

Protocol Design and Optimization

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INTRODUCTION

Ultimately, all medical care should be designed and then delivered with the goal of improving patient outcomes and experience. What constitutes a positive encounter will vary from one patient to another (eg, pain relief in terminal cancer vs curative resection in operable oncologic disease), so care pathways should be tailored to address individual patients' needs. This tenet holds as true for imaging as for any other specialty. In this series, we have argued that delivering better patient care can be achieved through an understanding of the imaging value chain. This begins when an imaging examination is requested and ends when actionable information is delivered to caregivers in a timely manner. This longitudinal perspective promotes the opportunity to evaluate and improve each link in the value chain to optimize imaging's contribution to better care. In a previous article, we addressed the first link in this chain: imaging appropriateness, scheduling, and patient preparation. In this article, we address the next link: imaging protocol design and optimization.

THE PROBLEM

An inappropriate imaging examination provides little or no value to either a patient or a referring physician. Similarly, even if a test is appropriate, an incorrect or suboptimal imaging protocol will reduce, and sometimes negate, imaging's contribution to a patient's care. This may seem obvious, as with a patient with pelvic pain whose imaging includes only the abdomen, but it is sometimes less apparent (eg, suspected renal stone disease is evaluated with a contrast-enhanced CT study). Other errors are subtler, such as suboptimal bolus timing, slice thickness, or planes of reconstruction. Perhaps most subtle of all is the radiation dose delivered to the patient. No matter how subtle, all contribute to less than optimal outcomes.

Using decision support algorithms, referring physicians will usually choose the appropriate examination types, and many will be aware of the need for appropriate imaging protocols (eg, contrast-enhanced imaging in malignant disease), but they cannot be expected to know the gamut of complex protocols available to radiologists. Ultimately, it is up to radiologists to dictate which protocol is most suitable for a particular patient in a particular situation. But therein lies a problem. Contemporary equipment and the number of available parameters for protocol design have become so diverse and complicated that even many subspecialty radiologists are not always aware of the ideal protocol for a given patient with a given disease at a particular time. Furthermore, with the advent and increasing deployment of precision medicine, whereby patient care is rapidly becoming driven and delivered according to unique biomarker data and patient preferences, it is now too overwhelming for most radiologists to optimally and uniquely tailor each examination. Consequently, many departments are unable to uniformly design and deliver optimal protocols for every circumstance. For example, more than 50% of abdominal CT protocols do not currently adhere to the ACR Appropriateness Criteria[®] concerning anatomic coverage [1]. Further exacerbating the issue, sufficient and seamless clinical data are often not easily available to radiologists, so it is not surprising that variation abounds, even within the same section of the same department.

In an attempt to mitigate this variation, some institutions insist that radiologists evaluate imaging requisitions before protocol approval, particularly for cross-sectional imaging. Although such initiatives are laudable, they are inherently inefficient, cumbersome, and prone to error. The advent of electronic medical records has helped somewhat, but the data harbored in

such repositories are often difficult to extract. Furthermore, radiologists themselves are often the sources of protocol variation, violating even set departmental policies. Residents and fellows are particularly susceptible to this dynamic (sometimes referred to as "protocol creep"), in fear that some staff members may disapprove of shorter and simpler protocols. Sometimes one radiologist may believe that his or her unique approach is superior to their colleagues', and sometimes whole subspecialty divisions within the same department will demand different protocols for the same clinical indication (eg, spine imaging by musculoskeletal radiologists vs neuroradiologists). Such variation often introduces error and waste into the value chain, which together diminish the patient (and referring physician) experience.

Perhaps the greatest variation in protocol design stems from radiation dose management. Although the harmful effects of low-dose radiation are still debated, most agree that optimal protocols should adhere to the principle of ALARA (as low as reasonably achievable). Many radiologists, however, disagree on what constitutes a diagnostic image, with some preferring greater image clarity (and higher dose) than others. Furthermore, many radiologists do not have a working understanding of the physics of dose reduction (eg, volumetric CT dose index), thereby impeding a uniform approach to ALARA. This idiosyncrasy, compounded by patient, modality, vendor, and disease differences, accounts for a wide range of delivered doses for the same clinical indication, which can vary by as much as 2-fold to 3-fold [2], with some reports of up to 10-fold dose variation [3]. Granted, some variation is clearly necessary for different clinical situations (eg, for children vs adults, for kidney stones vs pancreatic cancer) and scanner types (eg, lower dose for CT scanners with iterative reconstruction), but such excessive variations are

unwarranted for identical clinical situations and scanner types. In short, protocol variation is rampant across the nation, and even within some institutions, thereby reducing appropriateness, quality, safety, efficiency and patient satisfaction, the 5 pillars of Imaging 3.0™.

THE SOLUTION

As with many solutions that foster better performance from the imaging value chain, standardization should be implemented whenever possible. Elimination of suboptimal protocols inevitably leads to a more predictable and consistent delivery of best practices, which in turn reduces error and improves patient outcomes. Some might argue that too much standardization is naive given the complexity of patient presentations, particularly in an era of patient choice and precision medicine. Indeed, numerous protocols will be necessary, but this very fact should encourage more standardization for a given clinical presentation rather than less, lest it serve to foster continued idiosyncrasy and the described errors. To be sure, radiologists will, from time to time, need to exercise judgment and modify standard protocols, but such intentional variation should be the exception rather than the rule. Inevitably, an occasional patient may be required to return if the initial protocol was retrospectively deemed inadequate. Although inconvenient to that particular patient, a focus on population needs means that the overwhelming majority of patients will experience less risk (eg, less contrast material, less radiation) and more convenience (eg, shorter imaging times), resulting in overall gains for patients and facilities alike. Successful implementation requires that departments operate in a collaborative manner to determine optimal protocols and minimize noncompliance.

But what exactly is an optimal protocol? Dissent exists, even among experts, as to the many nuances. Much data and consensus guidance, however, are available. Two recent articles, for example, offer practical advice on how to consistently adhere to ALARA and simultaneously optimize protocol design [4,5]. It certainly behooves all radiologists to have a working understanding of the basics of dose reduction to minimize dose delivery. National societies too offer a wealth of information on protocol optimization (particularly concerning radiation dose), and readers are encouraged to familiarize themselves with the Image Wisely® and Image Gently® initiatives and the ACR directives on modality-specific protocol optimization [6]. Departments are encouraged to subscribe to the ACR's national dose registry to benchmark their CT doses to national standards. Efforts by the American Association of Physicists in Medicine make vendor-specific and body region-specific CT protocols available [7].

Standardization inevitably means that most protocol selection will be increasingly automated, ideally using decision support systems at the time of an appropriate imaging request by a referring physician. If implemented meaningfully and effectively, it should then be unnecessary for radiologists to revalidate each and every examination request and protocol selection. Skilled technologists can alert radiologists to unforeseen patient circumstances, which might require protocol modifications. This may mean, paradoxically, less radiologist participation before imaging but greater participation at the time of patient scanning (ie, minimize lung CT coverage for nodule follow-up) [8]. Under current delivery models, such an approach will challenge busy radiologists because it will require a far more "hands-on" approach to optimal protocol delivery. Some might

argue that this moves away from standardization, but this approach should strike the necessary balance between commoditization and radiologist relevance. Such approaches support the standardization process while ensuring that individual patients' needs and circumstances are addressed.

In summary, far too much protocol variation exists across the nation, even within many departments. That variation undermines the delivery of best practices and patient outcomes, both key goals of Imaging 3.0. Radiologists must assume leadership roles in standardizing their imaging protocols and monitoring quality and safety compliance.

The next article in the series will address optimizing modality operations.

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