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The Quality/Safety Medical Index: Implementation and Analysis

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Abstract Medical analytics relating to quality and safety measures have become particularly timely and of high importance in contemporary medical practice. In medical imaging, the dynamic relationship between medical imaging quality and radiation safety creates challenges in quantifying quality or safety independently. By creating a standardized measurement which simultaneously accounts for quality and safety measures (i.e., quality safety index), one can in theory create a standardized method for combined quality and safety analysis, which in turn can be analyzed in the context of individual patient, exam, and clinical profiles. The derived index measures can be entered into a centralized database, which in turn can be used for comparative performance of individual and institutional service providers. In addition, data analytics can be used to create customizable educational resources for providers and patients, clinical decision support tools, technology performance analysis, and clinical/economic outcomes research.

Keywords Data mining · Decision support · Image quality analysis · Radiation dose

Introduction

The concepts of medical data analytics referable to quality and safety measures are taking on increasing importance in medical practice. A variety of factors contribute to this increased attention to medical quality and safety including (but not limited to) increased accountability among medical service providers (at both individual and institutional levels), expectations for increased medical data access and transparency, financial reimbursement models tied to quality measures, and patient empowerment.

The net result of these combined technologic, financial, societal, and psychological factors is the creation of large medical databases, which in theory provide analytical tools for creating objective methods for quantifying quality and safety measures. As these databases increase in size and scope, one can theoretically create customizable context, user, and technology-specific analytics which provide both health care consumers and providers with objective context and user-specific data analytics. If successfully created and implemented, this dynamic approach to medical analytics can support the practices of personalized and evidence-based medicine, which collectively aim to customize medical decision making in accordance with the unique attributes of individual patients (i.e., personalized medicine), based upon available medical data and empirical best practice guidelines (i.e., evidence-based medicine).

There are three fundamental challenges which currently preclude creating these objective data analytics for quantifying quality and safety in medical practice. The first is the inconsistency and non-uniformity of medical data (i.e., non-standardized data), which precludes the creation of large referenceable medical databases. Examples of non-standardized data include free text (i.e., narrative) reports occurring throughout medical practice including (but not limited to) operative reports, consultation and progress notes, history and physical exams, hospital discharge summaries, and imaging/clinical test reports. The second challenge to creating objective and personalized data analytics is the current practice of applying medical data analytics to large patient populations, without taking into account the subtle nuances and differences which define individual patients and their medical conditions. While the sheer number of confounding variables and potential interaction effects create challenges in

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defining optimal care (based upon data analysis) for each individual patient, there is nonetheless great opportunity for adapting medical data to individual patient attributes, in accordance with major patient profile attributes and characteristics. By doing so, primary variables (e.g., individual disease processes) would be taken into account with secondary variables (e.g., patient compliance, body habitus) to determine "best practice" guidelines in accordance with both disease and individual patient attributes. The third challenge to creating objective quality and safety analytics in medicine is the fact that these two variables (i.e., quality and safety) do not always move in concert with one another (i.e., discordant).

An example of this dynamic relationship between quality, safety, and patient profiles can be illustrated with the performance of a medical imaging exam (e.g., CT). The same CT exam (e.g., chest CT) is being performed on two different patients (patient A: thin, compliant, low morbidity and patient B: obese, non-compliant, increased morbidity). If the same CT exam protocol was being performed, one would expect significant differences in medical image quality in accordance with the different patient profiles (i.e., the image quality for patient A would be higher than that of patient B due to a combination of body habitus, motion, and poorer health). At the same time, the radiation dose for the exam on patient A would likely be lower than the radiation dose of patient B (due to the different body thickness required for photons to pass through). The resulting image quality and radiation dose (i.e., safety) for patient A would both be superior to patient B assuming the same CT exam protocol is used. Now, let us suppose that the CT exam protocol is adjusted to accommodate these patient profile differences. In order to accommodate for increased noise associated with patient B obesity, the CT acquisition parameters are modified so as to minimize noise and improve image quality. This modification will in turn increase radiation dose (i.e., decrease safety). In order to improve image quality for patient B, a sacrifice is made which decreases safety, by increasing radiation dose. This negative interaction effect between safety and quality for patient B is not observed for patient A, where the quality and safety measures move in tandem with one another due to the fact that patient A's profile allows for lower radiation dose and high-quality measures. The net result is that the relationship between quality and safety is dynamic and affected by a number of patient-specific variables.

If the goal of medical service delivery is to simultaneously optimize quality and safety, then we must create standardized data which provides the ability to perform large sample size meta-analysis. At the same time, it is important to create context and user-specific analytics which can take into account the myriad of variables related to technology, patient attributes, and clinical differences which abound in everyday practice. If such a methodology can be created and validated, one would in theory have a mechanism to improve clinical outcomes (ideally at the point of patient care), perform objective comparative analysis (of service and technology providers), provide data-driven education and training tools, and create financial reimbursement models directly tied to quality and safety measures.

Implementation Strategy

The concept and methodology for creating a standardized quality/safety index (QSI) in medical imaging was described in a companion article [1]. This index utilizes individual standardized image quality and radiation dose metrics (using a Likert scale), which when combined with one another create a standardized index measure ranging from 0.2 to 5.0. While the principle medical imaging application refers to measures of image quality and radiation dose, the concept of the QSI can be applied to other applications in medical imaging including contrast administration and interventional procedures. Applications outside of the medical imaging domain could include radiation therapy, pharmaceutical administration, and surgery. For discussion purposes, the primary application of image quality and radiation dose will serve as the application of principle interest in this article.

Since identification of "comparable" imaging data is an essential component of data analysis and the scoring criteria used, it is imperative that each individual exam being prospectively evaluated is analyzed in the context of comparable imaging exams. A number of variables can factor into this determination of comparability (Table 1). Early adoption would in large part be limited to more simplistic and straightforward variables such as imaging modality, anatomy,

Table 1 Variables used in determination of exam comparability (creation of the peer reference group)

Variables
1. Imaging modality
2. Anatomic region/organ system
3. Exam type (e.g., preventive, diagnostic, surveillance)
4. Clinical context (e.g., clinical indication, presumptive/established diagnoses).
5. Patient clinical profile (e.g., body habitus, BMI, compliance, underlying medical conditions)
6. Patient radiation profile (e.g., radiation dose history, genetic susceptibility, personal sensitivity)
7. Technology in use (e.g., imaging modality hardware and software)
8. Imaging exam history (e.g., prior imaging studies, documented report findings)
9. Institutional profile (e.g., institution size and type, geographic location, academic status)
10. Technologist profile (e.g., clinical experience, education/training)

institutional provider profile, and exam type. As more data is accumulated (and the database expands in depth and breadth), additional variables can be incorporated into the analysis of exam comparability; such as clinical context, patient clinical profile, and technology in use. In the future, as genetic and data mining techniques are refined, variables such as the patient radiation profile and imaging history can be included in the analysis, but this is relatively impractical in current practice. The important point to be made is that quality and safety analyses are not only exam specific but also context and patient specific.

The derived databases can be created at local, regional, and national levels in a manner similar to those of existing radiation dose registries, which have been (or are being) created by the American College of Radiology (http://www.acr.org/Quality-Safety/National-Radiology-Data-Registry/Dose-Index-Registry), American College of Cardiology (https://www.ncdr.com/webncdr), and US Food and Drug Administration (http://www.fda.gov/RadiationEmittingProducts/RadiaitonSafety/RadiaitonDoseReduction/ucm199994.htm). The commonalities for these radiation dose registries are centralized data collection, creation of national diagnostic reference levels, and aggregation of publicly and freely available data.

Before the data could be recorded into these centralized databases, it would first require validation and verification, in order to ensure the data being recorded is accurate and reproducible. This process can be facilitated through the creation of industry wide standards (e.g., DICOM, HL-7), which could be created through the combined efforts of professional societies (e.g., AAPM, ASRT, RSNA) and industry (e.g., modality and information system manufacturers). The management of these databases could be performed by third-party providers who have established experience and expertise in medical database health care organizations (Leapfrog Group, Howard Hughes Medical Institute, Robert wood Johnson Foundation) with proven track records in quality, safety, and medical research. By effectively separating the responsibilities of data standardization, verification, analysis, and dissemination, the proposed system could in theory improve data accountability and reliability.

Another important component of the implementation strategy is the creation of multi-disciplinary teams of health care experts representing the diverse fields of technology, medical physicists, service delivery, and administration. In current medical imaging practice, these responsibilities are largely compartmentalized and often performed in isolation to one another, which can negatively impact quality and safety. By fostering the active collaboration of medical physicists, technologists, radiologists, clinicians, technology vendors, administrators, and payers, one can conceivably improve quality and safety outcomes in medical practice. One way to facilitate this collaboration is through the creation of multi-disciplinary review committees which could serve in an oversight role to ensure data accuracy, compliance with community standards, and quality assurance. One practical role for this multi-disciplinary group would be to review, audit, and provide feedback to service providers who are routinely providing subjective image quality scores for the QSI database. By intermittently and randomly auditing the data being provided, knowledge can be gained regarding the accuracy of the data, requirement for remedial education, and opportunities for quality/safety improvement (e.g., technology upgrades, decision support tools). By providing these services, these multi-disciplinary groups could effectively serve as consultants and educators to both the service and technology provider communities, with the goal of continuously improving quality and safety deliverables. Payers could elect to actively or passively participate in the process and consider directly incorporating QSI analyses into reimbursement.

Lastly (and perhaps most importantly), the QSI data and derived analytics could in part be made available to the general public to assist patients with health care decision making and education. In the end, patient education can not only promote competition and accountability in the medical community but also facilitate improved health outcomes.

Data Analytics

The primary sets of analytics which can be derived from the QSI database are comparative performance analyses which encompass both individual and institutional stakeholders involved in the ordering, performance, and payment of medical imaging services. On an institutional level, analysis of medical imaging quality and safety is a complex and multi-factorial process, involving multiple operators and technologies. The collective result of these efforts can provide consumers of medical imaging services with a quantitative performance record, which can be evaluated on either global or more granular levels. This data can be utilized by institutional leaders to identify the relative strengths and weaknesses of the medical imaging department, with the goal of continuous quality improvement. In addition to providing valuable insight to administration overseeing medical imaging service delivery, these same institutional analytics can also be used to assist medical imaging consumers in provider selection (on a non-emergent basis). Patients, referring clinicians, and third-party payers can in theory utilize this data to optimize quality and safety measures specific to the individual exam, clinical context, and patient attributes by selecting service providers who have demonstrated historical quality and safety metrics, commensurate with the specific needs and preferences of the consumer. At the same time, the utilization of medical imaging services and provider selection can serve as a valuable tool

for patients when selecting clinician and insurance providers. If for example, a third-party insurance provider is routinely utilizing lower quality/safety imaging providers within their defined networks and limiting access (or increasing out of pocket expense) to higher quality/safety imaging providers, this may be important data for the educated consumer in driving the selection of insurance providers. The same type of analysis can be done to evaluate clinician medical imaging utilization and provider referrals. The goal is to create a data-driven method for *quantitative accountability*, in which transparent, accessible, and methodologically sound data can be used to enhance quality and safety metrics related to the delivery of medical imaging services, specific to the exam, clinical context, and individual patient.

In a similar fashion, individual operators or stakeholders can also undergo analysis, with the goal of identifying their individual strengths and weaknesses for the purposes of *customizable* education and training, workflow distribution, and implementation of decision support tools. If for example, an individual technologist or radiologist is demonstrated to have poorer quality/safety index measures for a specific exam type, this individual can target education and training efforts on the specific areas of greatest need. At the same time, an administrator (or automated scheduling program) can elect to use these operator-specific performance analytics to modify workflow distribution, with the goal of assigning more difficult imaging exams to available staff who have demonstrated the highest measures of quality/safety proficiency. While the capability of selective workflow distribution may not be practical for smaller size imaging service providers, it may be relevant for larger imaging providers (e.g., tertiary care institutions, teleradiology practices). As an example, a CT exam protocol calling for maximal radiation dose reduction (at the cost of increased noise and diminished quality) may require interpretation by a radiologist who has consistently demonstrated higher performance metrics (e.g., diagnostics confidence, interpretation accuracy, follow-up recommendations) than their peers. The same principle of targeted workflow distribution can also be applied to technology, when multiple options are available. If for example, an imaging department has three CT scanners available for a technically and clinically challenging exam (e.g., cardiac CT on an obese patient), the QSI database could be used to identify the specific CT scanner which has demonstrated the highest QSI scores for that specific exam type and patient profile and preferentially assign the exam to that specific scanner (if practical).

The ability to perform customizable comparative technology analysis can also be used in the processes of technology procurement and upgrades. An intuitional provider seeking to upgrade or purchase new technology could in theory use the QSI database to compare technology quality and safety performance specific to their clinical needs and economic resources. If for example, an institution wanted to promote a new type of imaging service (e.g., cardiac CT), they could utilize the QSI data to compare quality and safety data specific to their current CT technology, available upgrades, and new technology. This comparative QSI data could in turn be correlated with cost, in order to generate an effective quality and safety return on investment (ROI). At the same time, technology vendors could use this objective and unbiased data for the purposes of research and development (R & D) planning, by identifying those areas in which their technology platform is deficient relative to their competitors and/or specific areas of quality and safety deficiencies which could effectively become market differentiators.

The concepts of data-driven innovation can also be applied to medical economics. The current static model of economic reimbursement for medical imaging service delivery is largely devoid of quality and safety analysis. Imaging providers effectively receive the same payment for service regardless of quality/safety performance, which indirectly incentivizes providers to focus efforts on maximizing productivity and workflow which may lead to diminished image quality and patient safety. If, on the other hand, objective QSI data was used to create a dynamic reimbursement model tied to imaging quality and safety, one could in theory provide real and tangible economic incentives to prioritize quality and safety over productivity. By having the ability to stratify service providers in accordance with institutional profile groups, providers would be analyzed on a level playing field and be compensated in a fair and equitable manner relative to their peers. The dynamic nature of the QSI database and derived analytics would also provide for real-time trending analysis, which would allow for continuous refinement and adjustment of the reimbursement rates (as opposed to annual adjustments). In the end, the goals of these QSI analytics remain the same, use objective data to drive continuous quality and safety improvement, provide a reliable means for data-driven accountability, and provide tangible economic incentives based upon performance.

Decision Support

Medical decision support delivered through information system technology has been shown to improve clinical performance and patient safety, with clinical efforts largely focused on pharmaceutical selection and administration [2–4]. In radiology, most decision support to date has focused on utilization of imaging services through the implementation of radiology order entry technology [5, 6]. The areas of image quality and radiation safety represent opportunities for future decision support, with the goal of utilizing referenceable databases for improved medical imaging quality and safety at the point of care.

In the current workflow model for elective imaging exams, the patient arrives at the date and time of the scheduled exam and undergoes image acquisition after a brief interview with the imaging staff. The technologist performing the imaging study customarily selects an imaging protocol from a predefined list of protocol options which have been created by the technology vendor. These protocols may undergo modification by the imaging staff based upon practical experience and individual preferences of the imaging staff (e.g., technologists, radiologists). On occasion, the technologist may elect to modify the protocol based on information contained within the patient's historical imaging folder. Rarely, is imaging data extraneous to the patient used in protocol refinement. This workflow model is largely the result of limited data availability and accessibility, coupled with workflow and time constraints.

The QSI database is predicated on the concept that if standardized imaging data related to quality and safety was easily accessible and understandable, one could in theory utilize this data to prospectively modify the current protocol based on exam and patient-specific clinical requirements. The technologist or radiologist responsible for protocol optimization could in effect input the quality and radiation safety requirements, along with the specific search parameters of interest (e.g., technology in use, patient profile, clinical context). The database could in turn identify comparable exams which fulfill the search criteria in rank order, with the option to review the corresponding image protocol and/or images. If desired, the corresponding protocol could be imported from the database to the imaging modality and used for the current exam being performed. The idea is to leverage pre-existing data from comparable exams to for prospective quality and safety optimization.

Another decision support tool for protocol optimization can be created using available computer noise simulation models, which allow introduction of Gaussian-distributed random noise to simulate the increased noise associated with radiation dose reduction [7–10]. A sample image from the anatomic region of primary clinical concern can be obtained using "conventional" acquisition parameters and then undergo simulated radiation dose reduction through the introduction of noise. As the image becomes degraded in quality, the operator can subjectively determine the point of maximal dose reduction, which equates to the minimal level of image quality which allows for accurate diagnosis. The corresponding noise level can then be used to derive corresponding acquisition parameters, which when correlated with the QSI database of comparable exams will provide an estimated QSI score. Following completion of exam performance, the "estimated" and "actual" QSI scores can be correlated to determine the accuracy of the simulation model and subsequently be used for iterative refinement of the computer simulation tool. A variation of this application could consist of the ability to use a sliding scale tool function in which the operator can manually adjust radiation dose estimates and dynamically visualize the changing appearance of the sample images. Once the final "idealized" image has been selected, the corresponding acquisition protocol parameters will be presented for use. The goals of these decision support tools is to prospectively optimize protocol parameters in an effort to achieve the highest QSI score specific to the exam, clinical context, patient, and available technology.

Another decision support feature aimed at protocol optimization utilizes QSI data contained within each individual patient's historical medical imaging record. Once implemented, each individual imaging study utilizing ionizing radiation will have an associated QSI score. These collective and exam-specific QSI scores can be presented for review to the operator at the time of protocol determination, providing a snapshot as to QSI expectations for the current study as well as identification of the highest historical PSI scores which are relevant to the current exam. A patient with consistently low PSI scores (e.g., high morbidity, non-compliance, deficient technology) would alert the operator to the increased need for expanded QSI database mining, while a patient with previously high PSI scores can have the prior protocol serve as a default for the current study with a reasonably high expectation for a similarly high PSI score on the current study. Automated analysis of each patient's PSI database takes on increased relevance for patients with chronic medical conditions and prolonged hospitalizations, in which numerous historical medical imaging studies are available for review and analysis. Since the unique attributes of each individual patient and technology used will have a profound effect on PSI, this historical data becomes extremely valuable in protocol optimization at the point of care and arguably creates an advantage for those imaging providers which take greatest advantage of readily available data.

Conclusion

The ability to correlate QSI data with radiology report outcome data (e.g., interpretation accuracy, diagnostic confidence, follow-up recommendations) can eventually lead to the creation of data-driven best practice guidelines specific to exam type, clinical context, patient attributes, and provider profiles. The ultimate goal is to translate this data into objective improvements in medical imaging quality, patient safety, and clinical outcomes, while making data readily accessible and understandable to all health care practitioners and consumers.

The innovation described is aimed at improving medical imaging quality and patient safety at the point of care, when data analysis and intervention has the greatest potential for improved outcomes. The longitudinal analysis of QSI data provides an opportunity for quantitative accountability and improved performance for all stakeholders including medical

imaging service providers, referring clinicians, patients, and third-party payers. Those service providers who are deficient in education/training, utilize limited technology, or fail to incorporate available data workflow and decision making will ultimately be exposed through longitudinal data and performance analysis. Ironically, this creates a unique opportunity for the medical imaging community to reaffirm its vital role in optimizing quality and safety, and creates an opportunity to decommoditize radiology practice, by creating data-driven economic incentives to the highest quality and safety performers.

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