYSES OF PATIENT RADIATION SAFETY INITIATIVES**

#### **SWOT Framework**

A SWOT analytical framework was used to evaluate the eight global patient radiation safety initiatives within the ISRQSA. A SWOT analysis is a popular strategic tool used to evaluate high-level organization and planning within the public health sector (Nawaz, Ali Khan, & Khan, 2013). Additionally, it is a straightforward framework that addresses and evaluates internal and external variables influencing the organization or initiative (Coman & Ronen, 2009).

For the SWOT analyses, both academic peer-reviewed literature and grey literature were included. Academic literature was obtained from the Web of Science and Pubmed databases. In these databases, keywords, in addition to the name of each initiative, were used to gather appropriate articles. Examples of search criteria keywords include "patient", "radiation", "safety", "initiatives", "guidelines", and "global", as well as a combination of these keywords. Articles were incorporated if they were published within the last ten years and if they contained information relevant to the radiation safety initiative.

In addition to peer-reviewed academic literature, high quality grey literature, such as websites and articles, were also used. Furthermore, the contributed conference papers from the 2017 IAEA "International Conference on Radiation Protection in Medicine: Achieving Change in Practice" were included. This conference reviewed the development and progression of the global patient radiation safety initiatives since 2012. As such, they provided valuable information for the SWOT analyses.

#### **AfroSafe**

The AfroSafe campaign was launched in 2015 at the 8<sup>th</sup> Biennial Pan African Congress of Radiology and Imaging in Nairobi, Kenya (AfroSafe, 2015). Radiation health workers advocated for the development of this campaign to increase awareness and address issues regarding radiation safety throughout Africa (AfroSafe, 2015). The AfroSafe campaign encourages stakeholders to promote radiation safety by adhering to the standards, policies, strategies, and activities outlined in the *BCfA* in order to maximize the benefits of MI modalities that utilize IR (AfroSafe, 2015).

#### Strengths

Because radiation health workers facilitated the development of the AfroSafe campaign, there is motivation and support from healthcare professionals to implement radiation safety protocols and standards. In turn, the AfroSafe campaign provides a framework to aid healthcare professionals and policymakers in making well-informed decisions (Mansouri & Khelassi-Toutaoui, 2017). Furthermore, the AfroSafe campaign outlines clear goals and direction through their Matrix Tool Booklet, which explicitly describes how they align with all ten of the *BCfA* recommendations (AfroSafe, 2015).

#### Weaknesses

Although radiation health workers support the AfroSafe campaign, it is acknowledged that there are still misconceptions, along with a lack of awareness, amongst healthcare professionals regarding the harm of IR from MI (Mansouri & Khelassi-Toutaoui, 2017). Additionally, many African countries lack the proper MI infrastructure and financial resources to support the implementation of the AfroSafe

campaign (AfroSafe, 2015). It is also unclear how information is disseminated to educate healthcare professionals as well as the general public.

## Opportunities

To address the lack of infrastructure in various African countries, the IAEA has supported the implementation of the AfroSafe campaign by aiding in the development of MI infrastructure and technical abilities (Mansouri & Khelassi-Toutaoui, 2017). The AfroSafe campaign has also leveraged the knowledge and expertise from more developed global patient radiation safety initiatives including EuroSafe Imaging and Image Gently (AfroSafe, 2015). In addition, many countries within Africa are currently investing in the development of their healthcare sectors, given the increase in both communicable diseases and NCDs, and therefore, the political climate is supportive of the AfroSafe campaign (Mansouri & Khelassi-Toutaoui, 2017).

#### Threats

The AfroSafe campaign faces several unique challenges given the economic and political insecurities of many member countries (AfroSafe, 2015; Mansouri & Khelassi-Toutaoui, 2017). Additionally, significant social and cultural barriers could significantly hinder their success (AfroSafe, 2015; Mansouri & Khelassi-Toutaoui, 2017).

#### ArabSafe

The ArabSafe group is the most recent ISRQSA patient radiation safety initiative.

They were first recognized in January 2017 during the Arab Health Conference in

Dubai, United Arab Emirates (UAE) and were further established in May 2017 during

the Pan Arab Radiology Conference (Almarzoogi et al., 2017). The ArabSafe group was

modeled after EuroSafe Imaging and aims to promote radiation safety culture throughout the Arab region, support self-regulation, and increase radiation safety awareness by engaging patients, healthcare professionals, and the general public (ArabSafe, 2016). In order to effectively meet these objectives, the ArabSafe group is divided into the UAE, Egypt, Algeria, and Saudi chapters and is expected to expand throughout the Arabian Gulf regions to create a Gulf Cooperation Council chapter (Almarzoogi et al., 2017).

## Strengths

The collective goals and priorities of the independent ArabSafe group chapters are clearly presented on their website. The implementation of national chapters within the ArabSafe group suggests that they have considerable support from the Arab medical radiation community. Additionally, the activities and campaigns implemented in each chapter are able to cater to the individual needs of each respective region.

#### Weaknesses

Because the ArabSafe group was only implemented 18 months ago, it is still in the early stages of development. Furthermore, the ArabSafe group objectives appear to only align with five of the ten *BCfA* recommendations. As such, they could further develop their objectives to more holistically encompass all ten *BCfA* guidelines.

### **Opportunities**

Because the ArabSafe group is in the early stages of development, they are able to greatly benefit from the knowledge and expertise of more established initiatives. In fact, representatives from EuroSafe Imaging and AfroSafe were present during the Arab

Health Conference where the ArabSafe group was first introduced (Almarzooqi et al., 2017). Also, the radiation medical community is well established throughout the Middle East, and as a result, there are many professional associations available to support the ArabSafe group objectives.

#### Threats

As the newest member of the ISRQSA, the specific ArabSafe objectives have yet to become established into everyday practice. Consequently, there may not be immediate changes regarding everyday patient care given the current lack of awareness regarding patient radiation safety.

## Canada Safe Imaging

Canada Safe Imaging is a multidisciplinary and collaborative initiative that was first established in December 2015 at the annual Radiological Society of North America meeting by the Canadian Association of Radiologists, Canadian Association of Medical Radiation Technologists, and Canadian Organization of Medical Physicists (Koff & Castelli, 2017). Canada Safe Imaging aims to improve radiation safety awareness amongst Canadian healthcare professionals while establishing evidence-informed national guidelines that align with the *BCfA* (Koff & Castelli, 2017).

## Strengths

Canada Safe Imaging is a multidisciplinary initiative with a wide range of representation from stakeholders including government agencies, professional associations, universities, research institutes, hospitals, and the private sector (Koff & Castelli, 2017). This has resulted in a holistic approach to radiation safety throughout

Canada. Canada Safe Imaging leverages the knowledge of expert stakeholders, such as Choosing Wisely Canada, for initiative activities. The Canada Safe Imaging website, available in both English and French, also has an easily accessible and extensive FAQ section with answers provided in collaboration with the Radiation Safety Institute of Canada and the Centre d'Expertise Clinique en Radioprotection (Koff & Castelli, 2017). Additionally, Canada Safe Imaging has conducted thorough environmental scans in order to understand current roles of stakeholders involved in medical radiation safety at the regional, provincial, and national levels.

#### Weaknesses

Although Canada Safe Imaging has been established since 2015, it has been slow to gain momentum. Pilot projects implementing radiation safety frameworks have just begun in select provinces (Koff & Castelli, 2017). This implies that there may be insufficient financial and human resources needed to implement initiative projects.

#### **Opportunities**

A wide range of regional, provincial, and national stakeholders and well established professional associations support the Canada Safe Imaging. Therefore, once a national strategy is created, there is enormous opportunity for effective large-scale implementation on the ground level. Once developed, the Canada Safe Imaging initiative will be able to refer to more successful global initiatives, such as EuroSafe Imaging, Image Gently, and Image Wisely, for further implementation strategies.

#### Threats

In Canada, healthcare regulation and delivery is the responsibility of each independent province; therefore, forming a national strategy regarding patient safety in MI will require significant political support. In addition, monitoring harmonious implementation of the national strategy may be difficult since provincial and territorial governments hold different views and priorities. Similarly to other initiatives and campaigns, MI infrastructure and available resources vary between provincial and territorial jurisdictions. As such, Canada Safe Imaging may face similar threats seen in low and middle-income countries when encouraging the implementation of the guidelines in remote Northern communities.

## **EuroSafe Imaging**

The European Society for Radiology introduced the EuroSafe Imaging alliance in 2014 at the European Congress of Radiology (Frija, 2017). EuroSafe Imaging is an established and successful multi-stakeholder initiative that uses a comprehensive and holistic approach to promote medical radiation protection, quality, and safety across Europe (EuroSafe, 2018; Frija, 2017).

## Strengths

EuroSafe Imaging is an alliance with significant support and representation from a wide array of medical radiation professional associations across Europe. The European Society for Radiology has developed 13 action items modeled after the *BCfA* that aim to improve MI quality and radiation safety (EuroSafe Imaging, 2018). Currently, pilot projects are being implemented throughout Europe to enforce these action items to

enhance the justification and optimization of IR in MI, while increasing capacity for professional education and international research collaboration (Frija, 2017).

In order to hold institutions accountable to implementing and maintaining the action items, a EuroSafe Imaging Star program has been created. To obtain star ratings, institutions must voluntarily submit a 26-item self-evaluation outlining various MI quality and radiation safety items (Frija, 2017). The organized internal structure and initiative governance of the EuroSafe Imaging alliance also significantly contributes to their success. In addition to EuroSafe Imaging, there are five successful subgroups, each with their own projects and priorities (Frija, 2017). These subgroups are:

- 1. Appropriate Image Quality;
- 2. Clinical DRLs;
- 3. European CT Dose Repository;
- 4. Ask EuroSafe Imaging; and
- 5. Pediatric Imaging (EuroSage Imaging, 2018; Frija, 2017).

The EuroSafe Imaging website is also a strength of the alliance as it is user-friendly and contains detailed information that is easily accessible. Overall, the EuroSafe Imaging alliance fosters collaboration amongst diverse stakeholders and bolsters significant financial and human resources.

#### Weaknesses

Although the EuroSafe Imaging alliance is significantly developed and is widely recognized globally as a leader in patient radiation safety initiatives, a significant gap has been observed with regards to patient and public engagement. Improving the

benefit-risk dialogue of radiological procedures with patients is a EuroSafe Imaging action item; however, the current programming mainly engages healthcare professionals and professional associations through academic dissemination.

## Opportunities

The EuroSafe Imaging alliance is highly regarded on a global scale and was one of the first initiatives to be introduced after the *BCfA* was released. Therefore, it has a unique opportunity to serve, as it is currently doing, as an adoptable model and extremely valuable resource to future initiatives. In addition, because the alliance is established amongst the medical radiation community, it can now begin to target other more diverse stakeholders to become integrated into academic curricula at all levels.

#### Threats

The EuroSafe Imaging clinical environment focus may hinder its application on a large scale. Additionally, the clinical application focus may alienate patients as well as the general public, and discourage future education and awareness campaigns.

## Image Gently

The Image Gently alliance was first initiated in the United States in 2007 by the Alliance for Radiation Safety in Pediatric Imaging, a coalition of like-minded healthcare professionals founded by the Society for Pediatric Radiology, the American Association of Physicists in Medicine, the American College of Radiology, as well as the American Society of Radiologic Technologists (Image Gently, 2014; Jafari & Daus, 2013). It was subsequently launched in 2008 and has since grown to include approximately 100 diverse organizations (Image Gently, 2014; Frush & Strauss, 2017). They promote safe

pediatric imaging while providing education on the use of IR in MI for patients, their families, and healthcare professionals (Image Gently, 2014; Jafari & Daus, 2013).

### Strengths

The Image Gently alliance was the first of its kind and is widely recognized as a global leader in radiation safety. They transitioned naturally to align with the *BCfA* in 2012 and became a role model in the ISRQSA. Similarly to EuroSafe Imaging, the Image Gently alliance is well structured and has effective governance. This structure has enabled the successful launch of eight independent campaigns. These campaigns are well known for educating patients and their families on the benefits of IM while raising awareness for IR optimization (Frush & Strauss, 2017).

Additionally, Image Gently receives annual financial and human resource support from a variety of contributors including the American Association of Physicists in Medicine, the American College of Radiology, the American Society of Radiologic Technologists, and the Society for Pediatric Radiology (Frush & Strauss, 2017; Image Gently, 2014). They have also received small external grants to support their initiative (Image Gently, 2014). Lastly, information regarding the Image Gently initiative is easily accessible and their website is user-friendly.

#### Weaknesses

The Image Gently alliance is led by a steering committee consisting of diverse stakeholders within the medical community (Image Gently, 2014). Decisions are made based on a consensus from the steering committee; however, because there is such vast representation, a consensus may be difficult to obtain and the resulting decisions

may not reflect the interests of all members. In addition, the Image Gently alliance does not explicitly state how their campaigns align with the *BCfA* recommendations as they were released after the alliance was well established.

## Opportunities

Because the Image Gently alliance is well established and has over a decade of experience implementing radiation safety education and awareness campaigns, they have the opportunity to develop training protocols and programs for future initiatives, especially as it pertains to children. They also have the ability for a large outreach project to correct misconceptions regarding IR in MI with the general public, given their credibility and influence as an alliance.

#### Threats

Many of the potential threats to the Image Gently alliance and their implemented campaigns appear to have been addressed; however, misconceptions among parents regarding the use of radiation in MI with their children are still present within the United States. Therefore, it is important that the Image Gently alliance continues their outreach and educational campaigns regarding optimization and justification.

#### Image Wisely

The Image Wisely campaign was initiated in the United States in 2009 by the American College of Radiology and Radiological Society of North America to address the alarming rise of patient IR exposure from MI, with a particular focus on adults (Image Wisely, 2018; Mayo-Smith & Morin, 2017; Mayo-Smith, 2018). It was subsequently launched in 2010 during the annual Radiological Society of North America

meeting (Jafari & Daus, 2013; Mayo-Smith & Morin, 2017; Mayo-Smith, 2018). Image Wisely aims to promote awareness and educate adult patients and healthcare professionals regarding IR exposure while advocating for the elimination of unnecessary MI procedures (Image Wisely, 2018; Jafari & Daus, 2013; Mayo-Smith & Morin, 2017; Mayo-Smith, 2018). Additionally, Image Wisely works directly with MI facilities to facilitate optimum dose usage (Mayo-Smith, 2018).

## Strengths

Image Wisely works closely with the Image Gently alliance to advocate for patients while promoting the implementation of the ALARA principle throughout the United States (Mayo-Smith, 2018). Image Wisely utilizes a variety of means to convey their messaging, including social media and an engaging website (Mayo-Smith & Morin, 2017). They also offer free continuing education credit through their website for healthcare professionals after completing investigations of case studies (Mayo-Smith & Morin, 2017). Image Wisely also issues a certificate to individuals and facilities that pledge to their initiative; however, this pledge must be renewed annually, thus encouraging individuals to return to their website (Mayo-Smith & Morin, 2017).

Image Wisely also has a strong internal structure and governance. Their executive committee consists of volunteer representatives from the American College of Radiology, the Radiological Society of North America, the American Association of Physicists in Medicine, and the American Society of Radiologic Technologists (Mayo-Smith & Morin, 2017). They also engage other stakeholders and experts from various professional associations and promote American College of Radiology activities.

#### Weaknesses

Although the Image Wisely website is informative, the majority of its information is targeted to medical professionals rather than to patients and the general public. It has also been stated that keeping this information up to date is difficult and time-consuming (Mayo-Smith, 2018). In addition, Image Wisely operates on a limited budget, which could hinder their program outreach moving forward.

## **Opportunities**

As an established and successful radiation safety awareness campaign, Image Wisely can engage a variety of stakeholders to improve outreach to patients and the public. Additionally, because this initiative is well established, widely recognized, and modeled on a global scale, it has been very influential for the development and implementation of newer global patient radiation safety campaigns.

#### Threats

The Image Wisely campaign faces many challenges similar to other developed initiatives including Image Gently and EuroSafe Imaging. Because their executive committee consists of volunteers, it may be difficult to recruit professionals to continue to manage and drive the initiative. Additionally, it may be difficult to keep medical professionals engaged in the website material and radiation safety as a whole. There is also a lack of accountability for institutions once they pledge to the Image Wisely initiative and receive a certificate of recognition.

## Japan Safe Imaging

In June 2016, the Japan Radiological Society established Japan Safe Imaging to facilitate safe and more efficient MI throughout Japan (Kumamaru et al., 2017). Japan Safe Imaging aims to enhance the distribution of medical radiation equipment while monitoring and managing radiation doses and promoting MI standardization, optimization, and justification (Kumamaru et al., 2017).

## Strengths

Because the Japan Radiological Society, a prominent medical association, developed the Japan Safe Imaging initiative, they have received significant financial and government support to drive their projects (Kumamaru et al., 2017). This has involved the collaboration of 176 radiologists throughout Japan to create an imaging guideline in conjunction with the Japanese College of Imaging (Kumamaru et al., 2017). This pilot imaging referral guideline, which consists of a scaling system to determine if patients qualify for MI referrals, has also been validated by external academic sources (Kumamaru et al., 2017).

#### Weaknesses

Although it is inferred that there is significant support both in terms of human resources as well as in funding availability, information regarding the Japan Safe Imaging is difficult to access as there is no website or central area to disseminate information. Information regarding the potential risks of low dose radiation is crucial in Japan as they have the largest proportion of CT scanners per population, and as a result, it is easy and affordable to access CT imaging modalities (Kumamaru et al., 2017). Additionally, this lack of information can be seen to contribute to the ongoing gap

of education and awareness present throughout Japan regarding the harm of IR in MI.

Also, it is difficult to determine how this initiative aligns with the *BCfA*.

## Opportunities

Because the Japan Safe Imaging initiative has government support, as well as a raised general awareness of the effects of IR given the Fukishima incident, there is a unique opportunity to engage diverse stakeholders to capitalize on the raised public awareness of IR through targeted educational campaigns (O'Connor, 2017).

Additionally, they are able to receive valuable information on best practices for initiative implementation given their close alignment with EuroSafe Imaging.

#### Threats

The Japan Safe Imaging initiative faces many unique challenges given the form of healthcare delivery and the abundance of CT scanners in Japan. Therefore, there is significant overutilization of CT imaging modalities that are unjustly requested by patients. Because the healthcare system is fee-for-service, patients are able to easily obtain and access a CT scan (Kumamaru et al., 2017). Furthermore, the Japan Safe Imaging initiative will face significant challenges in changing MI culture, both in the public and in the medical community, as overutilization is deeply engrained and now, unfortunately, common practice (Kumamaru et al., 2017).

### LatinSafe

The LatinSafe alliance was first envisioned in May 2015 at the 45<sup>th</sup> Paulist Radiology Conference in Sao Paulo, Brazil by radiologists representing the interests of Argentina, Brazil, Chile and the USA (LatinSafe, n.d.). The goal of the LatinSafe alliance

is to advocate for the radiological protection of patients in MI throughout Latin America by following the *BCfA* (Bernardo, Santos, Morgado, & Almeida, 2017).

## Strengths

The LatinSafe alliance is unique within Latin America and was the first initiative of its kind to provide information in both Spanish and Portuguese (LatinSafe, n.d.). The executive committee of this alliance includes representatives from all over Latin America who are affiliated with various medical radiation associations and have vested, and non-biased, interest in advancing patient radiation protection in MI (LatinSafe, n.d.).

The LatinSafe alliance has a strong focus on patient and healthcare professional awareness and education in both their adult and pediatric programming (Bernardo et al., 2017). Specifically, their pediatric initiative was modeled after Image Gently (LatinSafe, n.d.). It also appears that the LatinSafe alliance has significant ground-level support and human resources.

#### Weaknesses

The LatinSafe alliance has implemented various strategies with the goals of educating patients, students, and current healthcare professionals on patient radiation protection in MI (Bernardo et al., 2017). However, it is difficult to determine the success of these strategies, as the data are currently unavailable. It is also unclear where the strategies are being implemented and how they align with the *BCfA*.

#### **Opportunities**

As the LatinSafe alliance was being developed, it was modeled after more established and successful initiatives including EuroSafe Imaging, Image Gently, and

Image Wisely (LatinSafe, n.d.). Also, since the main focus of this alliance is education, there is an opportunity for the initiative to engage post-secondary institutions to become integrated into curricula at the undergraduate, graduate, and resident levels (Bernardo et al., 2017). The LatinSafe alliance also appears to be significantly motivated by research, and as a result, has recognized the need to disseminate evidence-informed information to private and public health authorities, as well as the academic community. Overall, it appears that there are many other stakeholders who can be engaged in order to further the advancement and implementation of the radiation protection guidelines.

#### **Threats**

The LatinSafe alliance appears to experience many of the same challenges as other global patient radiation safety initiatives. These include systematic challenges and discrepancies in the justification and optimization of MI procedures, along with the lack of radiation protection culture in medicine (Vano et al., 2018). In addition, due to the emphasis on education and awareness, it is inferred that a current threat is the lack of public and healthcare professional knowledge regarding radiation protection in MI. Similar to other global patient radiation safety initiatives, Bernardo and colleagues (2017) describe how there is a lack of funding available to implement necessary precautions and further programming.

## **CHAPTER 4: GLOBAL PATIENT RADIATION SAFETY MOVING FORWARD**

#### **Global Patient Radiation Safety Initiative Commonalities**

Overall, the global patient radiation safety initiatives within the ISRQSA are unique in their priorities, delivery, and development; however, they share key commonalities that have contributed to their independent success. Each initiative shares the key similarity in which they align with the IAEA and the WHO *BCfA*. The degree to which each independent initiative aligns with the *BCfA* appears to be dependent on the timeline of their establishment. For example, the Image Gently alliance and Image Wisely were formed and launched two to four years prior to the release of the *BCfA*. Consequently, their campaign goals and priorities were already well established and were slightly modified to align with the stated *BCfA* recommendations. The other initiatives, however, were developed in response to the *BCfA* with the Image Gently alliance and Image Wisely as key examples of similar innovative initiatives. As a result, the initiatives established after 2014 are more centered on the *BCfA* as opposed to radiation protection in general.

Many of the initiatives also share similar implementation strategies, outlined by their priorities, campaign objectives, and internal structure including governance. Many initiatives, particularly LatinSafe, EuroSafe Imaging, Image Gently, and Image Wisely, have explicit volunteer committees dedicated to the progression of each independent initiative. Also, the initiatives share the fact that they were launched by medical radiation professionals and associated associations, although they differ in the degree of support received by these groups, as well as the overall ownership and autonomy over the direction of the initiative.

In addition, the initiatives are also heavily involved and supportive of the dissemination of credible information through online sources, including their websites and social media, as well as outreach education and awareness campaigns. Although this information is mostly targeted for healthcare professionals with a background in radiation sciences, information is also made available for patients and their families. The IAEA has recently reported success in communicating pertinent information regarding IR within medicine to health professionals, patients, and the public through the use of their website (Rehani & Holmberg, 2015). This demonstrates that websites with the purpose of educating a variety of populations are an effective means of disseminating information regarding patient radiation safety.

Many of the initiatives also share similar weaknesses, including a lack of available financial and human resources dedicated to enhancing awareness and educational efforts regarding IR in MI. Other common weaknesses include a lack of initiative direction and outlined goals and objectives. Additionally, information describing some initiatives was difficult to access. Another weakness that was observed across many initiatives was the lack of patient engagement, both in terms of ground-level educational outreach programs, as well as patient representation and the involvement of patient associations.

There are similar opportunities for each initiative to become more engaged in their communities and with influential and diverse stakeholders to further their reach to the general public. Because these initiatives are encompassed under the same ISRQSA umbrella, there is an opportunity for more established initiatives to offer support and

expertise regarding the implementation of campaigns, and to share their credible resources.

The threats to each initiative are highly dependent on how well each initiative has addressed their identified weaknesses, although some threats are also dependent on geographical location. Some initiatives were facing engrained MI culture as a significant threat. This will require a long-term shift in local attitudes in order to be appropriately addressed. Additionally, some areas with implemented initiatives are facing rapidly rising populations, as well as political, financial, and healthcare instabilities.

## **Future Implementation Recommendations**

By conducting independent SWOT analyses, key factors that contributed to the success of each global patient radiation safety initiative were identified.

Recommendations that align with these factors have been developed to guide future

global patient radiation safety initiative implementation. These recommendations

include:

- Establishing a clear internal structure with strong governance that includes wide representation from key influential stakeholders;
- Gaining financial resources and in-kind support from government and well established professional associations to sustain large-scale campaigns and subsequent projects from government;
- 3. Developing goals and objectives that clearly align with the *BCfA* and address regional and national MI needs:

- 4. Utilizing a variety of media, including an effective, engaging, and user-friendly website along with social media campaigns, to raise awareness and promote education to government and healthcare professionals, as well as patients, their families, and the general public; and
- 5. Obtaining first-hand experiential insight from leaders of current global patient radiation safety initiatives to share resources and leverage expertise to ensure continuation of successful transnational initiatives.

## **Conclusions**

MI is becoming more prominent in primary healthcare, and therefore, patient radiation protection has emerged as a global priority. These global initiatives are also garnering public support and interest due to prime political environments and recent global events elevating the risks of radiation. This paper, specifically, emphasized the importance of patient radiation safety and introduced each of the initiatives within the ISRQSA prior to conducting a SWOT analysis.

Although the purpose of the 2017 IAEA "International Conference on Radiation Protection in Medicine: Achieving Change in Practice" was to update the global community on the progression of these initiatives, there is a current gap in the literature outlining these large-scale initiatives in addition to their overall impact on promoting radiation safety. This is also understandably difficult given the independent development of each initiative, each with their own goals and priorities targeting the needs of local communities and national priorities.

This paper analyzed each initiative independently in order to gain further understanding of their respective progression and success. In conclusion, five recommendations were presented with the hope that they will be considered during the implementation of future patient radiation safety initiatives. The benefits of using IR in MI are widely known; however, it is important that these initiatives continue to engage the global community to advocate and promote the safety of patients worldwide.

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