How to Use a Registry to Evaluate Techniques and Evaluate Tests of Change

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“How every hospital should follow every patient it treats long enough to determine whether the treatment has been successful, and then to inquire ‘if not, why not’ with a view to preventing similar failures in the future” - Ernest Amory Codman 1914

Wide variation in Cardiopulmonary bypass (CPB) practice exists across cardiac centers. This variation is relate to many factors, to a large extent it is related to cultural attributes such as local practice patterns, the practices at the institution where clinicians obtained their training, and historical preference. New techniques are reported in the peer-reviewed literature frequently. The pace with which these techniques are adopted is variable. Today’s presentations in this session on types of CPB systems exemplifies wildly divergent approaches. Clinicians have a moral obligation to examine the care that they provide to patients and determine how well that care compares to the current best evidence. Dissemination of new knowledge has always been challenging. Even after it was shown that citrus fruits prevent scurvy, it took the British Navy 264 years for citrus fruits to be widely adopted to prevent scurvy in sailors. More recently, Pronovost and colleagues showed the tremendous value of implementing a simple bundle of proven practices related to central line placement that produced a significant reduction in infections, reduced costs, and mortality. Berry and colleagues in a similar way translated 20 evidence based guidelines related to CABG into 40 measureable process variables in their cardiac program.

A registry provides a useful means to measure care locally and to leverage the natural variation that exists across centers by examining practice patterns. Such examination may be used, to validate or dismiss recent innovations. Measure of both process variables and patient outcomes should be considered. A registry may also be used to measure local adherence to published guidelines. Variation in outcomes across centers may be used to discover positive deviance that may be used to discover attributes of local practices that may be associated with superior care.

The Northern New England Cardiovascular Disease Study Group exists to develop and exchange information concerning the treatment of cardiovascular disease. It is a regional, voluntary, multi-disciplinary group of clinicians, hospital administrators, and health care research personnel who seek to improve continuously the quality, safety, effectiveness, and cost of medical interventions in cardiovascular disease. The NNE has registries that include procedures from cardiac centers in VT, NH and ME. Specific registries exist for every one of the following procedures performed in the member states- Percutaneous coronary interventions, cardiac surgery, cardiac anesthesia, and cardiovascular perfusion- for more than 200,000 procedures to date. Captured data is routinely validated by NNE Data Base Managers against hospital billing and discharge records.
This information is valuable for clinicians as they reflect on their practices and may be helpful as new knowledge emerges from clinical trials. For example, in July of 2009 Lopes and colleagues reported that endovascular vein harvest is independently associated with vein-graft failure and adverse clinical outcomes. These reported findings resulted in news headlines across the country. Using our surgical registry, we were able to test their hypothesis against actual patient outcomes in Northern New England. Upon review of more than 10,000 procedures in Northern New England we found no such association.

In 2008 perfusionists from the NNE Group New reported the rate of compliance to published guidelines from Shann and colleagues (see appendix 1). The NNECDSG regional perfusion group has committed to track performance longitudinally around published recommendations and feed the information back to the centers.

In areas where practice deviates from the evidence base, regional quality improvement projects are developed to reduce this gap. Regular reports are generated to examine this gap and to document improvement in performance and to also determine if the improvement is sustained. The registries are valuable in that practice patterns are documented along with clinical outcomes. The perfusion registry has been used to study the relationship between anemia and low output failure and mortality, temperature management during CPB and adverse outcomes, and to assess the effectiveness of a regional quality improvement effort around temperature management during CPB.

Other prospective registries exist such as New York State, the Society of Thoracic Surgeons. Historically, these registries have been invaluable tools for local performance improvement by providing participating centers with benchmarks for many outcome and process measures. Reports generated from these registries over the last two decades and subsequent performance improvement work are largely credited for the reduction in mortality secondary to CABG surgery. Unfortunately these registries do not contain specific information related to CPB techniques. Recently the STS congenital database has been updated to include more variables related to CPB complications and CPB process variables.

The International Consortium of Evidence Based Perfusion is endeavoring to create a registry that efficiently collects perfusion specific data from many institutions both nationally and internationally. These data could be synthesized into reports and provide feedback to individual centers regarding their practice and outcomes relative to other participating centers. These data would allow for benchmarking and performance improvement as well as information regarding best practices. The registry would lend to more of a sense of community within the perfusion profession and allow centers and individuals to learn from one another. At the outset, the ICEBP is choosing to concentrate the registry’s data collection reporting on five areas of focus:

1. Patient demographics (to adjust for potential patient-level confounders)
2. Compliance with guidelines/recommendations on the practice of cardiopulmonary bypass (amend list as the ICEBP publishes guidelines)
3. Cell processing and filtration
4. Renal management
5. Factors influencing patients having low cardiac output subsequent to surgery

The registry’s standard reports are being designed to answer three user questions:

1. How am I doing?
2. How do I compare to my colleagues (regionally, nationally, or internationally)?
3. Has my performance changed over time?

Once the registry matures, it will be possible to compare the effectiveness of various CPB systems, like the ones discussed here today and understand the effectiveness of these systems. A registry of this scope will provide new knowledge about the science of healthcare delivery.

“The fundamental problem with the quality of American medicine is that we’ve failed to view delivery of health care as a science. The tasks of medical science fall into three buckets. One is understanding disease biology. One is finding effective therapies. And one is insuring those therapies are delivered effectively. That third bucket has been almost totally ignored by research funders, government, and academia. It’s viewed as the art of medicine. That’s a mistake, a huge mistake. And from a taxpayer’s perspective it’s outrageous.” -Peter Pronovost 2009

References


vi Likosky et al NEJM Letter to the Editor Volume 361:1907-1910 November 5, 2009


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ICEBP Website http://www.bestpracticeperfusion.org