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The Qualified Clinical Data Registry: A Pathway to Success within MACRA

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ABBREVIATIONS: ACR = American College of Radiology; CMS = Centers for Medicare & Medicaid Services; MACRA = Medicare Access and CHIP Reauthorization Act; MIPS = Merit-based Incentive Payment System; NRDR = National Radiology Data Registry; PQRS = Physician Quality Reporting System; QCDR = Qualified Clinical Data Registry

Clinical data registries are data bases that collect anonymous patient information focused around a specific diagnosis or health condition for scientific, clinical, or policy purposes. Registries help to assess real-world outcomes in the practice of medicine.[1] By comparing a practice's process and outcome measures to regional and national performance benchmarks, registries have the potential to improve the quality of patient care by facilitating the development of quality improvement projects.[2]

A Qualified Clinical Data Registry (QCDR) is a distinct designation from a clinical data registry or qualified registry. The Centers for Medicare & Medicaid Services (CMS) defines a QCDR as an entity that "collects medical and/or clinical data for the purpose of patient and disease tracking with the goal of improved patient care."[3] Critically, a QCDR is specifically approved by CMS as one of the mechanisms for reporting into the new Merit-based Incentive Payment System (MIPS) as part of the new Quality Payment Program. The details of this new value-based payment system have been outlined in prior reviews.[4-6] Despite the new administration after the 2016 federal elections, the Quality Payment Program, and specifically the MIPS pathway, is expected to remain in place.[7]

The QCDR was initially conceived by the American Taxpayer Relief Act of 2012[8] as a mechanism to allow specialty societies to develop relevant specialty-specific metrics for reporting to the Physician Quality and Reporting System (PQRS) as an alternative to the existing, narrower in scope, generic measures previously accepted by CMS. However, QCDRs must reach a higher level of rigor than other registries, fulfilling CMS requirements regarding the demonstration of improvements in quality and efficiency. Some of the specific requirements imposed by CMS include: being established for at least 1 year before the first data-collecting year as a QCDR; having a minimum participation of 50 groups; not being locally owned or managed by an individual or single-specialty practice; the ability to publicly report quality measure results; and transparency on data collection, specific data elements, and risk models.[9] The QCDR first served as a reporting mechanism for PQRS in 2014.[8,10]

CMS has incentivized the usage of QCDRs under the new MIPS through the Medicare Access and CHIP (Children's Health Insurance Program) Reauthorization Act (MACRA). In the early years of the Quality Payment Program mandated by MACRA, MIPS will be the most common payment pathway for radiologists.[3] In the MACRA Final Rule, CMS expressed that by allowing for the use of QCDRs to report data into the 3 MIPS performance categories that require data submission, QCDRs "will become a viable option for MIPS-eligible clinicians."[11] CMS further asserted "these flexible options will allow MIPS-eligible clinicians to more easily meet the submission criteria for MIPS, which in turn will positively affect their final score." The MIPS final score will determine the negative and positive payment adjustments. The potential negative payment adjustment in 2017 is 4%, increasing to 9% by 2022.[11]

QCDRs have evolved in response to long-standing legislative mandates and reports from governmental organizations. This article provides a historical perspective of clinical data registries, the evolution of quality reporting, and the critical role QCDRs will play in MIPS reporting.

HISTORICAL CONTEXT

In 1986, the Health Care Financing Administration, now known as CMS, released raw mortality data for coronary artery bypass grafting operations stratified by institution.[12] However, the government published this data without risk stratifying patients, thus

From the Department of Radiology (M.M.C.), The University of Texas MD Anderson Cancer Center, Houston, Texas; Department of Radiology (A.B.R.), NYU Langone Medical Center, New York, New York; Hackensack Radiology Group (G.N.N.), Riveredge, New Jersey; South Texas Radiology Group (E.S.), San Antonio, Texas; Department of Radiology (G.M.), Weill Cornell Medical College, New York; Department of Anesthesiology and Perioperative Medicine (L.M.), University of Louisville, Louisville, Kentucky; and Department of Radiology (J.A.H.), Massachusetts General Hospital, Boston, Massachusetts.

Please address correspondence to Melissa M. Chen, MD, Department of Radiology, The University of Texas MD Anderson Cancer Center, 1400 Pressler St, Unit 1482, Room #FCT 16.5032, Houston, TX 77030; e-mail: melissa.mei.chen@gmail.com; @MelissaChenMD

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failing to take into account patient-level factors that affect postoperative mortality and clinical outcomes. The data cast hospitals and providers with higher-risk patients and seemingly worse outcomes in an unfavorable light. In response, the Society of Thoracic Surgery (STS) formulated a novel plan to develop its own classification system to combat this oversimplification of quality reporting. The Society established the first data registry in 1989.[13,14] The STS National Database has grown to include 3 different clinical areas: adult cardiac, general thoracic, and congenital heart surgery. It is now one of the most established clinical data registries and considered the "gold standard."[15]

The Institute of Medicine's publication *Crossing the Quality Chasm: A New Health System for the 21st Century* outlined a strategic plan for how to improve the delivery of health care.[16] The report, published in 2001, highlighted the importance of aligning payment policy with financial incentives and paved the way for the legislatively mandated establishment of "pay for performance" programs.[17] Specifically, the Tax Relief and Health Care Act of 2006 established PQRS.[18] PQRS became a permanent program under the Medicare Improvements for Patients and Providers Act in 2008.[19,20] The payment adjustments under PQRS have evolved from bonus payments for successful reporting (1.5% at the inception of the program) to penalties for unsuccessful reporting (starting in 2015).

The Tax Relief and Health Care Act of 2006 also mandated that eligible professionals should be able to provide data on quality measures through an appropriate medical registry, specifically citing the STS National Database as an example.[18] Support for clinical data registries continued with the American Taxpayer Relief Act of 2012, which prompted the establishment of QCDRs as an approved reporting mechanism for PQRS, as previously discussed. Despite this legislative momentum toward adoption, adoption of QCDRs as a reporting mechanism has remained historically low.

QCDR FOR RADIOLOGY

As a response to the shifting focus toward quality and value-based payments, the American College of Radiology (ACR), in collaboration with other specialty societies, developed its own clinical data registry, the National Radiology Data Registry (NRDR).[2] The development of the ACR's NRDR began with the National Oncology PET Registry, a joint effort with the Academy of Molecular Imaging and the American College of Radiology Imaging Network, which became functional on March 6, 2008. The registry was developed in response to a CMS-proposed expansion of coverage for PET using ^{18}F-FDG. PET imaging for cancers and indications previously not reimbursed by CMS were eligible for reimbursement if the referring physician and billing providers submitted data to a clinical registry. In April 2009, based in part on peer-reviewed data registry results, CMS officially expanded coverage of PET to include the evaluation of nearly all types of cancer and also allowed the use of PET in subsequent treatment strategy evaluations for an expanded number of cancers.[21] Building on this experience, and further recognizing the importance of expanding their data base of metrics for radiologists, the ACR developed several other registries.[22] Some of the relevant metrics that neuroradiologists can report by using the NRDR include the measurement of carotid stenosis, appropriate imaging follow-up for incidental thyroid nodules, and door-to-puncture time for endovascular stroke treatment.

Importantly, in 2015, CMS approved the ACR's NRDR, through a self-nomination process, as a QCDR that will enable radiologists to succeed in the MIPS pathway.[23] The NRDR was 1 of 36 approved QCDRs in the initial year, which has nearly doubled in size to 69 CMS-approved QCDRs for 2016.[24,25]

Other registries specific to neuroradiologists include the Neurovascular Quality Initiative and the North American Spine Society Spine Registry. The Neurovascular Quality Initiative allows neurointerventionalists to compare processes, complication rates, and lengths of stay as well as medical device effectiveness. The Society of NeuroInterventional Surgery has announced plans to convert the Neurovascular Quality Initiative into a QCDR. The North American Spine Society Spine Registry is a diagnosis-based outcomes data registry that will track patient care and patient-reported outcomes. Although still in its pilot phase and not an approved Neurovascular Quality Initiative, the North American Spine Society Spine Registry may be an opportunity for neuroradiologists.[26] Members of the American Society of Neuroradiology will be well positioned to participate in the NRDR, Neurovascular Quality Initiative, or North American Spine Society Spine Registry.[27]

CRITICAL ROLE OF QCDRs

In the MACRA Final Rule released in October 2016, CMS finalized its intention to incorporate data submitted via QCDRs into the MIPS.[11] MIPS consolidates into a single program 3 previously existing federal quality programs: PQRS, the Medicare EHR (electronic health record) Incentive Program (formerly known as Meaningful Use), and the Value-Based Modifier. The Quality category replaces PQRS, the Advancing Care Information category replaces the Medicare EHR Incentive Program, and the Cost category replaces the Value-Based Modifier. MIPS also incorporates a new category called Improvement Activities, which addresses patient access, beneficiary engagement, and population health efforts. QCDRs will satisfy reporting into 3 of the 4 MIPS categories: Quality, Advancing Care Information, and Improvement Activities. The fourth category, Cost, will not require physicians to report and will be assessed by CMS based on administrative claims data obtained from submitted clinician billing claims. Under MIPS, clinicians' performance in these 4 categories will contribute to a "Final Score" determined on a 100-point scale. The weighting of the 4 categories in computing the Final Score will be gradually phased in over the first 3 years of the program. For example, the Cost category will be weighted to 0% for all providers in the first performance year of 2017, not contributing to the Final Score until subsequent years. In addition, the weighting will be adjusted to give special considerations to clinicians with infrequent face-to-face patient interaction. Further details of this scoring system have been previously described and are beyond the scope of this review.[27]

MIPS will adjust payments based on the actual level of performance within each category, measure, and activity. In the MIPS Quality category, participating clinicians will be required to submit 6 quality metrics, including 1 outcome measure if available.

2017 Finalized MIPS radiology measure set

MIPS Measures	Data Submission Method
Exposure dose or time reported for procedures using fluoroscopy	Registry
Inappropriate use of "Probably Benign" assessment category in mammography screening	Claims, Registry
Correlation with existing imaging studies for all patients undergoing bone scintigraphy	Claims, Registry
Stenosis measurement in carotid imaging reports	Claims, Registry
Reminder system for screening mammograms	Claims, Registry
Use of a standardized nomenclature for CT imaging	Registry
Count of potential high-dose radiation imaging studies: CT and cardiac nuclear medicine studies	Registry
Reporting to a radiation dose index registry	Registry
CT images available for patient follow-up and comparison purposes	Registry
Search for prior CT studies through a secure, authorized, media-free, shared archive	Registry
Follow-up CT imaging for incidentally detected pulmonary nodules according to recommended guidelines	Registry
Appropriate follow-up imaging for incidental abdominal lesions	Claims, Registry
Appropriate follow-up imaging for incidental thyroid nodules in patients	Claims, Registry
Use of dose-lowering techniques	Claims, Registry
Biopsy follow-up	Registry

Mechanisms for submitting Quality metrics to MIPS will include: claims data, electronic health record submission, a CMS Web interface (only for groups of 25 or more), a qualified registry, and, as previously noted, a QCDR. This listing of options by CMS highlights the distinct nature of a qualified registry and a QCDR.

For radiologists within a single-specialty practice, the submission options for the Quality category are claims-based, a qualified registry, or a QCDR. Claims-based submission can only be reported at an individual level, not at the group level, and requires the successful reporting of 6 measures. The Quality Payment Program Final Rule lists MIPS measures for individual specialties. A total of 7 measures are listed for diagnostic radiology when using claims-based reporting.[11] Radiologists practicing primarily at a subspecialty level have a more limited number of MIPS measures available to them when using claims or qualified registry reporting mechanisms and, therefore, may find it difficult to reach the minimum threshold of 6 measures (Table). But radiologists may more easily satisfy the MIPS Quality category requirements by using a qualified registry or QCDR through the Group Practice Reporting Option. For example, a dedicated neuroradiologist who is only able to report by using MIPS measures may only have 2–3 total applicable measures: stenosis measurement in carotid imaging reports and appropriate follow-up imaging for incidental thyroid nodules in patients. Accordingly, many neuroradiologists reporting individually could not meet the Quality reporting requirements under MIPS. With the Group Practice Reporting Option, groups may submit by using a qualified registry or a QCDR to consolidate quality measures across the practice, more easily meeting the requirement of 6 measures. Moreover, QCDRs include non-MIPS measures, which are specific to the QCDR and distinct from MIPS measures such as median dose-length product for CT head/brain without contrast and Report Turnaround Time: CT.[9] Because QCDRs may report both MIPS and non-MIPS measures, this increased flexibility enables successful reporting congruent with MACRA's and CMS' intention to encourage the use of QCDRs.

The use of QCDRs has other advantages such as bonus points in the Quality category. Each reported measure in the Quality category will be scored on a decile-based, 10-point scale by using established benchmarks obtained 2 years before the performance period. Bonus points are available if reporting high-priority measures based on specific national quality domains such as outcome, appropriate use, patient safety, efficiency, patient experience, and care coordination. The ACR NRDR QCDR gives users access to a larger number of high-priority measures, and hence, bonus points, compared with the other MIPS reporting mechanisms. Bonus points in the Quality category are also available for reporting measures by using "end-to-end" electronic reporting based on certified electronic health record technology.[11] End-to-end electronic reporting refers to the use of automated software to aggregate measurement data, calculate measures, perform filtering of measurement data, and submit electronically to CMS via a Web interface. Although the exact CMS guidelines for bonus points based on end-to-end reporting require further clarification from CMS as of this writing, it is possible that several measures within the ACR NRDR QCDR may be eligible if properly captured and submitted.

Another key benefit of the QCDR is the provision of more frequent feedback to providers than CMS currently provides through the Quality and Resource Use Reports.[28] The Quality and Resource Use Reports are a biannual report that demonstrates how groups and solo practitioners perform on quality and cost measures. Quality measures included in the Quality and Resource Use Reports are drawn from PQRS measures, Consumer Assessment of Health Care Providers and Systems (CAHPS) for PQRS surveys, and claims-based quality outcome measures. Cost measures are calculated by using CMS administrative claims. Each group practice receives composite scores in quality and cost. Scores in each of these 2 areas are classified as either "high," "average," or "low." This scoring system has been phased in from 2014–2016 to determine positive, neutral, or negative payment adjustments under the Value Modifier program. Although CMS provides midyear feedback, the data included is from June of the prior year to July of the current year, which may limit a group's ability to understand its performance in a particular calendar year. The NRDR provides more frequent quarterly feedback,

thereby allowing for groups to make process improvements to potentially improve their performance in a measure before the year's end, with the ultimate goal of improved quality and outcomes.

The use of QCDRs can facilitate the reporting of other MIPS performance categories as well. For example, participation in the NRDR provides opportunities for Improvement Activities not available in other reporting mechanisms in this newly introduced MIPS performance.[29] Although too numerous to list, a few examples include "participation in a QCDR that promotes": collaborative learning network opportunities that are interactive, use of patient-engagement tools, processes and tools that engage patients for adherence to a treatment plan, and leveraging a QCDR to promote the use of patient-reported outcome tools. Although some of the listed Improvement Activities are not relevant to radiology, the specific inclusion of QCDR as a tool for these activities highlights the importance and future potential opportunities for radiology. A few proposed Improvement Activities for radiologists include using clinical decision support to optimize the use of imaging examinations and decrease low value imaging examinations, using the ACR NRDR to receive performance feedback to assess practice and identify areas of improvement, and improving the timeliness of radiology reports to referring physicians to use in developing treatment plans by monitoring radiology report turnaround times through participation in the ACR NRDR.[30]

BENEFITS BEYOND MACRA

As demonstrated by the impact of the National Oncology PET Registry reporting on PET/CT, registries play a key role in expanding Medicare coverage for important techniques and procedures. More recently, in response to efforts by the ACR and a coalition of other patient-advocacy groups, CMS approved reimbursement for lung cancer screening with the requirement of reporting to a "CMS-approved registry" (ie, the NRDR Lung Cancer Screening Registry).[31] This trend of linking reimbursement to registry reporting is likely to continue and will facilitate radiologists in demonstrating their value to patient care. Indeed, clinical registries stand to be a centerpiece of CMS' increasing embracement of evidence-based coverage determination.

The NRDR offers an opportunity to improve patient care by providing national benchmark data on a variety of radiology-specific process and outcome measures. Multiple registries within the NRDR benchmark radiation dose to improve patient safety. The National Mammography Database, CT Colonography Registry, and Lung Cancer Screening Registry benchmark the positive predictive value of the radiologist's diagnosis, which is the ultimate value the radiologist provides to patient care.[22] The well-established Society of Thoracic Surgery has already demonstrated that this cycle of feedback and comparison of results heightens awareness, encourages self-assessment and analysis of processes, and ultimately improves patient outcomes.[32]

Aside from improving quality of care and preserving reimbursements, physicians will need to ensure that their professional reputation is maintained. The Affordable Care Act mandated a Web site, Physician Compare,[33] that provides publicly available quality information regarding physicians and other health care professionals enrolled in Medicare.[18] This Web site is intended to increase transparency and allow patients to directly compare their providers. Performance data from MIPS will be incorporated into the information included on Physician Compare. Physicians who do not participate in MIPS reporting may be perceived as inferior to their peers using this platform.[27] This level of public transparency through this tool further increases the importance for radiologists to pursue actions, such as the use of QCDRs, to ensure their success under MIPS.

FUTURE DIRECTIONS

Despite the potential repeal of the Affordable Care Act, the payment reform mandated by MACRA and subsequently implemented by CMS, which heavily links physician reimbursements to quality, will continue. The intent of MACRA is to move physicians into Alternative Payment Models.[34] Neuroradiologists will need to focus their research efforts on real-world cost comparisons of imaging recommendations. In particular, when determining guidelines for follow-up of incidental findings, neuroradiologists need to analyze the cost to follow or not follow a finding. In addition, neuroradiologists should become leaders in their local health networks to increase their visibility and demonstrate their value. By actively engaging with their health networks, neuroradiologists can help to direct the transition to Alternative Payment Models.

CONCLUSIONS

Legislation dating back to 2006 took incremental steps toward encouraging the use of clinical registries for quality reporting. In 2012, the notion of a QCDR was codified legislatively. QCDR use is expected to dramatically increase as its utility is emphasized and rewarded in MACRA. Organized radiology helped pioneer the use of QCDRs through the NRDR. Participation in QCDRs, including but not specifically the NRDR, will help radiologists achieve a high Final Score in the MIPS pathway in MACRA, which will be critical for their reimbursements and public reputation alike. As a result, QCDRs are poised to experience dramatically increased use in the near term and, in turn, help radiologists improve the quality of patient care.

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