How to Harness Clinical Data Registry Power to Improve Outcomes

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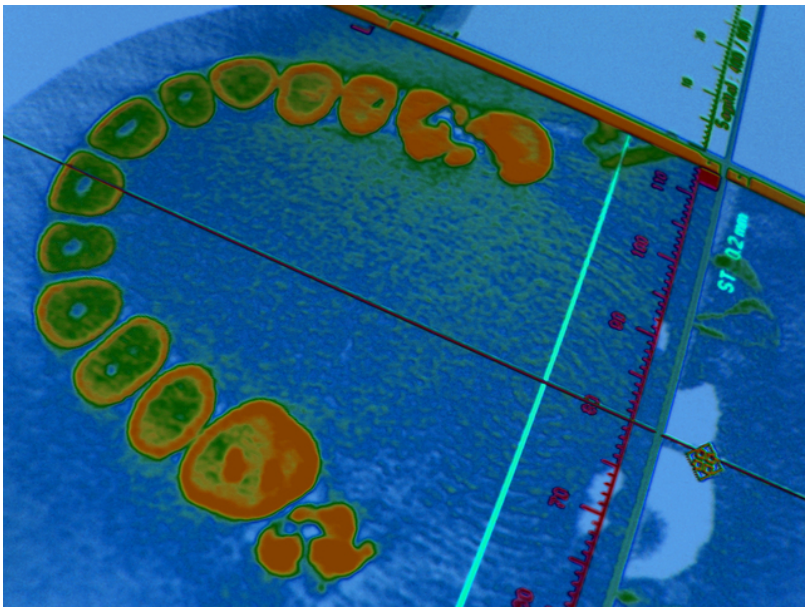

At the center of Medicare's Value-Based Health Care, the Clinical Data Registry (CDR) is introducing new possibilities for outcomes improvement. Under this month's final rules, Medicare expanded the role of Specialized Registry and Clinical Data Registry reporting in its future Meaningful Use program. Specifically, CMS initiated provider reporting to a "Specialized Registry" in 2015 as an option to meet Stage 2 requirements, while establishing the CDR as the future avenue for capturing outcome data over time.

The question now is: *How* can we use a CDR to improve patient health? Some providers may "check the box" on Meaningful Use objectives by reporting to a Specialized Registry (later CDR), but others will see the opportunity to use the large mass of gathered data to do important research.

As CDRs and other large data sets become commonplace, number crunching will lead to associations between variables. The identified patient data in a CDR will allow for a more complete picture of how patients fare under varied circumstances of clinical characteristics and use of medical resources. However, associations are not enough to improve outcomes because they are relationships, but not necessarily cause-and-effect. Only experiments can be used to determine what improves care. Using a CDR for those experiments will be much more likely to advance care—and the science of improving outcomes. Here are our thoughts on how that should happen:

There's a Difference Between Observations and Experiments

There are two types of comparison data: observational and experimental. Observational data are just that, observations of patients, their medical care choices and their outcomes. Patients

have different life experiences, have different clinical characteristics and will experience different medical tests and treatments. Most of all, patients will have different outcomes.

Researchers examining these data sets use techniques to equalize, as best they can, differences in peoples' clinical characteristics, to determine if one kind of medical care serves patients better than other kinds. Observational data, then, describe differences between people who are treated one way versus another and indicate if the noted differences in observed outcomes are due to the different treatments.

But observational data are insufficient to know how to improve care. It's difficult to determine if one treatment is better than another when people are free to chose from a plethora of tests and treatments, and when physicians and health systems are free to prescribe at will. There are numerous examples of mistakes in care due to choosing tests and treatments based on observational data. Estrogen use in women is just one example. Observational data suggested that women using estrogens had better outcomes. When experiments were conducted rather than observational studies, however, the observed better outcomes with estrogen use not only disappeared—they actually reversed.

Four Ways to Experiment Through a CDR

Experiments improve inferences from CDR data for two main reasons. First, experiments limit the number of medical options available, and second, experiments balance potential predicting variables between compared groups of patients. There are four types of experiments:

1. Pre/Post Time Series Trial

These experiments are commonplace in quality improvement. For example, a health system decides to become a "medical home" and then compares patient outcomes prior to and after being designated. In one study, an intensive quality improvement project/intervention was conducted pre and post at five hospitals. Patient outcomes (hospital readmissions, length of stay) improved in the post-time period and the project was deemed successful.

However, later, the authors compared a like group of hospitals without the quality improvement project and found the same amount of improvement over time in the no-treatment group of hospitals. Hence, the intervention was not the cause of improvement; rather, the relentless advance of improving care in general was the underlying cause of the change. Pre/post design studies are weak experiments, as appropriate control populations are difficult to obtain and compare.

2. N-of-1 Clinical Trial

This trial is the most powerful study design for research at the individual level. In this type of study, a patient is both the treatment and control group. A patient receives a treatment and outcomes are measured. After a time, the patient takes another treatment and, again, outcomes are measured. The patient and the physician are unaware what the treatments are. At the end of the experiment, the patient and physician are shown the study drugs and results.

These individual patient trials find differences in how people respond to agents. For example, studies in groups of patients found that acetaminophen and non-steroidal agents were no different in terms of reducing pain in groups of patients with osteoarthritis of the knee. Hence, based on this trial's result, the cheaper, least expensive treatment would be best on average for all patients. When this trial was repeated using an N-of-1 design, however, about 50 percent of patients were better on one or the other treatments. Thus, N-of-1 trials help individuals and always maximize both individual and population outcomes. These trials are difficult to do on populations of patients, however.

3. Randomized Controlled Trial (RCT)

In this experiment, patients are invited to be in a study and then randomized to one treatment or another. The RCT limits the number of treatments by proscribing what patients will receive. The randomization, likewise, attempts to balance clinical factors that may influence the relationship between the treatments and outcomes. RCTs are important clinical trial designs and are a standard of cause-effect research. However, RCTs have limitations, in that they are expensive, time consuming, take too long to gain and report insights, and may study too limited numbers and types of patients.

4. N-of-1 Population-based Trial

In an N-of-1 population-based trial, a CDR is used with a full population of patients. The CDR collates and presents data over time on important clinical outcomes for all patients. Typically, a practice group's or system's patient population has stable outcome percents over time. For example, the average and range of A1C levels vary little over time for all diabetic patients cared for by a practice group.

With stable outcome data in a CDR, a practice group may apply a treatment or quality improvement effort for all patients in the CDR. Outcome changes can be tracked pre- and post-intervention in all patients. A practice group may then change the intervention, again on the entire population, and watch for changes in outcomes. The advantages of these trials are that a limited set of treatments may be tried, outcome data is already available, the entire population of patients can be evaluated and, most importantly, like the N-of-1 individual patient trials, the

population serves as its own control group. There are advantages and disadvantages of the RCT and the N-of-1 population-based clinical trials that go beyond the scope of this post.

Experiments Will Tell The Real Story

The future of medical care is in answers to research questions. We believe that our medical systems will move from asking us simply to report pre-defined measures of quality, to asking us to prove that we can get better at providing quality. Quality and cost-of-care reports will ultimately require comparisons to show/prove that we are better than we used to be, or better than others. The only meaningful comparisons, however, will be done with thoughtfully conceptualized experiments.

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