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March 29, 2010

Thomas S. Tenforde, PhD.
President
National Council on Radiation Protection & Measurements
7910 Woodmen Avenue, Suite 400
Bethesda, MD 20814-3095

Re: NCRP SC 2-3 Draft Report, Radiation Dose Management for Fluoroscopically-Guided Interventional Procedures

Dear Dr. Tenforde:

The American College of Cardiology (ACC) is pleased to submit comments on the draft report of the National Council on Radiation Protection & Measurements (NCRP) on radiation dose management for fluoroscopically-guided interventional procedures. The ACC is a professional medical society and teaching institution made up of 37,000 cardiovascular professionals from around the world – including 90 percent of practicing cardiologists in the United States and a growing number of registered nurses, clinical nurse specialists, nurse practitioners, physician assistants and clinical pharmacists. We appreciate the opportunity to provide input on the managing radiation dosage for fluoroscopically-guided interventional procedures.

Radiation generated by fluoroscopic procedures has increasing relevance for the cardiovascular community as diagnostic catheterization, stenting, device placement, and catheter ablation are used more frequently for the treatment of atrial fibrillation. The draft report is a comprehensive, updated review of the management of radiation delivery during interventional procedures that are routinely guided by fluoroscopy. The ACC commends the NCRP for its well-written report. The pragmatic approach that the report takes to radiation safety, balancing the intended benefits of the procedure against the radiation risk, is commendable. The College appreciates the effort made by the NCRP to include recommendations that highlight ways to measure radiation dosage, while also addressing the challenges in accurately doing so at the patient level.

The mission of the American College of Cardiology is to advocate for quality cardiovascular care — through education, research promotion, development and application of standards and guidelines — and to influence health care policy.

Specific comments

Report

The ACC strongly agrees with the as low as reasonably achievable (ALARA) principle cited throughout the document starting on p. 13, line 8.

The ACC and the ACC Foundation (ACCF) is a leader in promoting high quality, appropriate cardiovascular care and has developed a series of guidelines and appropriate use criteria to assist cardiovascular professionals in doing so. As such, the ACCF should be mentioned alongside other physician organizations when appropriateness criteria are referenced. For instance, on page 33, lines 4 through 6, the text currently states, “Professional societies such as the American College of Radiology have used the concept of appropriateness to rank the suitability of FGI and other radiology procedures for the diagnosis and treatment of a variety of disease states (ACR, 2009).” The ACC urges the NCRP to amend this language to state, “Professional societies such as the American College of Radiology and the American College of Cardiology have used the concept of appropriateness to rank the suitability of FGI and other imaging procedures for the diagnosis and treatment of a variety of disease states.”

The ACC supports the use of clinical trials to measure radiation dosage. Currently, page 33, line 15 states “Most studies of FGI procedures that evaluate risk and benefit do not consider radiation risk at all.” The ACC proposes that NCRP consider adding a recommendation on the inclusion of radiation dose in clinical trial design for future FGI studies to highlight the point made in this statement.

While concerns around radiation frequently focus on patients, it is important to consider the radiation risk for healthcare employees and machine operators. On page 37 of the report, there is a case study highlighting cardiac ablation risk in adolescents. The ACC urges the NCRP to consider adding a case study on machine or operator issues related to exposure based on recent press stories to highlight not only high risk procedures described in the case study included in the report.

The ACC agrees with the paragraph beginning on page 51, line 21. Reported fluoroscopy times associated with AF ablation are highly variable in the literature. However, a 2004 study of 15 patients who underwent AF ablation (Lickfett, et al. *Circulation*. 2004;110:3003-3010) reported that the mean fluoroscopy durations for AF procedures were 67.8 ± 21 minutes in the right anterior oblique (RAO) and 61.9 ± 16.6 minutes in the left anterior oblique (LAO) projection.” Based on that particular study, nearly every patient who undergoes an AF ablation would need to be notified that he or she was exposed to substantial radiation and would need a formal follow-up plan. The current recommendation could lead to unnecessary anxiety for many patients undergoing certain procedures, such as AF ablation, and could result in significant liability for physicians who perform AF ablation.

On page 66, lines 6-10, Recommendation 6 addresses the use of effective dose (E) for quantitative estimates of stochastic risk for individual patients or patient groups. The ACC recommends that the NCRP consider clarifying further the use of E for worker dose estimates, but not patient dose estimate. While the rationale for this distinction is implicitly understood

based on the difference in exposure, additional text explicitly explaining the rationale would be helpful.

Additionally, the ACC has concerns regarding the inclusion of fluoroscopy time within the recommendations. Specifically, based on the language discussed above and the example provided which highlights the limits of using fluoroscopy time, the ACC urges the NCRP to remove the "...or ** Minutes of Fluoroscopy" in definitions and recommendation throughout the document, including page 80, Recommendation 6 and Table 3.1. Additionally, since fluoroscopy time has little to do with the radiation dose, the ACC proposes removing this from Table 4.7. Most of the radiation minimizing measures done (i.e., frame rate, shutters, etc.) do not minimize fluoroscopy time in a lab can give $<100\text{GyCm}^2$ of radiation if there is a low frame rate and $>300\text{GyCm}^2$ if it is an obese patient with Cine runs.

On page 86, lines 9 -24, the ACC suggests mentioning the use of magnetically steered catheters (Stereotaxis makes one such device) for EP and other interventional procedures, intended to reduce fluoroscopy time by more efficient placement of catheters. In addition, there are methods to minimize radiation exposure with the use of "fluoroscopy-save mode" rather than cine when high resolution is not needed. For instance, with new equipment, it is no longer necessary to utilize cine to document balloon inflations, stent deployments, or for the limited femoral arteriography at the conclusion of most procedures.

The ACC also has concerns regarding the discussion on page 95, lines 13-23. There is a recommendation for using a toggle to deactivate fluoroscopy at times to avoid inadvertent delivery of fluoroscopy, and there is a recommendation against the use of door interlocks that can cause sudden termination of fluoroscopy during a critical portion of an intervention when someone opens the door. However, there is no discussion of the advantages and disadvantages of automatic time-outs that deactivate the fluoroscopy unit after every five minutes and are in common usage. This time-out feature can be disruptive. The ACC urges the NCRP to include a discussion of automatic time-outs programmed into the equipment to highlight the risks and benefits of this feature.

Also included in the report are a number of sections on follow-up care. On pages 18 and 144, as well as Recommendation 20, Section 4.3.4.4 states that follow up responsibility should remain the responsibility of the interventionalist for one year. The ACC believes that this requirement may be excessive for some interventionalists. Thus, the ACC urges the NCRP to recommend that follow-up for a year should be ensured by a physician. This can be accomplished via notification to the patient's primary care/referring physician. In fact, this should be done regardless, given that an internist may be more likely to receive the non-cardiac complaints (i.e., rashes and burns) from the patient.

Additionally, page 142, line 1, Section 4.3.4.3 , as well as page 144, line 8, Recommendation 20, correctly emphasizes that the physician is the member of the care team who is primarily responsible for minimizing the radiation dose to the patient. Related to Recommendation 20, paragraph 6.1.4, beginning on page 188, line 18, discusses having indirect support staff witness clinical procedures from time to time. Given their importance to the procedure, the ACC proposes that this paragraph be augmented to encourage the indirect support staff to do more

than merely witness the procedures from time to time. The ACC believes that the role of the indirect support staff should be emphasized more than it currently is in the NCRP report. The support staff should have a greater role than merely inspecting equipment periodically and being available as a resource when issues arise. They should be encouraged to be an integral part of the team by regularly being present during procedures and actively providing constructive practical advice to the team to minimize radiation to the patient, physician, and staff.

Currently, page 144, line 11 states, “All relevant signs and symptoms shall be regarded as radiogenic unless an alternative diagnosis is established.” The ACC urges the NCRP to clarify what is meant by the term “relevant” in Recommendation 20. The assumption is that this refers to deterministic effects related to the skin, but a more specific list of examples would be helpful.

Page 137, lines 15 to 23, and page 145, lines 2 to 18, address assessment of patient radiation dosage. The ACC urges the NCRP to consider adding a recommendation and/or text related to the role of registries in tracking radiation dose by procedure and setting normative ranges in the quality assurance section. Clinical data registries can play a critical role in collecting real world patient-level radiation exposure data. The ACC National Cardiovascular Data Registry (NCDR) Cath PCI Registry now requires participants to report either fluoroscopy time to the nearest 0.1 minute and/or fluoroscopy dose to the nearest integer in milligrays for patients undergoing diagnostic cardiac catheterization or percutaneous coronary intervention (PCI). Similar data elements are planned for the Safety of Atrial Fibrillation Ablation Registry Initiative (SAFARI) which will gather data on patients undergoing atrial fibrillation ablation.

Page 175, lines 6 -15, the ACC recommends that the NCRP consider discussing further tracking radiation exposure in a manner that combines all laboratories in which a person may work or ever has worked. For example, investigation of the feasibility of establishing a national databank for occupational radiation exposure in the US might be mentioned here. The databank might be similar to the National Practitioner Data Bank that covers physicians as they move from state to state.

Currently, beginning on page 225, line 11, the report states, “Approximately 15 to 30 % of the adult population studied with coronary angiography had normal coronary arteries. This reflected limitations due to the specificity of the clinical and noninvasive tests criteria used for patient selection. However, as the sensitivity and specificity of noninvasive studies has improved, this percentage of normal studies has progressively declined (Section B.1.2).” There is more recently published data that shows normal rates at catheterization may be higher than 15-30 %. Patel, et al demonstrated that 67% of all patients referred for diagnostic cardiac catheterization for evaluation of presumed coronary artery disease (CAD) without documented history of myocardial infarction, previous percutaneous coronary intervention or coronary artery bypass graft surgery were found to have non-obstructive or insignificant CAD. This 67% “unobstructive CAD represents a population that is 20% of the total **number** of patients referred for cath) (NEJM, March 11, 2010; 362: 886-895) and limited data to suggest any improvement in NI testing. The ACC recommends that this data replace the data presently cited in the report.

Appendices

The ACC recommends that the text in Appendix A – Cost Benefit Analysis, beginning on page 210, be replaced with a reference list and new text stating that the literature is often challenging, but is constantly being improved.

Additionally, the ACC recommends that the text in Appendix B- Risk Benefit Analysis be replaced with a reference list of the most relevant guidelines and appropriate use criteria where they are available. Given the nature of the clinical literature, the relevance of this section of the document is likely to become outdated fairly quickly.

However, if Appendix B is kept in the document, the ACC recommends that the NCRP consider the following:

- On page 232, lines 12-20, there is a lengthy discussion of alternative procedures that would not require fluoroscopy and the risks and benefits of those alternatives. Specifically, the document states that there are no surgical alternatives available to cardiac resynchronization therapy. However, surgical epicardial placement of left ventricular lead is an alternative that would greatly diminish fluoroscopy time and radiation exposure. This, of course, should be considered against the potential complications of a thoracotomy.
- The electrophysiology community has taken great steps toward limiting radiation exposure in performing complex ablations with the assistance of 3D mapping. While this is outside the scope of the document, the ACC would recommend discussing it in the context of alternative methods of reducing radiation exposure (page 233, line 15).
- The report mentions that surgical ventricular tachycardia (VT) ablations are performed when other cardiac surgery is considered. However, it is actually rare for surgical VT ablations to be performed at all, even when other cardiac surgeries are required.

The ACC appreciates the opportunity to provide these comments to the NCRP. If you have any questions or concerns regarding these comments, please contact Lisa P. Goldstein at (202) 375-6527 or via e-mail at lgoldstein@acc.org.

Sincerely,



Ralph G. Brindis, M.D., M.P.H., F.A.C.C.
President

cc: Jack Lewin, MD – CEO, ACC