Technical Communication

The Hyperbaric Oxygen Therapy Registry: Driving quality and demonstrating compliance

Caroline E. Fife, MD 1,2; Kristen A. Eckert, MPhil 3

1 Baylor College of Medicine, Houston, Texas U.S.
2 The US Wound Registry, The Woodlands, Texas U.S.
3 TeamHealth 3Strategic Solutions Inc., Cody, Wyoming U.S.

CORRESPONDING AUTHOR: Caroline E. Fife – cfife@uswoundregistry.com

ABSTRACT

Objective: To provide an update on the status of provider participation in the US Wound Registry (USWR) and its specialty registry the Hyperbaric Oxygen Therapy Registry (HBOTR), which provide much-needed national benchmarking and quality measurement services for hyperbaric medicine.

Methods: Providers can meet many requirements of the Merit-Based Incentive Payment System (MIPS) and simultaneously participate in the HBOTR by transmitting Continuity of Care Documents (CCDs) directly from their certified electronic health record (EHR) or by reporting hyperbaric quality measures, the specifications for which are available free of charge for download from the registry website as electronic clinical quality measures for installation into any certified EHR. Computerized systems parse the structured data transmitted to the USWR. Patients undergoing hyperbaric oxygen (HBO₂) therapy are allocated to the HBOTR and stored in that specialty registry database. The data can be queried for benchmarking, quality reporting, public policy, or specialized data projects.

Results: Since January 2012, 917,758 clinic visits have captured the data of 199,158 patients in the USWR, 3,697 of whom underwent HBO₂ therapy. Among 27,404 patients with 62,843 diabetic foot ulcers (DFUs) captured, 9,908 DFUs (15.7%) were treated with HBO₂ therapy. Between January 2016 and September 2017, the benchmark rate for the 1,000 DFUs treated with HBO₂ was 7.3%, with an average of 28 treatments per patient. There are 2,100 providers who report data to the USWR by transmitting CCDs from their EHR and 688 who submit quality measure data, 300 (43.6%) of whom transmit HBO₂ quality data.

INTRODUCTION

Hyperbaric medicine practitioners are under unprecedented scrutiny to demonstrate their compliance with Medicare coverage policy, their adherence to clinical practice guidelines, and the clinical effectiveness of hyperbaric oxygen (HBO₂) therapy, all of which can be achieved by participating in a Qualified Clinical Data Registry (QCDR). Fraud and abuse may account for more than 30% of Medicare’s budget, with yet more wasted from inappropriate use, because evidence-based guidelines are followed only about half of the time [1]. It is hoped that widespread adoption of health information technology will help to reduce waste, improve compliance, and identify fraud, enabling the new Quality Payment Program (QPP) to improve value through quality reporting and practice improvement. Clinical data registries are the means by which the Centers for Medicare and Medicaid Services (CMS) hopes to partner with clinicians to achieve these goals. It is no coincidence that the pace of health care payment reform gained momentum after the 2009 passage of the HITECH Act (Health Information Technology for Economic and Clinical Health), as demonstrated by the timeline in Figure 1. As practitioners and hospitals in the United States were compelled to purchase and use certified electronic health records (EHRs) in specific

KEYWORDS: HBO₂ therapy; registry; electronic health records; quality measure; QCDR; benchmarking
Establishment of the Intellicure Research Consortium and its registry

CMS created “Qualified Data Registries,” and the IRC is among the first 32 recognized for PQRI/PQRS quality reporting

Value-Based Modifier created by the passage of the ACA to adjust payments based on quality of care and performance in alignment with PQRS

Intellicure, Inc (The Woodlands, TX) funded a 501(c)(3) nonprofit organization called the Chronic Disease Registry, doing business as the USWR, so that hyperbaric medicine and wound care practitioners could report to a registry regardless of EHR vendor

PQRS (then known as PQRI) initiated as a “pay for performance” program to provide providers with financial incentives to report quality data

Passage of the HITECH ACT

EHR Incentive Programs established to promote MU (Stage 1) of certified EHR technology

CMS recognized the USWR as a QCDR along with 14 QCDR quality measures

PQRS began to issue a negative payment adjustment to eligible providers and practices who did not satisfactorily report quality measure data

Stage 2 MU began mandating that providers transmit data from their EHR to a specialty registry to avoid a 2% negative payment adjustment

Last year of PQRS, which transitioned to MIPS under the OPP

CMS recognized the USWR among the first MIPS registries and approved hyperbaric quality measures developed with UHMS among its QCDR measures

UHMS and the USWR developed hyperbaric-specific quality measures, including risk-stratified outcome measures and an appropriate use measure

USWR sponsored the HBOTR to enable hyperbaric practitioners to meet MU requirements via CCD transmission

First year of MIPS under which providers earn a payment adjustment by reporting quality measures (replacing PQRS), improvement activities, Advancing Care Information (replacing MU), and cost (replacing Value-Based Modifier)

Passage of MACRA, which created the OPP

UHMS and the USWR developed hyperbaric-specific quality measures, including risk-stratified outcome measures and an appropriate use measure

USWR sponsored the HBOTR to enable hyperbaric practitioners to meet MU requirements via CCD transmission

First year of MIPS under which providers earn a payment adjustment by reporting quality measures (replacing PQRS), improvement activities, Advancing Care Information (replacing MU), and cost (replacing Value-Based Modifier)
ways, CMS transitioned optional incentive programs into mandatory ones. This culminated in the QPP, which began on January 1, 2017 [2]. Most practitioners are now subject to the Merit-Based Incentive Payment System (MIPS) and its various reporting requirements, which are facilitated by participation in QCDRs and enabled by the EHRs most have already adopted.

Clinicians willingly participate in registries whenever substantial reimbursement is tied to participation (e.g., implanted defibrillators, venous ablation, prosthetic joints, stroke, and trauma center recognition) [3]. Registries created by some specialties (e.g., cardiology and orthopedic surgery) have received ample funding from the device and drug manufacturers wishing to utilize their data. This symbiotic relationship with industry defrays the cost of providing registry services to clinicians, which can easily require millions of dollars per year, in part to cover the outsourcing of the highly technical services required to calculate quality measure data and transmit it to CMS in a secure fashion on their behalf.

Hyperbaric medicine practitioners lack regulatory mandates to drive registry participation. The subspecialty of Undersea and Hyperbaric Medicine (UHM) attracts no significant financial support from industry. HBO2 therapy has, however, attracted the scrutiny of the Office of the Inspector General (OIG), which analyzed Medicare claims from 1995 to 1998 and concluded that nearly 32% of patients received HBO2 for non-covered conditions or with inadequate documentation to justify it, and another 37% received questionable quality care due to the lack of appropriate testing or insufficient documentation [4]. It is possible to draw a direct line from the unfavorable 2000 OIG report to Medicare’s “specialty registry” via direct transmission of patient data from the providers’ EHR [10]. The USWR sponsored the Hyperbaric Oxygen Therapy Registry (HBOTR) to enable hyperbaric practitioners to meet MU requirements simply via the transmission of Continuity of Care

FIGURE 1 legend.
ACA = Patient Protection and Affordable Care Act; CCD = Continuity of Care Document; CMS = The Centers for Medicare and Medicaid Services; EHR = electronic health record; HBOTR = Hyperbaric Oxygen Therapy Registry; HITECH = Health Information Technology for Economic and Clinical Health; MACRA = The Medicare Access and CHIP Reauthorization Act of 2015; MIPS = Merit-based Incentive Payment System; MU = Meaningful Use; PQRI = Physician Quality Reporting Initiative; PORS = Physician Quality Reporting System; QCDR = Qualified Clinical Data Registry; OPP = Quality Payment Program; UHMS = Undersea and Hyperbaric Medical Society; USWR = US Wound Registry
Documents (CCDs) (Figure 1). All EHRs must be able to transmit CCDs as a condition of certification. This information summary represents an efficient and increasingly popular method of specialty registry enrollment, because it does not require any laborious secondary data entry. In June 2017, the USWR was among the first MIPS registries recognized by CMS [11], which also approved four UHMS-developed hyperbaric quality measures as QCQDR measures [9,11] (Figure 1). This technical report is an update on the status of provider participation in the USWR and its specialty registry the HBOTR, which leverages mandatory reporting requirements to provide much-needed national benchmarking and quality measurement services for the subspecialty of UHM.

METHODS
The HBOTR (via the USWR) harnesses the requirements of MIPS to automate registry data submission directly from any certified EHR so that no secondary data entry is required, enabling a viable and enduring hyperbaric specialty registry despite the absence of a monetary incentive to participate in one and the absence of the funding model that exists in other specialties [10]. A complete description of how the USWR harnesses EHR data to fulfill quality reporting requirements was recently published [3]. Computerized systems parse the structured clinical data accrued at point of care, which are transmitted to the USWR and stored in one or more of the appropriate specialty registry databases. Patients undergoing HBO2 therapy are allocated to the HBOTR, which can be queried for benchmarking, quality reporting, public policy, or specialized data projects. An independent institutional review board (The Woodlands IRB) reviews data use proposals and ensures protection of health information.

To ensure that hyperbaric quality measures could be submitted by any certified EHR and that the program is thus vendor-neutral, the USWR programmed all hyperbaric quality measures as electronic clinical quality measures (eCQMs) and posted the specifications open source for free download and installation [9]. A conservative estimate for programming a single eCQM is approximately $95,000 [Victoria Polich, Telligen, email communication, October 18, 2013]. In 2014, the UHMS provided the USWR with a one-time grant of $30,000 to defray the cost of developing hyperbaric quality measures. The USWR provided the remainder of the funding for the six original HBO2 eCQMs, all of which were accepted by CMS for reporting under HBO2 PQRS in 2014, although only some hyperbaric measures were accepted by CMS for reporting under MIPS in 2017. The UHMS provides no ongoing financial support for the USWR or the HBOTR, which are funded only by the nominal fees paid by practitioners to satisfy various Medicare quality reporting mandates. The following HBO2-specific quality measures were approved by CMS in 2017 for reporting through the USWR [12]:

- Appropriate use of HBO2 for DFUs, a measure which includes:
  - having a Wagner Grade 3 or higher lesion;
  - failure to achieve more than 30% wound closure over four weeks of care;
  - documented offloading at each visit over four weeks;
  - arterial vascular screening of leg ulcer patients once every 12 months;
  - nutritional screening of patients with leg ulcers.
- Blood glucose assessment in diabetics prior to HBO2, and vital sign assessment among all patients prior to HBO2 treatment.
- Wound healing or closure of Wagner Grade 3, 4 or 5 DFUs after HBO2 treatments [risk-stratified by the Wound Healing Index (WHI)].
- Major amputation (above the ankle) among patients with Wagner 3, 4, or 5 DFUs after HBO2 treatment (risk-stratified by the WHI) [9].

Providers can demonstrate their compliance with the highest possible standards of hyperbaric practice and report these quality measures for credit under MIPS via eCQMs installed in their EHR. However, because EHR vendors have created barriers to the installation of eCQMs, currently the most common method of participation in the HBOTR is the transmission of CCDs, which the USWR receives from a variety of EHR vendors and which provide detailed, structured data on patients including:

- all comorbid diagnoses: structured using the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM);
- procedures: structured using Current Procedural Terminology (CPT);
- medications and allergies: structured using RxNorm;
• laboratory results and vital signs: structured using LOINC, the Logical Observation Identifiers Names and Codes;
• demographics: structured using the Systematized Nomenclature of Medicine (SNOMED) [3].

RESULTS

Transmission of CCDs to the USWR/HBOTR from any certified EHR

Since January 2012, 917,758 clinic visits have captured the data of 199,158 patients, 3,697 of whom have undergone HBO2 therapy. The top three conditions treated with HBO2 have been DFUs, radionecrosis (e.g., late effects of radiation), and osteomyelitis. There have been 27,404 patients with 62,843 DFUs captured in the USWR, of which 9,908 DFUs (15.7%) were treated with HBO2. Between January 2016 and September 2017, the benchmark rate for 1,000 DFUs treated with HBO2 was 7.33%, with an average of 28 treatments per patient. As a result of the Stage 2 MU mandate of 2016, 2,100 providers now report data to the USWR by transmitting CCDs from their EHR.

There are many ways to use HBOTR CCD data in research and to improve quality of care and compliance at the provider and practice level. HBOTR data were recently used in an evaluation of the physician work involved in monitoring patients undergoing HBO2 treatment, which was presented to the American Medical Association/Specialty Society Relative Value Scale Update Committee (AMA-RUC) to understand the complexity of these patients and help determine the updated reimbursement rate of physician hyperbaric chamber supervision [10]. We demonstrated that the average HBO2 patient has 10 comorbid conditions and takes 12 medications. This report was previously published by Undersea and Hyperbaric Medicine, and the project is credited with preventing a substantial decrease in the reimbursement rate of hyperbaric chamber supervision [10].

Other research possibilities include:
• the generation of reports for hyperbaric facility accreditation containing diagnoses treated with HBO2 and patient count;
• the identification of Hierarchical Condition Category of patients undergoing HBO2;
• the comparison of individual practitioner performance of specific metrics with national benchmark standards (e.g., debridements by provider) [3];
• tracking the volume of interventions compared to benchmark (e.g., number of HBO2 treatments per diagnosis) [3].

Reporting of quality measures (including eCQM transmission)

At present, a total of 688 providers are submitting quality measure data to the USWR, 300 (43.6%) of whom transmit data on HBO2 quality, demonstrating that a sizable proportion of USWR participants are also contributing to the HBOTR. At this time, the USWR/HBOTR is the only registry available that aims to improve the quality of care provided to patients of wound care and hyperbaric medicine via public reporting of benchmark rates. Among 103 clinics that participate in the HBOTR by reporting quality measure data, there are 2,512 patients with 4,203 DFUs who have undergone HBO2 treatment. The reported rate of arterial testing documented among these patients with DFUs is very high at 85% (2,138 tests/2,512 patients). However, only 31% of patients with DFUs (778) have adequate offloading documented at each visit, while just over half (52.7%; 1,325 patients) have their HgA1c documented. These data do not mean that only half of the patients have their HgA1c checked or that only one-third receive regular offloading; it merely indicates that some documentation on these interventions is lacking. However, given the rapid expansion of HBO2 prepayment review and the likely expansion of HBO2 prior authorization programs, both of which necessitate the religious documentation of A1C and offloading (among other aspects of care) in order to support the medical necessity of HBO2, clinicians can use quality measure performance to identify the areas where improvement is needed to withstand the scrutiny of these programs.

HBOTR data also suggest that reporting quality data to CMS may improve the quality of care actually provided to patients. For example, among practitioners who reported the arterial screening measure to CMS in 2016, the average performance rate was 69% compared to 25.7% for those who did not report this measure. While it is possible that non-reporters were simply less likely to document arterial screening, the dramatic difference between reporters and non-reporters suggests a real difference in the patient care provided and that quality measure reporting drives quality of care. That is certainly the premise of the QPP program.
As with the transmission of CCDs, the quality measures collected via the USWR/HBOTR can be used in a variety of research projects. Our previous publication establishing standards for wound registry data in clinical research provides greater detail regarding the types of projects performed to date using USWR data [3], which are also possible with HBOTR data. Possibilities include:

- comparative effectiveness of HBO2 research;
- the comparison of a risk-stratified healing rate compared to a predicted healing rate;
- the generation of benchmarking reports and performance improvement (e.g., “Do the Right Thing™” quality initiative) [3];
- the creation of a facility acuity score [3,13];
- the creation of a provider performance dashboard linked to quality measures and performance metrics for each quality indicator.

DISCUSSION

A QCDR is a CMS-approved entity that collects medical and/or clinical data for the purpose of patient and disease tracking in order to foster improvement in the quality of patient care. Many clinicians participate in the USWR simply by transmitting CCDs. Even though CCDs do not contain outcome information, their structured data are highly valuable. For example, comorbid conditions can be used to identify the Hierarchical Condition Category of hyperbaric patients. This can profoundly impact reimbursement under a variety of payment arrangements. CMS is encouraging clinicians to engage with QCDRs that compare their performance with national benchmark standards as part of Clinical Practice Improvement Activities (CPIAs). The availability of national benchmarking may become increasingly important as various federal agencies increase their scrutiny of HBO2 therapy and wound care practices. Registries offering national benchmarking can enable providers convicted of Medicare fraud to continue participating in that federal program. The goal of an enforcement tool like a Corporate Integrity Agreement is to improve both quality of patient care and compliance with health care regulations by performing internal audits as part of systematic Quality Performance Improvement Projects. To accomplish this, providers are generally required to submit data to a relevant registry, which enables benchmarking against the national aggregate, monitoring risk-adjusted patient outcomes, the creation of quality dashboards, and the identification of quality improvement goals. The USWR can provide benchmarking for many types of interventions relevant to wound care and hyperbaric medicine using only CCDs (e.g., number of debridements per patient, number of hyperbaric treatments per indication, comorbid conditions recorded per patient, etc.). This is a highly efficient method of participation in benchmarking since it requires no secondary data entry, is achievable with any certified EHR, can be performed remotely, and is very difficult to manipulate at the point of transmission. Examples have been provided in Figure 2 using HBOTR data.

Participation in the USWR QCDR is a way for providers to earn a positive payment adjustment under MIPS [3]. Practitioners receive bonus points for participating in CPIAs that involve national benchmarking, electronically submitting data to a specialty registry like the HBOTR, and reporting certain high-value quality measures (e.g., the risk-stratified outcome and appropriate use measures for HBO2), which can translate to bonus money experienced as a percentage of the provider’s billed Medicare Part B payments. Reporting wound care and hyperbaric-specific quality measures also has specialty-specific dividends. For example, reporting the quality measure “Appropriate Use of Hyperbaric Oxygen Therapy for DFUs” allows practitioners to assess the likely impact of HBO2 prior authorization on a clinical hyperbaric program. Clinicians reporting QCDR quality measures can create a dashboard for provider performance linked to quality measures, and the USWR can provide performance metrics for each quality indicator. A common criticism of process measures such as offloading or vascular screening is that they measure, in part, documentation compliance. However, for providers to successfully navigate both HBO2 prior authorization and prepayment review, optimal appropriate patient care must be both provided and documented. Engaging this process via an “appropriate use” quality measure merely imposes structure to the required documentation and may increase the likelihood of success with these programs. The HBOTR currently has nearly 3,700 patients who have undergone HBO2 and whose wounds can be risk-stratified using the WHI, allowing the creation of matched cohorts who did not receive HBO2 for whom structured data are available on all comorbid diseases, medications, physical findings, interventions, procedures and outcomes, and in whom it is possible to standardize care
using relevant quality measure data. When the data in CCDs are combined with risk-stratified outcomes, it is possible to perform cost-effectiveness studies that do not suffer from the weaknesses of previous analyses [3,6,8,11].

Only 16.2% of specialty medical societies have a registry in operation for their members to meet the mandatory reporting requirements of MIPS and MU [14]. Only about a quarter of the existing specialty registries receive independent federal funding, which means the majority are supported by society dues, industry grants, and the fees paid by participating clinicians. Thus, it seems the challenges of fostering a registry and engaging with MIPS are not unique to the field of hyperbaric medicine. The HBOTR, through the USWR, offers a solution to specialty registry reporting for hyperbaric medicine practitioners. This vast repository of data on hyperbaric patients was created without any funding, by leveraging the requirements of data transmission under PQRS and now MIPS, as well as MU. In the absence of a funding model, practitioners need to leverage the QPP to drive quality improvement and demonstrate compliance by participating in the HBOTR. It is worth noting that in its 2000 report, the OIG recommended the creation of a hyperbaric registry [4]. Participation in the USWR QCDR, if only via CCD transmission, can enable national benchmarking and Corporate Integrity Programs for providers and organizations, activities for which there is likely to be increased demand.

The identifier for the HBOTR on ClinicalTrials.gov is NCT02483650.

Acknowledgments
This manuscript was funded by the US Wound Registry.

Fife CE, Eckert KA
REFERENCES


