Best Practices Guidelines
On Imaging Clinical Decision Support Systems

Preface

In light of the evolving technological advances in the area of radiology utilization management, and specifically the emerging importance of clinical decision support[1] (CDS) systems, the Radiology Business Management Association (RBMA) and the American College of Radiology (ACR) determined that the previously published Best Practice Guidelines on Radiology Benefit Management Programs[2] should be revisited. While that guideline pointed to the use of evidence-based tools such as CDS, it did not delve into or provide guidance on CDS specifically. Thus, this document on best practices for CDS systems, developed by the ACR and the RBMA, is intended to provide guidance to regulators, payers, vendors, referring physicians, and radiology providers as to implementation, use and on-going evaluation of CDS systems. This document seeks to delineate certain optimal business practices for companies that supply CDS systems in order to ensure that their radiology utilization management products are a continuously improving, cost effective, efficient and reliable method of providing clinical and payer- neutral guidance for the appropriate ordering of imaging services. It is essential that these products be based on patients' clinical indications and high quality, evidence-based clinical imaging guidelines. Such guidelines serve as a benchmark against which CDS systems can be measured. The following best practice recommendations are based on ACR

[1] For the purposes of these guidelines, the authors consider "clinical decision support", "computerized decision support", "decision support", "computerized imaging order entry", and "computerized physician order entry with clinical decision support (CPOE/CDS)" as analogous terms.

[2] ACR-RBMA Best Practices Guidelines on Radiology Benefits Management Programs (2011); http://www.rbma.org/uploadedFiles/RBMA_Web_site/Advocacy/Advocacy_Payer_Relations/ACR-RBMA%20Best%20Practices%20for%20Radiology%20Benefits%20Management%20Programs.pdf

and RBMA member consensus and a review of utilization management practices under development or currently in use by CDS companies. Implementation of these best practices will promote transparency and help create a uniform process that will ease administrative burden on payers, treating clinicians, and radiology providers alike. This paper is not an endorsement of specific companies that supply CDS systems or their approach to the marketplace.

Background

While imaging unquestionably has significantly improved the quality of health care and increased value by saving money, it is an expensive tool. For numerous reasons inappropriate imaging does occur, which has led to efforts to improve appropriate use through several approaches. One such approach is the use of Radiology Benefit Managers (RBM). RBMs, either independent organizations or payer-owned, are contracted to determine the appropriateness of ordering advanced imaging procedures in the outpatient setting based on the patients' clinical indications (signs, symptoms, or diagnoses) as well as the third-party payers' internal proprietary guidelines. Determination of appropriateness, ostensibly based on these guidelines, is generally not transparent, may involve added administrative hurdles, and imposes a temporal, administrative and financial burden on ordering health care providers, radiologists and even insurers. Some payers also implement their own internal RBM program, usually in the form of prior-authorization[3]. Prior authorization of outpatient services before performance of the imaging study is often required for payment, and may involve selection of the imaging provider by the RBM. This selection process is sometimes referred to as "patient steerage." RBM steerage strategies often ignore patient care

[3] For the purposes of these guidelines, the authors consider "prior-authorization", "pre-certification", and "pre-authorization" as analogous terms.

integrated networks, provider physician and staff skills, experience, quality, and procedure protocol uniformity.

CDS systems provide a favorable alternative to RBMs and other pre-authorization approaches, as is apparent from a consideration of the characteristics of an ideal system to manage imaging utilization. The functional CDS system incorporates the following:

- Can readily be incorporated into daily work processes.
- Processes requests in real-time with minimal disruption or interference (i.e., moves from requests for imaging procedures, to approval and performance if indicated, or to communication between the requesting health care provider and the imaging expertise inherent in the CDS system if there are questions or concerns).
- It is efficient, user friendly, consistent and educational, with immediate feedback as to the recommendations.
- It is based on clinical guidelines that are produced using sound methodology, are evidence-based to the greatest extent possible, supplemented as needed by clinical expert opinion, transparent and readily reviewable and are regularly up-dated.
- By using sound guidelines and realistic systems, the CDS will allow real-time evaluation of the appropriateness of a requested imaging study and will eliminate the need for any other system of pre-evaluation or pre-certification.
- The CDS system will, through vendors, allow feedback between the creators of the guidelines and the users, and thereby facilitate both improved guidelines and local quality improvement for systems and for individual imaging ordering providers.

- Consequently, the CDS system will produce quality measure and outcome data.
- In order to assess continuous performance improvement longitudinally against benchmark data, the CDS system will supply utilization data to providers that support networks.

Providing decision support on the basis of widely-accepted evidence based utilization guidelines, such as the ACR Appropriateness Criteria®, at point of computer order entry meets these criteria. Proponents note that "CDS is a cost-effective, efficient, and reliable method for analyzing the clinical indications of a patient and comparing those indications to evidence based data sets, allowing physicians to recommend the most appropriate course of treatment for the patient. This can include a recommendation for no imaging study or to change the requested study to one that is more medically appropriate. The electronic CDS process serves as documentation that the patient is to receive the most appropriate care under the circumstances presented. The benefits of CDS leverage data, drive decision making, improve quality and safety, and help reduce costs by ensuring the right imaging study is recommended."[4] Several CDS systems are currently commercially available, and use of such systems is being widely considered by health care systems, payers and regulators.

CDS and RBM companies exhibit similarities and differences in their approach to utilization management. Both claim to utilize national specialty society-approved guidelines, and some supplement these guidelines with their own consensus processes. Unlike the RBM business model, CDS offers real time, electronically embedded guidance during the imaging ordering process, optimally eliminating the need for the referring or treating clinician

[4] Computerized Decision Support (CDS) Systems for Advanced Imaging Services, Imaging e-Ordering Coalition.

to take time away from patient care to obtain a pre-authorization and relay that to the imaging provider. RBMs, on the other hand, argue that CDS does not place the same level of accountability on referring physicians for their ordering habits. Several health systems and one state, however, have or are in the process of deploying public data which report and compare physicians ordering behavior. CDS vendors and some providers suggest this transparency offers accountability and more effectively influences practice patterns.

The RBM process provides no data about patient care quality or outcomes. RBM efforts are highly focused on controlled spending for imaging. This is appropriate but inadequate with regards to many other important concerns identified by government, healthcare reform advocates and providers. No data are available to individual physicians and their groups that would support education allow identification of the rare “problem provider”, or benchmark group performance. No data are available to support integrated care network process improvement or support accountable care organizations (ACO). There is no data stratification related to patient severity of illness. There is no effort or contribution towards promoting best medical practice standards, which often requires a broader understanding of patient care and evaluation that goes far beyond the ordering of an individual imaging test. A properly designed CDS can support all of these vital issues.

Clinical Patient Care Guidelines

The CDS should present the available choice of imaging procedures or range of imaging procedures determined as appropriate based on the medical evidence to the extent possible supplemented by clinical expertise. Determining the range of possibly appropriate imaging procedures is based

on indications, such as patient symptoms, information from prior exams, the patient/family medical history and risk factors, or clinical circumstances (e.g., emergent case). The degree to which this information is available at the point of ordering an imaging exam varies from patient to patient, procedure to procedure. Additionally, even with substantial information available, the CDS system will not account for every possible clinical scenario. There may be additional factors that impact the final decision for a specific case and there may be more than one procedure that is appropriate for the clinical indications or scenario.

For example, based on indications, history, risk factors, etc. entered into a CDS for a patient with suspected acute pancreatitis having severe abdominal pain, elevated amylase lipase, but without fever or elevated white blood cell count, but with hemoconcentration, oliguria and tachycardia the CDS algorithm may find all the following exams as appropriate: CT abdomen with contrast, CT abdomen without contrast, MRI abdomen without (including MRCP) and with contrast, MRI abdomen without contrast with MRCP, CT abdomen without and with contrast or US abdomen. At any particular institution or facility, practice variations, available staff, available scanners, patient allergies or other factors may determine the most expedient, efficacious exam choice capable of answering the clinical question.

The CDS should provide to the ordering clinician any procedure determined appropriate and not restrict selection to a specific exam whether defined by CPT® codes, charge master codes or other manner that a facility may code a procedure. The imaging provider may then determine that no imaging is required or that it is necessary to perform any exam, whether specified within the range of appropriate exams as determined by the CDS or not. In this manner, the CDS should provide the radiologist and treating clinician the

flexibility to choose the most appropriate imaging study based on the patient's indication(s). Furthermore, information from prior exams, the patient medical history and risk factors, family medical history, or clinical circumstances (e.g., emergent case) may necessitate a departure from results presented by a CDS that has been implemented with restrictive adherence to singular or non-inclusive groups of CPT coding or charge master mapping, which could potentially require a second CDS query.

Allowing a radiologist or other credentialed imaging interpreter to perform such appropriate imaging studies without requiring pre-approval, based on their exigent clinical condition, would avoid repeat studies, delays while attempting to revise an order to permit a more appropriate study, and additional administrative costs, as well as patient inconvenience and potentially unnecessary or repeated exposure to radiation and contrast.

Education of treating clinicians

CDS systems should provide real-time, 24/7 education and guidance for two purposes: first, to educate referring physicians and other ordering clinicians about the clinical information that needs to be submitted in the imaging prescription, and secondly to provide guidance (and education) as to the most appropriate exam, if any, for the specific clinical indications. Both must be accomplished in a way that is evidence-based, non-intrusive, sufficiently user friendly so that the system is accepted by ordering health care providers, payer-neutral and does not interfere with the physician-patient relationship. Further, referring physicians and their practice personnel should expect uniformity and consistency regarding the type and amount of clinical information needed, regardless of the payer, plan, intermediary or geography in which the study is performed or ordered. Similarly, in a risk sharing arrangement such as an ACO, credit should be given to the

performing provider when the initial order meets the appropriateness standard.

Use of national specialty guidelines

When a CDS algorithm varies from a specialty-specific guideline (e.g., ACR Practice Guidelines and Technical Standards, ACR Appropriateness Criteria®) for any reason, such as to add more specific guidance, this variation must be clearly embedded in the electronic tool, and offer transparency to the ordering physician and patient.

Outpatient Study Process

For outpatient procedure authorization and scheduling, provider accreditation and specific payment plan participation for each provider should be incorporated into the order entry database. Many current CDS systems do not include this information. Cumulative patient examination history should be immediately available to the ordering physician, to further facilitate the elimination of unnecessary or repeated examinations as well as reduction of patient exposure to radiation. Common examination requirements such as estimated Glomerular Filtration Rate (eGFR), history of a prior contrast reaction and other relevant risk factors should also be presented as appropriate. Providers should be able to present specific equipment identification numbers, along with physician, staff and site accreditation information in electronic format when requested.

Compliance with applicable laws and regulations

The utilization management process should be transparent and evidence-based. The methodology and data used in constructing the CDS algorithms need to be transparent, sound and available to the medical community and the public at large. Criteria should be evidence-based to the greatest extent

possible (through the use of the peer-reviewed literature, specialty guidelines, and sound, widely accepted guideline methodology), supplemented by expert opinion, so that they follow best medical practice. The CDS algorithms and resulting criteria should conform with applicable state and federal laws and regulations, be applied and administered consistently across geographic boundaries and authorizing entities by all third-party payers, and the imaging provider should be reimbursed for any medically appropriate studies they perform in accordance with the CDS algorithm, as long as the patient is eligible for coverage under the applicable provider agreement. Most importantly, any study that is found to be medically appropriate in accordance with the CDS algorithm should be deemed to be "pre-authorized" in accordance with applicable federal, state or local laws, rules or regulations relating to same.

Ability to override CDS guidance

CDS should offer a process whereby either the treating clinician or radiologist (with approval of the ordering physician) can override the CDS algorithm guidance within defined guidelines. This is necessary to assure that the physician, who may be aware of a patient's specific medical circumstances which may not have been specifically addressed in the CDS tool, can be the final decision maker on what test is ordered. However, all CDS systems should also have an inherent utilization review and quality improvement component. That is, their utilization patterns should be shared with the ordering physicians, and analyzed by the health care system locally, to evaluate to what extent ordering of imaging studies conforms to the CDS. This information should first be made available to each physician and the entity where the physician or other clinician practices. Data gathered regionally and nationally, through a CDS system, such as that of the ACR Appropriateness Criteria, can also be shared locally as an educational and QI

tool. Using this approach has several advantages: efficiency, ease of use, adaptability to individual circumstances that may fall outside the norm or the usual, ready evaluation of the patterns of use of individual ordering health care providers and use of this information for QI. Further, use of such systems will allow comparison of utilization and of outcomes among institutions and regions, to improve quality nationwide.

Process Consistency

Physicians (treating or interpreting), their patients, and their practice personnel should expect consistent interpretation and application of medically appropriate criteria across geographic boundaries and authorizing entities in accordance with applicable law. Predictability in the determination of medically appropriate studies will promote compliance, help mitigate burdensome administrative costs and promote the delivery of a uniformly high and improving quality of patient care. Conversely, inconsistent standards lead to uneven patient care, frustration on the part of referring and rendering physicians and their staff and patients, and unnecessary administrative cost.

Administrative Process Guidelines

Continuous ordering improvement process

As noted, CDS systems should allow a referring or rendering physician to override the guidance because such physician(s) may be aware of the need to update or further refine the CDS algorithms/guidelines. Each CDS company should clearly communicate what steps a physician should take to communicate a potential change which he or she recommends. The response to such suggestions by the CDS company should be timely and transparent.

These instances of exam order changes or CDS guidance “overrides” need to be part of the CDS system data reports so that appropriate algorithms and process improvements can be made over time.

Procedure Payment Process Consistency

Imaging services that have been conducted after a CDS has been consulted should not have reimbursement denied by a third-party payer after the fact on medical appropriateness grounds, as long as the patient is eligible for coverage under the applicable provider agreement. Providers need confidence that their CDS-approved services that have been documented in the electronic health record (EHR) or otherwise documented electronically will be reimbursed. Those third party payers who require a CDS consultation number to be included with the claim must provide a rectification and appeals process for any claim that is denied based on consultation number transmission errors, whether they are human or technical.

Reimbursement criteria should be applied and administered consistently across geographic boundaries and authorizing entities, not only with respect to medically appropriate criteria, but also without regard to a payer’s coverage and adjudication policies, i.e., ideally an imaging provider should receive reimbursement for a study that successfully utilized CDS regardless of payer, plan, or other administrative considerations.

Payers should ensure that all services vetted by CDS can be properly and timely transferred for accurate claims processing

The CDS vendor and their payer clients should have sufficient claims adjudication, electronic connectivity systems (i.e., currently a portal) and reconciliation processes in place so that studies found by the CDS algorithm

to be medically appropriate can be accurately expedited through the claims processing systems and reimbursed.

Payers should, across all of product lines and regardless of any internal utilization management programs, reimburse providers for all imaging studies that have been vetted by the CDS system

Payers should avoid "mixing" utilization management programs for their product lines by avoiding the use of multiple systems, i.e., both CDS and RBM. Such mixing creates added administration costs as well as confusion, since many patients do not know the details of their plans and the variability can be overlooked readily by referring physicians, their staff, or the staff of the imaging facility.

The CDS exam validation period should be from the date of the order by the referring physician through a period of 30- 60 days

The validation period should be considered to extend "from the date the tool was consulted" in order to avoid re-application or even payment denial. Furthermore, in order to promote patient and provider convenience and efficiency, the patients should be afforded the flexibility of scheduling anytime within the applicable validation period. This is especially important for some types of advanced imaging services which may not be available in all geographic areas, requiring the patient to arrange for travel for the services.

Transparency Recommendations

The collection of quality of imaging information, ordering behavior and cost data from practices should be fair, consistent, and accurate

Payers increasingly are exploring the use of comparative statistics of practices based on quality, ordering behavior and cost. While this could be a

useful resource for patients and employers, the value of such a product will depend largely on the accuracy of the underlying data and the reliability of comparisons. Further, it will require the use of consistent, transparent, high-quality imaging guidelines that are comparable, or identical, for any CDS systems. Accordingly, payers should have processes in place to ensure that the data are collected and shared consistently across practices, geographic boundaries and authorizing entities, using a common, transparent methodology and equivalent data sets and predictive modeling techniques. Further, the data should be subject to review by the practices prior to release and there should be the expectation that there will be frequent and easy updating of such data as the CDS system and the practice changes. A credible data dispute resolution process is essential to insure fairness to payers, providers, and the public alike. Resolution of a dispute which changes publicly reported data should be posted within 30 days of the final decision.

<u>CDS should provide regular performance reports over a specific period of time</u>

The CDS system should have the capability to provide detailed reports to the payer, providers and each referring physician on the ordering patterns of each referring physician, including his or her adherence to appropriateness guidelines that are the basis of the CDS system. Clear rules governing which data will be public and which data will be privileged should be clearly stated. Quality assurance data may be subject to legal protection.

<u>Benchmarking</u>

There is presently no credible accreditation process for CDS systems. Further, there are no nationally accepted CDS performance standards or metrics developed at this time. Our expectation is that such criteria will

emerge in the future. In the interim, each CDS system should establish and report performance metrics for system operations, physician and provider satisfaction and the like. These data should be reported for specific time intervals and as longitudinal trends.

CDS Criteria Revision

The CDS system and its algorithms should be regularly updated for new and revised clinical information (e.g., guidelines), changes in CPT coding, etc. Updates should be clearly communicated, readily apparent and smoothly incorporated when using the CDS tool.

Technology Issues

CDS should be part of an integrated healthcare system solution

Ideally, CDS should integrate seamlessly and on a real-time basis with the computerized clinical and management solutions utilized by the rendering physician, imaging facility (hospital or imaging center), and treating clinician without the need to separately purchase vendor specific HL-7 or other interfaces.

CDS should be capable of "mining" a patient's medical record for relevant information and include such information in its determination-making process.

A patient's medical record may contain information (e.g., prior studies, personal or family histories) that would be pertinent to the imaging study being evaluated along with the information given by the referring physician. A CDS that is integrated into a healthcare system solution (e.g., electronic health record, radiology information system, hospital information system) should be able to extract relevant patient information.

CDS can be successfully deployed in a variety of manners

A CDS can be a web-based process that generates an authorization number similar to an RBM program. This approach does not require disparate computer system integrations or HL-7 program interfaces. While less elegant than fully integrated solutions, it can be deployed relatively quickly and inexpensively. CDS could be deployed by a health plan as an improvement in their current utilization management solution. CDS could also be deployed by providers who then contract with payers to provide this front end utilization management. The underlying vision of much of this paper is that a CDS will be fully integrated into the institutional EHR process and deliver a superior decision process. The notion that all payers must accept an internal provider's CDS process as acceptable is neither mandated nor required today, but would be highly desirable. All of these approaches can add value if properly deployed and supported. All can operate at a lower cost versus RBM methods while achieving similar macro-economic results.

Conclusion

The ACR and the RBMA both are strong proponents of performing the right study, at the right time, in the right way for each individual patient. Toward that end, the ACR has over many years developed and updated ACR Appropriateness Criteria, ACR Guidelines and Standards, the most rigorous accreditation programs in imaging, and numerous quality improvement data registries. The ACR has also collaboratively developed and participated in the Image Gently, Image Wisely and Choosing Wisely campaigns. ACR activities have contributed significantly to guiding and improving patient imaging care in the United States; similar programs are now being developed in many other parts of the world. The ACR and RBMA firmly believe in and advocate for the adoption of CDS systems as a more effective and less costly process for ensuring appropriate imaging now and in the future. The RBM approach

is now recognized to be more costly, less efficient, and inadequate for our future healthcare policy goals and needs as a nation. The intention of this paper is to describe the most desirable characteristics of CDS systems, and to provide a frame work against which CDS performance, design and utilization can be measured.