AMERICAN ASSOCIATION of PHYSICISTS IN MEDICINE

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Joyce Marshall
The Joint Commission
Standards and Survey Methods
NPSG on Pediatric Computed Tomography
One Renaissance Blvd.
Oakbrook Terrace, IL 60181

Re: AAPM Comments on Proposed New National Patient Safety Goal on Pediatric Computed Tomography (CT) Imaging

Dear Ms. Marshall:

The American Association of Physicists in Medicine[1] (AAPM) appreciates the opportunity to provide comments to the Joint Commission regarding the Proposed New National Patient Safety Goal on Pediatric Computed Tomography (CT) Imaging.

Introduction

There is a perception among some physicians and patients that the low doses of ionizing radiation associated with medically appropriate imaging exams, particularly with CT, are dangerous. However, this inaccurate perception is not consistent with current consensus opinions from radiation protection and medical physics organizations [1-5]. Hence, medical professionals are left with a dilemma: if they emphasize dose management, they inadvertently reinforce the perception that the radiation doses used in medical imaging are dangerous. That is, if the doses are not dangerous, why is there so much effort to reduce the radiation dose from medical imaging? Here we address this issue.

Public perceptions of radiation

Conveying accurate information to medical personnel and patients, and even medical imaging physicists, about the small or non-existent risks associated with low doses of radiation can be difficult, in part due to

[1] The American Association of Physicists in Medicine (AAPM) is the premier organization in medical physics, a broadly based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. AAPM represents over 8,000 medical physicists.

their unfamiliarity with radiation dose measurement units and also in part due to the general belief in society that radiation is to be feared. This belief that all radiation is dangerous is negatively impacting patient care. For example, patients ask medical providers on a routine basis about the safety of CT scanning, and increasingly, physicians and radiology departments are encountering patients unwilling to receive a medically appropriate CT exam. What is needed is clear and accurate scientific information regarding the relative risks, and benefits, of the low doses of radiation used in medical imaging. An in depth review of these topics can be found in [6].

Risks from low doses of ionizing radiation

Most people are unfamiliar with the radiation dose that each of us is exposed to simply by living on Earth. In the United States (U.S.), the effective dose from natural sources in our environment (e.g., radon gas, cosmic rays, building materials) ranges from 1 to 20 mSv, with an average of ~3 mSv/year. Yet, there is no direct evidence of harm from these radiation dose levels. In fact, residents of states with higher background radiation have lower cancer rates relative to those from states with lower background radiation levels [7] and residents of regions in the world with very high background radiation levels (100-260 mSv per year) have been shown to have no increase in cancer risk compared to people living in areas with lower background dose levels [8].

Cohorts of individuals exposed to radiation have been extensively studied to estimate the effects of low doses of radiation, including workers in the nuclear power industry and the atomic bomb survivors. The largest such study evaluated a cohort of approximately 500,000 occupationally-exposed workers, across 15 countries, who received cumulative effective dose levels in the range of 30-60 mSv. No increase in cancer mortality compared to the general population was found after the Canadian data, which were found to be inaccurate, were removed from the study [9, 10]. In atomic bomb survivors, analyses of cancer incidence and mortality have also not demonstrated an increased risk from acute radiation doses below 100 mSv [11, 12].

Because of the lack of demonstration of long-term effects in the low dose range (<100 mSv), U.S. and international radiation protection organizations have repeatedly cautioned that risk estimates below 100 mSv have huge uncertainties. Similarly, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), in their 2012 report to the United Nations General Assembly, specifically noted that an increase in the incidence of adverse health effects in populations cannot be attributed to exposure to radiation doses at levels that are typical of global background levels of radiation, i.e. 1-20 mSv/year [2]. [Note: the effective dose from a head CT is 1-2 mSv and from a chest CT from 4 – 7 mSv. With all newer scanners, which feature dose reduction technologies, the doses are even lower.] In response to concerns raised by some authors that the large numbers of CT scans performed each year will result in a measurable increase in cancer incidence, UNSCEAR, the International Commission on Radiological Protection (ICRP) [3], the National Council on Radiation Protection and Measurements, the Health Physics Society (HPS) [4], and the AAPM [5], all explicitly stated that it is inappropriate to multiply highly uncertain risk estimates for radiation doses comparable to natural background levels by the millions of individuals undergoing CT and other imaging studies in order to predict radiation-induced health effects. Unfortunately, this inappropriate arithmetic is precisely what was done in several publications in prestigious medical journals [13, 14], and

alarmist reporting on these papers by major media outlets has caused great concern for medical professionals, patients, and their families.

Roles of the medical physicist in managing dose and communicating about risk

A medical physicist is a certified medical professional with education and clinical training in the safe and effective application of radiation in the fields of medical imaging and radiation therapy. They are certified by the American Board of Radiology. Medical physicists routinely monitor a practice's doses and compare them against national benchmarks, such as those provided by the American College of Radiology's (ACR) Dose Index Registry [15]. Medical physicists are available for consultation with patients or family members, and they often play an active role in the technical and radiation safety education of physicians and radiologic technologists. In addition, many medical physicists are active volunteers in their primary professional organization, the AAPM. With 8,400 members, the AAPM works to promote patient safety in medical imaging and radiation oncology through numerous education, research, and professional initiatives.

AAPM's Position Statement on Radiation Risks from Medical Imaging Procedures

As described above, medical physicists assist the medical imaging community in providing safe and effective imaging exams. Their effort to manage dose carefully is consistent with the AAPM's Professional Policy 25, *Position Statement on Radiation Risks from Medical Imaging Procedures,* which is reprinted here:

> *The American Association of Physicists in Medicine (AAPM) acknowledges that medical imaging procedures should be appropriate and conducted at the lowest radiation dose consistent with acquisition of the desired information. Discussion of risks related to radiation dose from medical imaging procedures should be accompanied by acknowledgement of the benefits of the procedures. Risks of medical imaging at effective doses below 50 mSv for single procedures or 100 mSv for multiple procedures over short time periods are too low to be detectable and may be non-existent. Predictions of hypothetical cancer incidence and deaths in patient populations exposed to such low doses are highly speculative and should be discouraged. These predictions are harmful because they lead to sensationalistic articles in the public media that cause some patients and parents to refuse medical imaging procedures, placing them at substantial risk by not receiving the clinical benefits of the prescribed procedures. AAPM members continually strive to improve medical imaging by lowering radiation levels and maximizing benefits of imaging procedures involving ionizing radiation.* [5]

The essential elements of the position statement represent a prudent and pragmatic approach to the dilemma discussed above (i.e., why would one work to reduce radiation dose when low doses of radiation (e.g., < 100 mSv) have not been shown to increase long term risks, and the doses of radiation from medical imaging are far below 100 mSv). These essential elements:

1. Support the radiation safety tenet of **justification**, i.e., "*medical imaging procedures should be appropriate"*.

2. Commit to patient safety in medical imaging, acknowledging the need to keep doses as low as is reasonable while also maintaining the diagnostic benefit of the exam or procedure. This supports the radiation safety tenet of **optimization**.
3. Acknowledge that the risks of medical imaging are very small, and may in fact be non-existent. This is in keeping with the consensus statements of the International Organization for Medical Physics, UNSCEAR, ICRP, HPS and AAPM [1-5].
4. Emphasize that the discussion of risk needs to be accompanied by discussion of medical benefit.
5. Express concern about the reporting of predicted cancers as though they were fact, and in particular, express concern that some patients are not receiving appropriate medical care due to fears of radiation exaggerated by such speculative reports.

Discussion

There have been far too many polarizing articles on the topic of radiation dose in CT. These serve only to perpetuate the discussion, leaving patients and their families with the impression that this is a deeply concerning issue. Rather, it is recommended that the correct approach is one that includes the five elements noted above. These neither brush aside the potential for risk, imaging indiscriminately or without the necessary expertise in dose management, nor propagate the alarmist message that CT is dangerous. As stated by the Biological Effects of Ionizing Radiation (BEIR) VII report, "At doses of 100 mSv or less, statistical limitations make it difficult to evaluate cancer risk in humans" and "… at relatively low doses, there is still uncertainty as to whether there is an association between radiation and disease, and if there is an association, there is uncertainty about whether it is causal or not" [16]. Above the 100-200 mSv range, it is known that the risk of long term effects is real, albeit small. Below these doses, it is known that the risk is difficult, if not impossible, to demonstrate. It may be real or it may not exist at all. Either way, it is certainly small compared to the very well demonstrated benefits derived from justified medical imaging. Walking this middle road – neither being alarmist nor careless – is what the AAPM and so many other imaging organizations recommend (e.g., ACR, the Radiological Society of North America, Image Gently®, Image Wisely®).

The Joint Commission's Proposed New National Patient Safety Goal on Pediatric Computed Tomography (CT) Imaging

With regard to the Proposed New National Patient Safety Goal on Pediatric Computed Tomography (CT) Imaging (NPSG.17.01.01), the AAPM wishes to express the following concerns:

1. *The risk of long term effects at the low doses of radiation associated with CT imaging has not been proven to exist,* even though radiation is the single most studied carcinogen on the planet. Unfortunately, several inadequate but much publicized papers in prestigious journals claimed to have demonstrated a statistically significant, albeit small, increase in risk from childhood CT. However, these studies suffered from a number of methodological flaws and have been heavily criticized by radiation protection organizations, including the International Commission on Radiation Protection. The results of these studies were discordant with most of the existing literature on the topic, and of great importance, failed to take into account the reason for the medical CT. Two later studies, which did account for the

indication for the CT exam as well as pre-existing risk factors for cancer found no increase is risk associated with childhood CT. Unfortunately, these latter studies have not been widely publicized. Reference [6] discusses these studies and issues in detail.

2. *This initiative serves to promulgate an unmerited sense of risk from CT scans*. Physicians and patients look to The Joint Commission to implement and enforce the high standards of quality and safety. Holding such an esteemed position, it is incumbent upon The Joint Commission to act on the highest level of scientific evidence. By developing and implementing a national patient safety goal that seeks to "protect" patients from a risk that has not been proven to exist, The Joint Commission reinforces many erroneous perceptions about radiation, and particularly about the radiation associated with CT imaging.

3. *Creating a practice safety goal related to the performance of certain medical exams, which have not proven to be dangerous, is not a useful investment of valuable health care resources.* The use of evidence-based guidelines to determine appropriate imaging strategies (Elements of Performance, EP, 1) is already the standard of good medical practice. Attempting to enforce this standard of care through EP 2 (implementation of criteria for the use of dual-phase head and chest exams), EP3 (monitoring compliance with EP2), and EP 4 (establishing goals for compliance with EP1 and EP2 and taking steps to improve when performance does not meet these goals) will require substantial time and effort by the involved stakeholders. These healthcare resources should be allocated toward addressing adverse effects that have been scientifically proven to exist. Further, the selection of these two specific pediatric imaging exams seems arbitrary and not evidence-based. The rate of dual-phase scans is already exceedingly low; data from the American College of Radiology's Dose Index Registry indicate that only about 0.5% of over 110,000 pediatric head CT exams involved the use of two scans. Thus it is not clear why these exams were selected for a NPSG, nor does the focus on these exams seem justifiable when considering the resources needed to comply.

4. *In an attempt to meet the criteria established in EP3, practices and physicians will face pressures to not order dual-phase examinations, even when they are medically the most appropriate exam.* Implicitly, when guidelines are established, adherence criteria established and monitored, and performance improvement required when guidelines are not met, the focus and reward is on compliance with the prescribed criteria. That is, there is a pressure to not perform an action that will be counted against the site, even though the performance of such tests may be considered medically necessary. We acknowledge that sites will be able to set what they believe are appropriate criteria that allow appropriate use of dual-phase exams when medically necessary. However, the mere monitoring of dual-phase exams will exert some level of pressure not to perform them. We do not agree with the imposition of metrics that might provide a disincentive to performing a medically appropriate action.

In summary, we believe that the imposition of any quality goals that provide a disincentive to ordering the proper medical exam in order to protect from a hypothetical risk that has not been proven to exist is not a responsible action. The demonstrated benefit of CT imaging [17] dictates that physicians continue to refine their diagnoses and increase their clinical confidence, without concerns for compliance with the proposed arbitrary "safety" goal. Further, compliance with such goals will unnecessarily consume valuable healthcare resources. Finally, the mere existence of this patient safety metric will reinforce the erroneous perception

that the low doses of radiation used in medical imaging are dangerous. Putting forth effort to alter medical practice, when no risk has been proven to exist, does not enhance safety. Rather, it wastes time and money, and further frightens patients and their families. We strongly encourage The Joint Commission to abandon NPSG.17.01.01, and instead to adopt an evidence-based position that is consistent with the positions of radiation protection experts, such as is described herein.

If you have questions please contact Lynne Fairobent, Senior Manager for Government Relations at lynne@aapm.org or 571-298-5641 or myself.

Sincerely,

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