# MACRA Match-up: How EHR Source Data Will Benefit Registry Research

written by Thomas Dent, M.D. | July 20, 2016

At the core of MACRA and MIPS requirements, Electronic Health Record (EHR) source data will soon become a key component for Registry research. Specifically, Clinical Performance Improvement Activities (CPIAs) are a required component of MIPS. Performance improvement efforts will no longer be optional. Quality data will be essential.

EHRs present an excellent data resource, but the data is not flawless. Registries are well suited for validating data and assessing performance using a continuous improvement model—testing an idea by changing a practice and measuring its impact. When done on a small scale, testing performance improvement activities and the feasibility of population-based interventions can provide valuable insights, identify corrective actions and save time and resources before implementing large scale interventions.

For EHR data to be used effectively, it will be necessary to strengthen that technology's distinctiveness from other HIT, rather than blurring functions. An EHR is an excellent resource to house patient data, reminders and patient-specific analytics. Registries, on the other hand, are better focused on actions and interventions across patient populations. Quality measures and performance are their unique expertise; blending these into EHR functions muddies the water and deviates from the true strengths of an EHR. Here we address how best to organize EHR data for consumption in research and performance improvement.

## How Are EHRs Best Used for Clinical Investigations?

Recently the FDA released a document that updates guidance for how to properly transfer information from EHRs into electronic case report forms (eCRFs) for clinical investigations.

Electronic transfer reduces data collection errors that may otherwise be introduced when hand-entering data from paper records. It is essential that research data be verifiable for quality and integrity.

These data collection guidelines have an acronym, ALCOA, a mnemonic for Attributable, Legible, Contemporaneous, Original and Accurate. Here is how these FDA principles may apply to a Registry:

Attributable: There is a record of who entered the data or the data's source. This is a basic function of an EHR and essential for an audit trail.

For a Registry that addresses performance and utilization measurement, attribution of patients and services to providers is essential for determining responsibility for patient care and addressing data results. The place and time of the data source must also be linked to the single data source

Legible: Electronic data and metadata can be read by humans; modifications should not obscure prior entries (legibility is usually not an issue with EHRs).

For a Registry, legibility translates into the capture of complete data. Integrating data from multiple sources is a responsibility some Registries assume; this collated data must be captured " as is" without modification.

Contemporaneous: The time of data entry into the eCRF should be close to the time of clinical activity.

For a Registry, identifying the timing of data is crucial (e.g. whether the clinical activity occurred within the parameters of performance measurement).
The timing of an action's occurrence (e.g. when a performance intervention started) must be included in order to assess and visualize the outcome results.
Recording the timing of an action's occurrence may also be a check on validity. Consider the true case of faulty pain scores entered in one Registry: for 10 percent of the patients, dual scores were entered at the same time for the same individuals with widely varying data, in some instances up to a full 10 pain score points.

Original: Data must include earliest records; changes and/or corrections should not obscure prior entries.

Performance assessment and improvement depend on the Registry having all the data, not just what may look good. At ICLOPS, we encountered a measure of performance (colorectal cancer screening) whose result was over-ridden at more current visits by a different result designed to satisfy reporting criteria (not the real

performance criteria of whether the screening had occurred). This served only to sidestep the question of performance improvement, rather than provide useful information.

Accurate: Data should be a valid representation of the source data; corrections should be documented. Quality control measures and processes are essential.

For both Registries and research entities, data validation is a requirement. This is of great importance when outcomes are being reported.

*(Note: An earlier Webinar provided more information on the FDA guidelines on EHR source data for research.)*

Research is the future of performance measurement. EHRs providing source data for both present and future needs must be ONC certified (the Office of the National Coordinator—the folks who set the standards for EHRs). Working with EHRs to measure provider performance and improvement efforts gives us insight into using EHR source data. The future of both research trials and pay-for-performance depends upon quality EHR data that conforms with the ALCOA standards.

## Using PDSA Cycles for Performance Improvement and Hypothesis Generation

One of the primary uses for EHR data should be to improve performance. Starting with an organization's quality staff, and supported by medical leadership, Plan-Do-Study-Act (PDSA) cycles allow study of improvement through repeat iterations of performance activities. It's best to start out with micro-interventions of one or two patients, which lessen the risk of misadventure and increase learning across the organization. These PDSA cycles generate hypotheses about what interventions are suitable for total population-based research efforts.

The Registry, with validated EHR data, should produce run-time charts of relevant outcomes, giving an overview of the outcome history. This is part of the planning and study processes of the PDSA cycle. The planning stage should ascertain that the outcome has been stable over time to ensure that variations around the mean aren't interpreted as improvement (or worsening) of the outcome results. If the anticipated intervention is to involve patients with significant variance (e.g. patients with a great improvement or worsening in LDL and HgbA1C levels), this caveat does not apply. In either case, a sufficient history of outcomes is necessary for the research to be of value.

According to Berwick and, before him, Werner and McNutt, quality improvement science offers an alternative to the anger and confusion of current inspection, reward and punishment activities. I agree with that assessment and believe that CPIAs offer a great opportunity for

provider and patient engagement and, ultimately, improved care.

## EHRs and Registries Should Collaborate Rather than Replicate Functions

EHRs are the tools of clinicians for managing individual patients' health care. Registries are the tools of those responsible for managing and improving quality and utilization. They perform complementary functions and should be used in tandem.

Both are needed to help solve the basic problem in health care: No one has the final answer to what "works," so research is required. We need quality data from EHRs, validated and employed by Registries to conduct performance improvement research that tests interventions. Techniques and processes must be studied as hypotheses and "proven." Engaging both clinicians and patients in this research is the great challenge for those in quality positions, who stand outside the patient-provider dyad. The Registry is essential to this process.

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