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· Outcomes Research

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Over the last decade, "outcomes" research became a catch phrase for healthcare administrators, providers and researchers, but outcomes research means different things to different people. For some, it is viewed as a way to provide more services for fewer dollars. For others, it means finding ways to regulate physician variability to improve care. Neither of these definitions fully describes the potential of this form of research. I believe outcomes research means moving beyond a research culture that shows us what can be done by surgeons, to one that emphasizes what should be done by surgeons. The "should" in that statement indicates a balance of the feasibility of an operative procedure with an assessment of the burden of that operation on the patient and society. Only by determining the impact of procedures in their totality can we understand what should be done rather than simply what can be done.

To do this, we have to consider the impact of the operation on the patient's life, both in the context of life expectancy and quality of life, while assessing the burden of that intervention for the patient and society. Since the publication of the Institute of Medicine report, *To Err is Human*, the public has focused on the "burden" of the healthcare system as it refers to adverse outcomes and medical errors. Answering the question, "What should we be doing?" requires that we address these adverse clinical outcomes in the context of system-level quality improvement.

To do this, outcomes researchers use a set of tools borrowed from health economics, decision analysis, epidemiology and biostatistics. To address this goal of system-level quality improvement for all areas of clinical interest, we use these tools to answer four necessary questions.

Can we determine the way surgical procedures impact the average patient?

Risk of adverse outcome is a component of all surgical procedures. While the informed consent process tries to address this by providing the patient with a summary of the expected risk, in fact what we really offer in the consent process are the results found in the published case series of the best practitioners in the field. For the vast majority of general surgical procedures, we simply don't know the community-level risk of adverse outcome. As such, we are unable to determine what should be considered the standard, who are the outliers (both good and bad), and what techniques work outside of the research environment. In the absence of a tracking system for outcomes, we often rely on estimates derived from randomized trials (which for most general surgical procedures have not been completed) or administrative data. Only by understanding the real level of risk can we determine the opportunities for improvement in the system.

The research I have been involved with has addressed this issue of community-level risk in commonly performed general surgical procedures by using administrative data. Determining population-level risk requires the analysis of large databases. For example, in evaluating rates of misdiagnosis in appendectomy, we studied 80,000 patient records and found that the rate of misdiagnosis in appendicitis has not improved in the past 13 years (~15% overall and ~25% in women of reproductive age) despite the growing availability of CT scanning. We studied over 30,000 patients undergoing cholecystectomy to describe the rates of major common bile duct (CBD) injury over time and found that rates of this outcome (0.025%) have not significantly improved with time.

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To study outcomes from antireflux procedures, we studied over 86,000 patients and found that while the rates of splenectomy have decreased significantly with time, the rates of in-hospital mortality and esophageal injury have not. Furthermore, while the rates of adverse outcome identified were low (~2% chance of splenectomy, <1% likelihood of death, ~1% chance of esophageal injury), these rates were between 2 and 20 times higher than results published in large case series.

This illustrates the importance of population-level results in estimating risk for the average patient. This research technique is also helpful in checking conventional wisdom about the benefits of new technology. For example, of ~10,000 patients undergoing incisional hernia repair, we quantified the rate of reoperative repair and found no improvement in this measure of recurrence in the era of laparoscopy. It is also important in addressing two important forms of bias in published estimates of outcome. Cholecystectomy-related bile duct injury is the leading source of surgical malpractice claims. Determining outcome after bile duct injury is challenging because the results of surgical experts are excellent (publication bias) while reports of cases that progress to litigation (selection bias) detail dismal outcomes.

We recently evaluated the risk of death after bile duct injury among all Medicare beneficiaries nationwide, and found they were 2.5 times more likely to die within the first few years after an injury compared to uninjured patients (Figure 1). Another way to assess the impact of care is to quantify patient-described outcomes as they relate to quality of life, function and well-being. Standard quality-of-life instruments measure chronic health states and do not adequately capture the dynamic process of pre-operative states, anticipatory stress, post-operative morbidity and then evolution to either recovery or chronic states. Working with industry, we are developing an internet-based interactive survey instrument aimed at capturing, quantifying and validating changes in Quality Adjusted Days (QAD) "lost" over the relevant time course of a patient. We hope that "lost" QADs will be an important outcome measurement tool that captures the patient-level burden of surgical procedures. By quantifying outcomes both on an individual and community level, we can then move on to the next step in improving clinical outcomes.

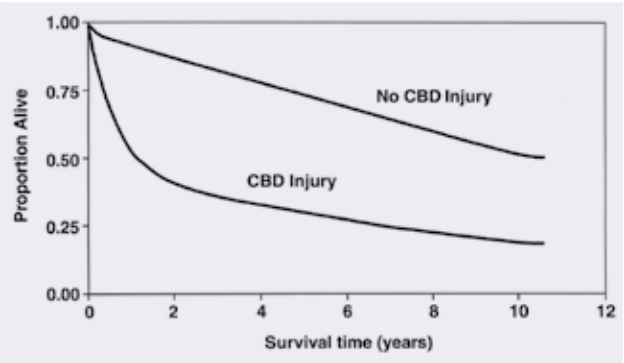

FIGURE 1. **Survival after bile duct injury in Medicare beneficiaries (n = 1.57 million)**

What are the avoidable factors associated with these adverse outcomes?

Health services researchers believe that most adverse outcomes have a system-level component. While all individuals make mistakes, it is a flawed system that allows these mistakes to adversely impact the patient. To that end, there are almost always avoidable factors that are associated with adverse outcomes. Understanding those associations and quantifying their impact is an important step in the quality improvement process. For example, using administrative data, we have quantified the degree to which both surgical inexperience and the failure to use a cholangiogram are associated with CBD injury. Surgical inexperience (a surgeon's 1st through 19th cholecystectomies) and failure to use a cholangiogram result in a 60-70% increase in the likelihood of CBD injury. When combined, these factors have even greater impact. Surgeons are 2.2 times more likely to have a CBD injury during their first 20 operations if they do not use a cholangiogram compared to procedures performed at later points in the experience

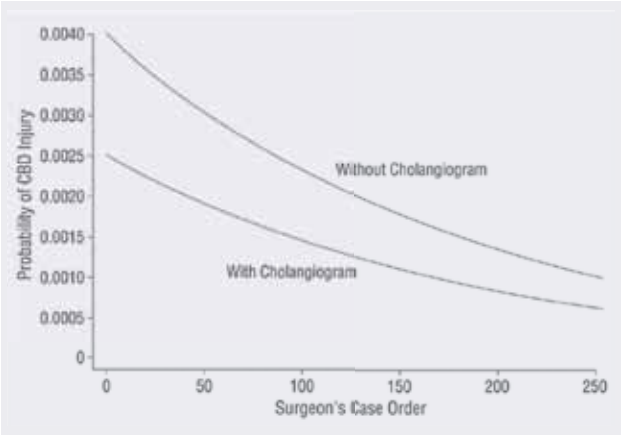

FIGURE 2. **Probability of bile duct injury with and without cholangiogram, by case-order of surgeon (n = 36,000)**

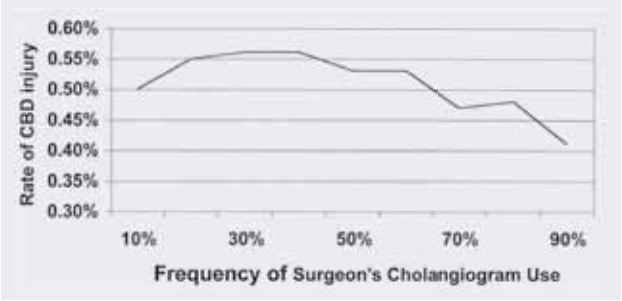

FIGURE 3. **The effect of increasing the surgeon's frequency of cholangiogram use on the rate of common bile duct (CBD) injury**

curve. Defining the risk relationship associated with CBD injury is also important in informing patients and surgeons of the predicted probability of this adverse outcome (Figure 2). This may be a more effective way of "informing" the informed consent process. This work was reinforced by a study of all Medicare beneficiaries undergoing cholecystectomy. In that study, we found that patients who did not have a cholangiogram were approximately 70% more likely to have had a CBD injury. We also determined that this "protective" effect of cholangiography was noted whether or not the surgeon was a routine or infrequent cholangiographer. The lowest rates of injuries were found among routine cholangiographers (Figure 3).

What are the implications (using cost/decision analysis and randomized trials) of avoiding those factors?

Once we have quantified the problem and determined the avoidable factors that influence these outcomes, we can try to imagine what the practice of clinical surgery would be like with these factors controlled. For example, a recently completed cost and decision analysis demonstrated that if routine cholangiograms were required, the cost per CBD injury avoided would range between $50-86,000. The incremental cost per operation of adding the cholangiogram would be $100. When considering the overwhelming costs (both system wide and medico-legal) of a CBD injury, this may be considered a cost effective intervention. Another example is a cost analysis showing that nationwide, nearly $740 million is spent each year on misdiagnosed appendicitis. Modeling potential ways to improve care is also being applied in a theoretical decision and cost analysis for routine CT scanning of patients with presumed appendicitis and teleproctoring in antireflux surgery. These models are often helpful when the practical barriers of a randomized trial are significant. With colleagues in the Division of General Surgery, we are hoping to develop and obtain funding for randomized trials in the management of appendicitis (routine versus selective CT scan use), for incisional hernia (laparoscopic versus open), and for the optimal management of patients with diverticulitis.

How can we make system level changes and monitor the impact of those changes?

The ultimate goal of this work is to improve surgical care for the average patient in the average hospital. The first steps are detailed above and involve getting good data and performing effective analyses. The next step is system-level change either on the local, professional organization, or statewide level. Another opportunity for system-level change is found in working with the main financial stakeholders. For example, in coordination with administrators from the Healthcare Financing Administration (Medicare) we are helping to determine the mechanisms that could be used to increase the number of cholangiograms performed nationwide. Similarly, administrators at Group Health Cooperative are interested in optimizing the care of patients with presumed appendicitis, and look to our analysis of their CT scan use as an opportunity to determine future care pathways.

In collaboration with the Washington State Health Care Authority, the Center for Medicare Services, the Foundation for Healthcare Quality, Medicaid and Qualis, our group is developing a statewide system for helping hospitals identify adverse outcome outlier status and use the techniques of the quality improvement community to address outliers. This Surgical Clinical Outcomes Assessment Project (SCOAP) is part of a 5-year project to create a surgical quality infrastructure in the state that will assure the incorporation of evidence-based approaches to surgical care in common practice. (http://depts.washington.edu/sorce/).

Involving the financial stakeholders may be the most effective way to improve system level care, but it may not be the best way. Over the last century, the surgical community has shown real leadership in addressing adverse outcomes and taking responsibility for them. The morbidity and mortality conference, so long a part of the surgical culture, was ahead of its time in trying to improve the results of future interventions by avoiding past mistakes. Unfortunately, it has become apparent that conferences alone cannot deal with system-level factors involved in adverse outcome. Outcomes researchers are doing just that, and the surgical community has an opportunity to use this research in leading the way towards quality improvement.

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