Electronic Health Records, Registries, and Quality Measures: What? Why? How?

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The transition from volume-based healthcare to value-based care is advancing via the reporting of quality measures, initially as a part of “pay for performance” within Medicare’s Physician Quality Reporting System (PQRS) initiative. However, “value-based purchasing” requirements within the Affordable Care Act will increase the percentage of reimbursement linked to the reporting of quality measures. Currently, only five PQRS measures are relevant to wound care, and the venous ulcer care measure will be retired this year. PQRS measures in wound care can only be reported via claims or qualified patient registries, and no wound care measures are endorsed by the National Quality Forum (NQF). The recent Health Information Technology for Economic and Clinical Health (HITECH) Act promoting the adoption of electronic health records (EHRs) requires quality reporting by clinicians wishing to access EHR adoption money. These clinicians will be able to comply with the next stage of “meaningful use” of EHRs, beginning in 2015, by submitting data to a qualified registry, and registry submission may eventually be required by Medicare for reimbursement of some wound care products and procedures. Other specialties are using registries to track adverse events, measure compliance with practice guidelines, and for comparative effectiveness data. Evidence-based measures should be developed as electronic measures that can be submitted directly from the clinicians’ EHR. New wound care measures should undergo testing for NQF endorsement. The not-for-profit U.S. Wound Registry is a qualified patient registry that is available for PQRS reporting, measure testing, and future registry submission requirements. The lack of tested wound care quality measures threatens the entire wound care industry, as quality-based reimbursement is not limited to physician payment. Quality measures are an increasingly important part of many Medicare payment systems, including those for acute care hospitals, hospital-based outpatient wound care departments, and accountable care organizations.

INTRODUCTION

EFFORTS ARE WELL UNDERWAY to transition the U.S. inpatient, outpatient, and shared savings payment systems from the “volume-driven”

model of healthcare to one that is determined by value and which links cost to improved patient outcomes. Volume-driven reimbursement can actually reward substandard care, as

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patients who stay in service the longest generate the greatest revenue for the qualified healthcare professional (QHP). The Affordable Care Act (ACA, also called “Obamacare”) includes a new value-based payment modifier that will be used to provide differential payments to QHPs, inpatient facilities, outpatient wound care departments, and accountable care organizations, based on quality and cost of care.¹

Most specialty societies are far along in their creation of quality measures and have facilitated the mechanism by which these measures can be reported to the Centers For Medicare and Medicaid Services (CMS), usually through the creation of qualified patient registries. Since wound care does not fall within any particular medical specialty, efforts to develop wound care quality measures have been left to other organizations such as the American Medical Association (AMA)–convened Physician Consortium for Performance Improvement® (PCPI) initiative, other specialty societies, or quality organizations. The five wound care quality measures so far created seem unlikely to either measure the quality of wound care services or to drive improved patient outcomes. The complete list of Physician Quality Reporting System (PQRS) measures is available from CMS, but Table 1 includes a brief summary of the five PQRS measures that are relevant to wound care.²

The movement away from fee-for-service began in earnest in 2006 with the Tax Relief and Health Care Act (TRHCA), which authorized CMS to establish and implement a Physician Quality Reporting Initiative (PQRI), now called PQRS, and often referred to as “pay for performance.” The Medicare Improvements for Patients and Providers Act (MIPAA) of 2008 authorized a 2% bonus of Medicare billing for QHPs who successfully reported quality measures, increasing to a total of 4% in 2011. In 2012, the “penalty” phase began in which reporting QHPs received only a 0.5% bonus for reporting but non-reporters suffered a 1.5% reduction in total Medicare reimbursement. Bonuses for reporting end next year (2014), and penalties begin escalating. In 2015, QHPs will lose 1.5% of their Medicare revenue for not reporting, increasing to a 2% reduction in 2016 and subsequent years. With the implementation of the ACA value-based purchasing index, substantial reductions of payment to wound care QHPs and hospitals are inevitable unless more and better measures are developed and data transmission to CMS is facilitated through certified electronic health records (EHRs).

DISCUSSION

Current wound care quality measures

Avedis Donabedian, considered the father of the medical quality initiative, defined an “outcome” as a change in an individual as a result of the care they received. Thus, patient outcomes should serve as a validation of the effectiveness and quality of medical care. Patient outcomes can be characterized by clinical endpoints (*e.g.*, amputation), functional status (*e.g.*, ambulation), or general well-being (*e.g.*, pain). It is also possible to measure the appropriateness of clinical interventions that are known to improve a desired outcome through process measures (*e.g.*, diabetic foot off-loading). Although CMS prefers measuring patient outcomes instead of processes, measuring wound care outcomes will be impossible until there is national consensus on the definition of wound outcomes. Thus, for wound care QHPs, compliance with processes such as off-loading may be easier to determine than a more subjective and multifactorial endpoint such as wound healing.

When PQRS was launched, no measures were relevant to wound care, but in 2009, one measure directly relevant to wound care was added: the percentage of patients with venous ulcers who were prescribed any type of compression once in the year during which they were treated. Since physicians participating in PQRS had to successfully report at least three measures to qualify for a bonus, wound care QHPs had to report on at least two measures that were not directly applicable to their wound care practice (*e.g.*, screening for fall risk, tobacco cessation counseling, diabetic blood pressure control, *etc.*).

In 2008, the AMA PCPI attempted to fill the gap in wound care measures and convened a committee through the American Academy of Plastic Surgery (AAPS), as participation is limited to specialties with seats on the AMA House of Delegates. A multidisciplinary working group headed by the AAPS recommended seven chronic wound care measures,³ two of which were selected by CMS for inclusion in PQRS. These two “overuse measures” are not performing a swab culture and not using a saline wet to dry dressing (Table 1).

Thus, currently a wound care expert participating in PQRI would be considered to have provided quality care if a venous ulcer patient is prescribed any type of compression once in the calendar year, a clinician never does a swab culture of any wound, any dressing other than saline wet to dry is used, a diabetic patient undergoes evaluation for peripheral neuropathy, and a diabetic patient is prescribed diabetic shoes (note

Table 1. Summary of the five Physician Quality Reporting System measures relevant to wound care

Measure Number	Measure Title	Description	Instructions
186	Chronic Wound Care: Use of Compression System in Patients with Venous Ulcers	Percentage of patients aged 18 years and older with a diagnosis of venous ulcer who were prescribed compression therapy within the 12-month reporting period	Reported once per reporting period
126	Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy—Neurological Evaluation	Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months	Reported at a minimum once per reporting period
127	Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention—Evaluation of Footwear	Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing	Reported at a minimum once per reporting period
245	Chronic Wound Care: Use of Wound Surface Culture Technique in Patients with Chronic Skin Ulcers	Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic skin ulcer without the use of a wound surface culture technique	Reported at each visit
246	Chronic Wound Care: The Use of Wet to Dry Dressings in Patients with Chronic Skin Ulcers	Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic skin ulcer without a prescription or recommendation to use wet to dry dressings	Reported at each visit

there are no measures directed at the actual treatment of a diabetic foot ulcer). None of these measures have been endorsed by the National Quality Forum (NQF). It seems unlikely that these measures will improve the outcome of patients living with chronic wounds or decrease the cost of caring for them. However, if quality measures become a large component of physician payment under the ACA, even substandard measures may be better than none at all.

Reporting quality data and the emergence of EHRs

At the initiation of PQRI in 2007, QHPs reported measures using their claims (a paper-based charge document). This method was not successful, because it was complex and laborious. In April 2008, CMS expanded the data collection process to include reporting data via “qualified patient registries”⁴ However, registry reporting was always meant to be temporary, with a goal to eventually have all QHPs report their measures directly from their EHRs. Theoretically, there are four different ways that an eligible provider (EP) can submit data to CMS. These approaches are as follows: (1) claims based, (2) registry based, (3) directly from an EHR, and (4) group practice reporting. Since neither the group practice nor the EHR direct options include any of the five current wound care measures, wound care QHPs can use only claims-based or registry-based reporting.

The passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009 changed the dynamics of the quality measure reporting process. HITECH made stimulus money available for clinicians who demonstrated the “meaningful use” of their EHR by a

number of metrics, including participation in quality reporting. To make electronic data sharing possible, all certified EHRs should use the health level 7 clinical document architecture. This consists of a mandatory textual part (which ensures human interpretation of the document) and “structured” parts (for software processing) that enable data to be shared. HITECH provided approximately \$44,000 per QHP, paid out in stages if they met certain program requirements that are still being developed by CMS. Under “Stage 2” of meaningful use beginning in 2015, providers wishing to obtain EHR bonus money should share data with a public health agency or a specialty registry by transmitting the data directly from their EHR. Medicare is also driving the PQRS program toward transmission of quality data directly from the EHR to CMS via “e-Measures.” The QHP will transmit clinical performance data to CMS, and CMS will calculate the “pass” or “fail” rate of the quality measure (rather than having the registry do it for them) and use this to determine subsequent bonus/penalty payments.

An example of PQRS in wound care: the venous ulcer measure

While EHRs may change the method of reporting, the real question remains, “What exactly, are we going to report in order to demonstrate quality in wound care?” The U.S. Wound Registry (USWR) is a nonprofit organization that has been a CMS-approved patient data registry since 2008 when PQRI/PQRS was initiated (formerly called the Intellicure Research Consortium [IRC]). Registry responsibilities are as follows: validate that the QHO is an EP, collect all the medical data needed for the measures the EP intends to report,

get the signed attestation from the QHP (permission from the QHP to report their data to CMS), calculate the measures (including de-identifying the data), and transmit the data to CMS in a secure fashion. After the USWR submits a QHP's PQRS report to CMS, CMS goes through their validation process and then mails a check to the QHP at the address associated with their tax identification number. A complete list of PQRS registries and the measures they report is available from CMS.⁴

PQRS data submission is a daunting job for a registry, particularly as some of the measures (such as the overuse measures) are highly complex to calculate. However, from 2008 to 2010, the USWR (as the IRC) offered reporting services free of charge to QHPs using a wound care-specific EHR that facilitated automation of the process. QHPs had only to sign the attestation and fax it back to the registry, and a few months later, they received a check from CMS, usually for several thousand dollars. It is important to note that during this time, the PQRI program was really a "pay for reporting" program, because it was not necessary for the QHPs to actually pass measures, only to successfully report them. Furthermore, while most EPs in the United States had at least some additional documentation burden to participate in PQRI, the wound care QHPs reporting via the USWR had no additional reporting burden, because the necessary documentation was incorporated into their EHR and the data were abstracted electronically from their clinical charts. Despite making the submission process for wound care QHPs both easy and free through the USWR, about 20% of providers refused to participate in PQRI. The USWR contacted the QHPs who declined to participate, and their reasons included (1) not wanting the government to "watch their practice" (suspicion), (2) lack of understanding regarding the pay for performance program (ignorance), (3) inability to get the paperwork faxed on time (the incentive money was simply not enough to make signing the attestation important), or (4) they were in an employment situation whereby another entity would receive the bonus money. For employed QHPs, the inability to directly receive bonus money removed all incentive to report and for many others, the 2% bonus was not sufficient to warrant the time to read and return the signed agreement.

To understand what went wrong for PQRI/PQRS in wound care, it may be worth exploring the details of the venous ulcer measure as an example. The venous ulcer compression measure had well-written

supporting materials detailing the high-level evidence base for compression in the healing of venous ulcers and clearly defining adequate compression (*e.g.*, multilayer bandages, Unna's boots, 30 mmHg stockings, *etc.*). However, the measure itself (the rules that determine how information is reported) allowed any type of compression to pass (*e.g.*, TED hose, ace bandages), and the compression only had to be prescribed once in a 12 month period. It is important to know that the PQRS reporting process acknowledges that a justifiable reason might exist for not performing any particular measure. There may have been a medical reason for not providing compression (*e.g.*, concern over arterial status), the patient may have refused compression, or there might have been a systems reason (certain supplies were not available). If a justification was provided for not performing compression, the measure was passed. From 2009 to 2013 (the final year in which the venous measure was used), all of the wound care QHPs reporting PQRI/PQRS data through the USWR passed the venous ulcer measure. In other words, if the definition of quality for venous ulcer care is to provide any type of compression to the leg once, then every wound care QHP practiced quality venous care. However, USWR data have so far failed to show a link between the performance of this measure and the likelihood of healing, as compression should be provided repeatedly (*e.g.*, at each visit) in order to achieve healing.

When the venous ulcer measure was created, specifying the type of compression used and/or tracking the frequency of its provision at each visit were not feasible, as most QHPs were still using paper charts. The adoption of certified EHRs makes it feasible to develop "per visit" process measures. CMS would likely agree to use process measures if a direct link can be made between the process and improved patient outcome. Fortunately, peer reviewed literature supports the association between regular compliance with adequate compression and the healing of venous stasis ulcers. Sadly, published data from the USWR has demonstrated that even among hospital-based outpatient wound care departments, patients with venous stasis ulcers receive adequate compression at only 17% of patient visits. The USWR data are even more disappointing regarding the provision of adequate off-loading for diabetic foot ulcers.⁵ Thus, in the field of wound care, improved patient care may need to begin with the reporting of per visit process measures to address the demonstrated gap between actual practice and evidence-based practice guidelines.

Feasibility testing of wound care quality measures is already underway using the USWR's "Do

the Right Thing[™] initiative (www.uswoundregistry.com/index.aspx). For example, one wound care management company (Precision Healthcare, Boca Raton, FL) that reports data through the USWR decided to focus on compliance with a few core clinical practice guidelines (CPGs), specifically vascular screening of all leg ulcers, compression bandaging for venous ulcers, adequate off-loading of diabetic foot ulcers, nutritional assessment of pressure ulcers, and the provision of an adequate support surface for pressure ulcers. As an added incentive, the hospital system that employs the QHPs decided to base a portion of QHP compensation on their implementation of these quality measures, exactly the scenario that CMS hopes to create with PQRS and other initiatives.

When QHPs involved in the “Do the Right Thing” initiative began receiving weekly feedback with quality reports, clinician implementation of proper off-loading among diabetic foot ulcer patients improved from 11% to 69%. In addition, clinician performance of vascular screening for venous ulcer patients improved from 53% to 77%, and provision of adequate compression improved from 27% to 79%. Importantly, measures were selected that were evidence based, relevant to the patient, and under the direct control of the clinician. Documentation was done at the point of care by the QHP in a specialty-specific EHR that used structured language for data entry, making it easy for QHPs to document what they did (or why they did *not* perform an intervention), and easy to extract data for reporting purposes.

Registries for data reporting

A registry is an organized system that uses observational study methods to collect uniform data in order to evaluate specified outcomes for a population. The Agency for Healthcare Research and Quality has produced an excellent document to guide registry development,⁶ a topic beyond the scope of this article. Scientific, data integrity, administration, confidentiality, sources of bias, and Institutional Review Board requirements are necessary. Data can be obtained in many different ways. While the USWR extracts data directly from EHRs and then transforms it into the registry format, it is possible for the USWR to receive data from other sources. Such data assimilation requires interoperability based on open standards that enable any willing provider to interface with an applicable registry. Syntactic interoperability (ability to exchange data) and semantic interoperability (ability to understand exchanged data) should be present.

Some registries exist only for PQRS data submission, but current uses of registries include determining whether clinicians follow evidence-based CPGs (*e.g.*, the American Heart Association’s “Get With the GuidelinesSM” initiative in stroke⁷), to evaluate clinical/cost effectiveness of care, and to monitor safety (*e.g.*, Kaiser Permanente’s National Total Joint Replacement Registry⁸). Registries can focus attention on specific aspects of a particular disease and allow QHPs to compare themselves and their patient outcomes with their peers for quality improvement projects. Manufacturers use them to identify patient populations that would be useful for product development, to facilitate trial design, and to understand how their products are used in the real world. This is necessary, because many studies have demonstrated disparities between the results of a product in clinical trial and the results obtained in actual clinical practice.⁹ Payers use registry data for coverage determinations. For example, with funding from industry, The National Cardiovascular Data Registry (NCDR[®]) sponsored by the American College of Cardiology, developed the implantable cardioverter defibrillator (ICD) registry¹⁰ in response to a CMS coverage with evidence development (CED) decision. In addition, they layered quality improvement and research goals into the CMS mandate. The registry was rapidly integrated into more than 2000 institutions and if CMS decides that the ICD registry is no longer needed, the registry can continue as a quality improvement program.

Recently, Medicare issued the first CED relevant to wound care in its National Coverage Determination (NCD) for Autologous Blood-Derived Products for Chronic Non-Healing Wounds (CAG-00190R3).¹¹ Furthermore, at least one Medicare Administrative Contractor (MAC) has issued draft language, suggesting that charges for cellular and/or tissue-based products for wounds would not be reimbursed unless the clinicians report their data to a registry.¹² The decision states that MAC will consider the option of covering these products, “only when used within clinical trials or active participation in a formal Registry incorporating the reporting of services provided as well as ongoing outcomes data.” It is worth noting that registry participation is one of the mechanisms by which clinicians can fulfill their Stage 2 meaningful use incentives in 2015; so, the language in this NCD is not out of line with developing initiatives, even though this requirement may not be included in the final coverage decision. Thus, it is clear that clinical data registries are becoming integral to both federal quality initiatives (testing

as well as reporting) and reimbursement for certain procedures or products.

CONCLUSION

The current venous ulcer measure is going to be retired from PQRS after 2013, as no measure sponsor has indicated a willingness to provide the mandatory testing in the unlikely event that this particular measure would pass testing. In the early years of PQRI, untested measures were allowed into PQRI. However, CMS is unlikely to accept future measures that have not undergone proper testing and endorsement, usually by the NQF. Thus, in 2014, there will be no measure of quality treatment of venous or diabetic foot ulcers unless the wound care industry decides to create and test them. The NQF Website provides detailed information on the rigorous measures testing process.¹³ Several conditions should be met before proposed measures are accepted even for consideration. If all conditions for consideration are met, candidate measures are evaluated for their suitability based on five sets of standardized criteria: importance, scientific acceptability, properties, usability, and feasibility. The endorsement process usually takes a year or more, and NQF endorsement alone does not ensure that CMS will select a measure for PQRS or any other quality program.

The measures testing process is evolving, because in the past, it was necessary to ensure that measures could be reported equally well via paper forms or via a qualified registry. CMS hopes that new measures will be developed as e-measures that are, in essence, the specifications of computer queries which enable transmission of data directly from the QHP's EHR to CMS. If measures similar to the USWR "Do The Right Thing" initiative were undergoing formal testing for NQF endorsement, it would be necessary to determine whether their performance leads to better patient outcomes (e.g., healing, or avoidance of, major amputation). Most measures, which fail the endorsement process, usually do so as a result of lack of a sufficient evidence base. Fortunately, many interventions in wound care have an evidence base that is sufficient to consider them for wound care quality measures. In addition to PQRS, registry reporting will likely be necessary to fulfill CMS requirements for HITECH bonus money and perhaps to ensure reimbursement for certain wound care services. It is clear that the lack of suitable wound care quality measures threatens the survival of wound care QHPs and services. Many specialty societies have partnered with industry to defray the cost of measure

development. Stakeholders in the wound care industry need a collaborative approach to the selection, creation, validation, and testing of an entire suite of quality measures (preferably electronically reported) so that wound care will not be left behind in the transition to a value-based healthcare system.

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Abbreviations and Acronyms

AAPS = American Academy of Plastic Surgery
 ACA = Affordable Care Act
 AMA = American Medical Association
 CED = coverage with evidence development
 CMS = Centers for Medicare & Medicaid Services
 CPG = clinical practice guidelines
 EHR = electronic health record
 EP = eligible provider
 HITECH = Health Information Technology for Economic and Clinical Health
 ICD = implantable cardioverter defibrillator
 IRC = Intellicure Research Consortium
 MAC = Medicare Administrative Contractor
 MIPAA = Medicare Improvements for Patients and Providers Act
 NCD = National Coverage Determination
 NCDR = National Cardiovascular Data Registry
 NQF = National Quality Forum
 PCPI = Physician Consortium for Performance Improvement
 PQRI = Physician Quality Reporting Initiative
 PQRS = Physician Quality Reporting System
 QHP = qualified healthcare professional
 TRHCA = Tax Relief and Health Care Act
 USWR = U.S. Wound Registry