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Creating Accountability in Image Quality Analysis. Part 2: Medical Imaging Accreditation

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Introduction

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires all non-hospital providers of advance diagnostic imaging (ADI) submitting technical reimbursement claims to Medicare to undergo a formal accreditation in order to qualify for continued Medicare reimbursement (http://www.govtrack.us/congress/bills/110/hr6331/text). ADI includes MRI, CT, and nuclear medicine imaging and does not include X-ray, ultrasound, and fluoroscopy. Mammography is covered separately by the Mammography Quality Standards Act (http://www.fda.gov/CDRH/MAMMOGRAPHY).

The quality standards which must be demonstrated by medical imaging providers in this accreditation process include the following (http://www.cms.gov/outreach-and-education/medicare-learning-network-MLN/MLNI):

1. Qualifications of medical personnel who are not physicians
2. Qualifications and responsibilities of medical directors and supervisory physicians
3. Procedures to ensure equipment being used meets performance specifications
4. Procedures to ensure the safety of both medical imaging beneficiaries and personnel
5. Establishment and maintenance of a quality assurance and quality control program to ensure reliability, clarity, and accuracy of image technical quality

The accreditation process is triennial and averages US $3,500 per imaging modality being evaluated. In the event that an applicant is determined to be noncompliant with the established standards, a corrective action plan is required, with the possibility of a site visit. After the accreditation process has been successfully completed, the provider is required to notify the accreditation organization of any change in service (e.g., equipment change).

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Limitations and Deficiencies

While the intended goal of the legislation is to improve the technical quality of medical imaging, a number of limitations and deficiencies exist in the current accreditation model, which has the potential to minimize the ultimate impact on image quality improvement. Perhaps the most obvious of these limitations is the fact that a large percentage of medical imaging studies are exempt from these quality standards, including general radiography which still accounts for the majority of medical imaging exams [1, 2]. In addition, these exempt imaging exams are often performed in facilities supervised by non-radiologists, which in theory heightens concerns over image quality and patient safety [3]. It would therefore seem logical for accreditation requirements to include all diagnostic medical imaging exams.

The accreditation requirements focus exclusively on medical imaging "technical" quality and largely ignore the professional component of medical imaging in the form of medical imaging interpretation. It is difficult to understand how medical imaging quality standards can be addressed in the absence of image interpretation, which constitutes the essence with which clinical diagnosis and management decisions are made. Excellent technical image quality in the absence of accurate and definitive diagnosis is of limited clinical value, and as a result, one can easily argue that any medical imaging accreditation process should include both the technical and "professional" components which collectively define quality of imaging services.

An equally important deficiency in the current accreditation model is the static and infrequent manner in which image quality is assessed. Current accreditation requirements call for triennial surveys, which if successfully passed essentially guarantees 3 years of continued reimbursements with little to no oversight. A lot can take place in those three intervening years; in the form of personnel, technical, and professional changes which can dramatically impact image quality. While service providers are required to report substantive changes in practice to the accreditation body, this is in large part left to the individual discretion of the service provider, who may be unaware or in a relative state of denial as to the negative impact practice change may have on image quality. In essence, the imaging provider is provided with a 3-year pass with which to operate, with minimal concern for continued scrutiny or oversight.

Lastly (and perhaps most importantly), the current accreditation model represents a "beauty contest" where imaging providers are allowed to select their best images for review in the accreditation process. The "real-world" technical challenges which exist in everyday practice (e.g., noncompliant, elderly, immobile, high morbidity, or obese patients) are discarded in lieu of the young, thin, relatively healthy, and ambulatory patient who can serve as a model for optimal image quality. At the same time, the images selected for submission are typically performed by the most experienced, educated, and talented technologists in order to maximize image quality. Minimal effort is made to submit and review image quality in the context of the *comprehensive* patient and technologist pool, which would more accurately reflect image quality in its everyday form.

If one seeks to create an accreditation process which embodies the stated MIPPA quality standards (i.e., ensure reliability, clarity, and accuracy of image technical quality), fundamental changes should be strongly considered.

Improvement Opportunity

The ultimate goal for any medical event is optimizing clinical outcome, and the performance of a medical imaging exam is no exception. There are four principle factors which affect clinical outcome for a medical imaging exam and these are technical (i.e., image) quality, interpretation accuracy, patient safety, and clinical efficacy. While existing accreditation standards focus almost exclusively on technical quality of the imaging dataset, it is important to include the other three components in quality analysis, if the end goal is to optimize clinical outcomes.

The inclusion of quality metrics related to diagnostic accuracy is perhaps the most challenging in contemporary medical practice, since evaluation of interpretation accuracy is largely performed retrospectively. As a result, the most logical method for incorporating diagnostic accuracy data into the overall quality analysis would consist of creating user, context, and exam-specific analytics which can be applied to the specific imaging exam being evaluated [4]. While this historical interpretation accuracy data may not be directly applicable to the medical imaging exam of record, it would reflect the composite data of relevance. The continuous refinement of this data provides an up to date measure of individual end user (i.e., radiologist) performance [5]. Radiologists and clinicians providing diagnostic interpretation of medical imaging exams would therefore be provided with a powerful incentive to continuously refine their skills, adopt decision support technologies, and perform targeted continuing medical education, in an effort to enhance their diagnostic performance measures. Evaluation of technical image quality with the addition of this interpretation accuracy data would provide far greater depth and reliability in medical imaging quality assessment, as relating to clinical outcomes.

Inclusion of data related to patient safety is another critical component of comprehensive medical imaging quality analysis and primarily consists of metrics related to ionizing radiation and contrast administration for diagnostic medical imaging [6, 7]. As radiation dose reduction takes on heightened importance in current practice, it is essential that this radiation data be collected, analyzed, and correlated in the context of technical image quality. It would be counterproductive and counterintuitive to evaluate technical image quality in the absence of radiation dose, since the two variables are directly related to one another. Technical image quality variables such as noise and exposure are directly impacted by radiation dose and if analyzed in isolation could actually encourage imaging providers to opt for higher radiation dose protocols to maximize technical quality measures. Relevant examples include "dose creep" for digital radiography and full-dose CT, which sacrifice radiation safety for improved technical image quality [8, 9]. From a practical standpoint, medical imaging providers utilizing aggressive radiation dose reduction strategies should be encouraged to do so, while taking into account the precarious balance between radiation safety and technical image quality. This radiation safety/image quality balance lies at the heart of many ongoing radiation dose reduction initiatives such as Image Gently [10] and, if used effectively, provides a means with which the medical imaging community can maintain its clinical importance and economic viability in the face of existing commoditization pressures and radiology outsourcing [11].

Clinical efficacy as it relates to medical imaging is another essential component of optimized clinical outcomes. This consists of a number of individual variables such as exam appropriateness, protocol optimization, and providing useful and definitive data relative to the clinical context prompting medical imaging. Unlike the other three categories

of quality indicators, this category is somewhat unique in that it is a shared effort which is determined by the combined efforts of the medical imaging provider and referring clinician. The referring clinician is relied upon to provide accurate and comprehensive clinical data relating to the request for medical imaging and if deficient or erroneous can result in inappropriate exam selection, use of a suboptimal protocol, and inaccurate and/or uncertain diagnosis. While technologies such as computerized physician order entry and the electronic patient record offer the potential for improved clinical data delivery, existing deficiencies related to technology integration and "gaming" can continue to result in deficient clinical data at the point of care [12]. The end result is that technical image quality, diagnostic accuracy, and clinical outcomes may be adversely affected by deficient and/or erroneous clinical data, and this underscores the importance of clinical efficacy in the comprehensive analysis of image quality.

In addition to taking into account these four principle factors affecting imaging quality, a number of other deficiencies and limitations of the existing accreditation process should be addressed (Table 1). First and foremost, it should be established that *all* providers of medical imaging services should be held accountable and be required to undergo accreditation. While the accreditation process should consist of uniform quality standards and methods of evaluation, it is important to realize that not all imaging service providers operate under comparable conditions. Geography, socioeconomic factors, institutional demographics, and the patient population served all have the potential to impact image quality deliverables and the accreditation process should take these factors into account, while ensuring that minimum quality expectations are maintained for accreditation. As an example, an inner city tertiary care hospital serving a patient population with complex and multiorgan disease might be expected to have slightly different image quality measures from that of a suburban community-based hospital serving a relatively healthy and economically affluent patient population. As a result of inter-provider variability, the accreditation process should incorporate a mechanism that can reliably and consistently address differences in exam complexity and factor this into the overall quality analysis [4]. The methodology and standards for measuring quality would not change, but a clinical exam complexity multiplier could be incorporated into the overall analysis to provide a mechanism for accounting for clinical context and the relative difficulty in exam performance.

One of the most glaring deficiencies in the current accreditation model is the selection process, which allows for imaging providers to preferentially select (i.e., cherry pick) those images of the highest technical quality for evaluation, which arguably defeats the very purpose of the intended process. The preferred alternative would be a random selection process where representative imaging exams from a pre-defined list of categories (e.g., pediatric, musculoskeletal, neurology) would be randomly selected and independently evaluated based upon the defined technical quality metrics, while also taking into account the clinical context, patient profile, and exam complexity. By using such a system, a provider would be neither penalized nor rewarded by the selection of "difficult" or "technically challenging" imaging exams, which can take a number of forms including noncompliant patients or complex disease processes. The goal would be to provide a mechanism to objectively characterize exam complexity and factor this into the overall quality analysis, thereby replacing self-selected "optimal" images with randomly selected real-world images.

The current model of triennial accreditation provides an opportunity for imaging providers to prepare for the review by undergoing internal analysis, review, and optimization every 3 years, as opposed to daily and continuous scrutiny, which should be the ultimate goal. The best way to circumvent this process is to create an accreditation process which routinely evaluates quality performance, thereby creating a mindset of continuous self-improvement and quality introspection. Since on-site inspections are not practical or cost effective, the accreditation organization would create an electronic infrastructure which allows for periodic access to the provider's network and randomized selection of imaging exams for quality analysis. This would to some extent allay anxiety on

Table 1 Proposed modifications to improve image quality accreditation

Quality variable	Current analysis	Recommended analysis
1. Requirements	Hospitals exempt	All providers
2. Modalities	CT, MRI, nuclear medicine	All modalities
3. Components of analysis	Image quality	Image and interpretation quality
4. Selection process	Provider selected	Random selection
5. Clinical context	Low priority	High priority
6. Periodicity	Triennial	Continuous
7. Outcomes	Pass/fail	Dynamic
8. Stakeholder assessment	Institutional	Multi-party
9. Methodology	Text/numerical	Image-centric
10. Data analytics	Proprietary	Standardized

the part of the provider, realizing that they have no control over the timing and selection of cases and therefore need to focus their everyday efforts on continuous quality-centric delivery. Anyone who has experienced a JCAHO inspection first hand can relate to the increased anxiety, resource allocation, and heightened internal preparations which occur every 3 years, followed by a relative quiescent period, often lacking in internal quality scrutiny [13]. By replacing this model of triennial review with one of continuous evaluation and feedback, one can postulate improved quality performance and more efficient resource utilization.

The current accreditation process is largely a pass/fail proposition which makes it relatively easy and straightforward on the part of the accreditor, but limits the potential education and intervention value on the part of the provider. If one draws an analogy to academics, the theory behind pass/fail grading is that it minimizes some of the anxiety associated with test taking and provides some degree of comfort on the part of test participants. The downside is that no effective differentiation is provided to those students who demonstrate exemplary test scores and who have expanded greater resources and effort than their counterparts who passed with far lower test scores [14, 15]. If the end goal is to reward and promote excellence in quality, it would seem logical to create an accreditation process which creates a well-defined methodology for passing requirements, but at the same time provides a mechanism for quality differentiation among the diverse population of "passing" service providers. At the same time, if the aforementioned recommendation for continuous quality assessment and feedback is incorporated into the accreditation process, a provider with lower quality scores would have the ability to demonstrate almost immediate improvement, as opposed to having to wait for the next 3-year cycle to occur. The end goal is to incentivize providers to continuously strive for quality improvement, based upon continuous quality data analysis and proactive and targeted interventions aimed to improving existing deficiencies. There is no greater motivator for quality improvement than competition, but it must be based upon a fair and level playing field and driven by objective data analysis.

Conclusion

While the current MIPPA accreditation process represents a step forward to promoting quality in medical imaging service delivery, a number of deficiencies exist in the current model; relating to timing, scope, methodology, and breadth of the quality metrics being analyzed. While the creation of these accreditation standards is largely tied to CMS reimbursement, this actually creates a unique opportunity for medical imaging providers to take an enhanced role in defining, promoting, and scrutinizing medical imaging quality. By expanding upon the quality standards and methodology in current use, the medical imaging community has a unique opportunity to introduce greater rigor and accountability in the process of defining and measuring medical imaging quality. The derived quality analytics could in turn be used to foster quality-centric education/training, research, establishment of best practice guidelines, technology development, medical economics, and innovation opportunities. This heightened focus on objective quality analysis is particularly timely given the commoditization pressures experienced by medical imaging service providers and technology producers. In the end, quality analysis leading to improved clinical outcomes should be the common goal for the entire medical imaging community.

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