Selecting the Right Test and Considering Relative Radiation Dose: The Value of the ACR Appropriateness Criteria®

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It is essentially universally accepted that imaging studies are not always used appropriately. Although overuse generates the greatest concern, both inappropriate overuse and underuse occur. Underuse may compromise patient care directly. Overuse adds unjustified cost to the healthcare system, at a time when it is obvious that the system is not functioning as efficiently or effectively as it should. It may lead to detection of incidental findings which then must be evaluated, often adding additional cost and anxiety, and often without real benefit. Further, if the inappropriate imaging involves ionizing radiation, this poses unjustified theoretical and likely actual long-term risk to patients and the population.

The use of imaging studies overall is clearly of great value in improving healthcare. When used appropriately, the risk-benefit ratio of imaging unquestionably favors using these capabilities. If imaging studies are used inappropriately, however, the possible risks of radiation (and the risks associated with elucidating unexpected findings) alter this balance. There is widespread concern about the effect on individual patients of repeated exposures, as well as concerns about the costs that may be unnecessarily added to our healthcare system. For these reasons, there is increasing interest in providing accurate guidance for the use of imaging procedures. This optimally means use of valid, methodologically sound clinical imaging guidelines.

Much of the focus on using clinical imaging guidelines to improve the appropriate use of imaging arose from a general interest in improving healthcare and, more recently, from requirements for prior certification as a means to control use and thereby costs. Prior certification, however, does not specifically require valid guidelines and does not necessarily lead to more appropriate use of imaging. It also adds a layer of administration, with attendant costs and difficulties for those ordering exams. Interest in clinical imaging guidelines has increased significantly with the CMS mandate to consult specified appropriate use criteria through an approved clinical decision support mechanism when ordering advanced diagnostic imaging services for Medicare patients.

There is, then, a major nationwide interest in and commitment to the use of clinical imaging guidelines. It is now feasible to incorporate them into electronic health records, to provide an effective clinical decision support tool for imaging. The major concerns are that not all available guidelines are actually evidence based; that they may not cover all situations; and that consequently, they are not necessarily clinically relevant to all for whom imaging is or should be considered. To be both valid and effective, clinical imaging guidelines must fulfill certain fairly well-defined criteria: they must be created using a widely-accepted and well-

defined methodology; they must be based on peer-reviewed, high quality published studies; all relevant stakeholders must be involved in a well-defined way in creating the guidelines; there must be disclosure of all potential conflicts of interest; and the guidelines must be regularly updated.

The American College of Radiology Appropriateness Criteria® (ACR AC) provide such a tool. They fulfill all the requirements for valid and effective clinical imaging guidelines, and are specified 'appropriate use criteria' (AUC) as defined by CMS. These clinical guidelines for the use of imaging are available on the ACR website and are easily searchable. Other such guidelines exist, both in this country and elsewhere, but the ACR AC have several important characteristics that support their broad use. Currently, ACR AC cover most common clinical settings and include nearly 140 major clinical concerns with 688 variants that are currently available. The ACR AC have been supplemented by empirically-developed clinical indications, to offer over 2500 distinct clinical variants and to form ACR Select™, a widely available electronic clinical decision support tool.

The ACR AC are developed as follows: there are 22 expert panels, with one or two for each specific anatomical area of interest (e.g., neuroradiology, cardiac, breast, musculoskeletal). Each panel has a chair, most have a vice-chair and each has 10-20 members. Each member is assigned one-to-three topics each year to prepare or to revise. One or more representatives from 26 non-radiology clinical specialty societies also participate on each topic.

The process starts with a systematic literature search, which identifies all available peer-reviewed articles relevant to that topic. The primary author reviews these articles and rates and selects those that are most relevant and valid, based on well-defined, reproducible and transparent criteria. The selected articles are summarized in an evidence table for the topic and are used to create a narrative. The articles are used to rate the strength of evidence for the recommendations that are promulgated.

The panel chair and vice-chair review the narrative and evidence table and make suggestions before circulating the draft to the other panelists. The ACR AC variant table consisting of all relevant imaging tests is then constructed, and each panelist rates each test on a standardized scale of 1 to 9, based on the relevant included publications, and considering the overall value, including risks and benefits, of each imaging study for the specific clinical condition. Ratings of 1-3 indicate a test is not usually appropriate; ratings of 4-6 mean a test may or may not be appropriate; and ratings of 7-9 mean a test is usually appropriate. The Rand UCLA appropriateness Delphi method is used, with up to three voting rounds, each followed as needed by a conference call, to reach consensus on ratings. After each topic is finalized, it is reviewed by the Panel chair and vice-chair and by staff. It is then published to the ACR AC website and submitted to the National Guidelines Clearinghouse (NGC), a database of evidence-based clinical practice guidelines and related documents maintained as a public resource by the Agency for Healthcare Research and Quality (AHRQ) of the U.S. Department of Health and Human Services. Each topic is then formally reviewed and revised yearly, as needed.

Radiation exposure is addressed using a similarly well-defined, uniform, and transparent methodology to create a relative radiation level (RRL) for each exam listed in the ACR AC. A radiation subcommittee has established guidelines for defining the radiation dose, as a relative risk based on population exposure For each specific exam (e.g., CT abdomen, CTA

lower extremities, chest x-ray, MRI head, pelvic ultrasound) a RRL of from 0 to 5 radiation symbols (☢)is applied. No radiation symbols (or O) corresponds to no radiation (e.g., an ultrasound or MR exam) and 5 (☢☢☢☢☢) corresponds to an effective adult dose estimate of 30-100 mSv. These dose estimates are based on the available published literature, supplemented as needed by the expert opinion of the medical physicists and the clinical expertise of the radiologists on the subcommittee. Relative radiation level ratings are reviewed annually or whenever a new procedure is added.

Further information on the ACR AC methodology can be found at www.acr.org/ac.

The votes of the panelists are based as much as possible on published, peer-reviewed studies supplemented as needed by expert opinion (since evidence is essentially never completely conclusive) and must balance clinical utility as defined in high quality studies, likely availability of equipment and expertise, and possible radiation and other risk. Thus it would be expected that in children an exam that uses ionizing radiation would be downgraded in cases where an exam that does not use ionizing radiation is also available and provides nearly equivalent information. For example, in the setting of suspected appendicitis, if the referring physician deems an imaging study to be necessary, an ultrasound exam would be rated higher (more appropriate) than CT for children and pregnant women, while the reverse would be true for most adults.

There is a clear need to improve the use of imaging in medical care. The role of imaging has grown dramatically over the last few decades. With the improvement in healthcare that his has engendered, there are, however, concerns about overuse, inappropriate use, and radiation exposure to individuals and the population. It is difficult to define optimal imaging due the many relevant variables, including patient characteristics, expertise, and the lack of sufficient high-quality studies to define the best use in all clinical settings. It is apparent, however, that clinical imaging guidelines are needed, and the ACR Appropriateness Criteria provide the best guidelines currently available, and are the only US guidelines that take into full account relative radiation exposure (RRL, or relative radiation level). The availability of ACR Select™, an enhanced and expanded platform based on ACR AC, as an electronic clinical decision support tool is a major advance in improving the risk-benefit ratio that must always be considered with the use of imaging, and in improving healthcare.

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