Comprehensive Quality Assurance for Cardiac Surgery

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Introduction

Many successful businesses worry about the quality of the goods and services they produce for a variety of practical and ethical reasons including competition, increased consumer awareness, and fear of government regulation or liability litigation. Industries sensitive to these issues not only expend resources to improve the quality of their output, but they also market their efforts to the public. Both the toy industry and the automobile business have improved the quality and safety of their products in the past twenty years and let their customers know of their efforts. Other businesses use a different strategy. For instance, many retail brokerage houses routinely under perform market indices, betray smaller customers, and survive or prosper despite regulation and lawsuits. They aggressively market the image of concern for their clients, but their outcomes repeatedly demonstrate the opposite. For them, simply talking about quality is enough.

How does one distinguish between these diametrically opposed approaches? The answer, of course, is to study results. Comprehensive quality assurance studies results to improve them; marketers study them to apply lipstick. One might think that the medical profession would be world leaders in quality assurance because of its strong ethical and charitable roots, but this is not the case. For a variety of reasons, some of which will be discussed here, medicine has been slow to develop vigorous frameworks to protect consumers and enhance their experience with physicians, and the results of this failure have degraded the relationship between physicians and patients.

In this document, we will briefly examine why medical practice has failed to develop and apply robust quality assurance algorithms, and then focus on cardiac surgery. We focus here for two reasons: first, cardiac surgery is politically susceptible because it is a large, high profile business that consumes substantial national resources, and second, because it is ethically susceptible – it carries a significant mortality rate. For these reasons, several state legislatures have already mandated public reporting of cardiac surgery results presumably hoping to improve them, or at least increase public awareness, but such efforts are no substitute for comprehensive quality assurance. That must come from within each cardiac surgery unit, and so we will describe the principles and structure of robust quality assurance hoping that our ideas will provide a sounding board for yet other ideas to improve outcomes in our craft.

History

Before doing so, however, let us consider why medicine in general, and cardiac surgery in particular, have not led the way in developing quality assurance mechanisms. This seems to be an historical accident that occurred during the early development of academic medicine in the United States. In the late 19th century, American medical leaders, trained in France and Germany, recognized the need to formalize medical training and supplant the haphazard apprenticeships that then characterized medical training in our country. A few American medical schools including Hopkins, Harvard, and Penn created the bellwether model of academic medicine that is still recognizable today. That model depended on education and research within a university as the primary means to train physicians and to improve the quality of care. These leaders would have argued that as their institutions and knowledge improved, patients would be satisfied with the quality of care they received. Their approach has made American medicine the envy of the world, but it created an institutional rather than a customer focus with some unforeseen and unfortunate results.

For instance, our forefathers understood clinical quality assurance as morbidity and mortality conference. In that venue, residents presented difficult cases and deaths followed by a heuristic and corrective group discussion that included both trainees and attendings. This approach may be summarized in the memorable phrase "forgive and remember." It is still a good technique, but no longer sufficient, especially for cardiac surgery. Here's why. First, non-academic institutions provide most medical care. Therefore most M and M conferences are not training experiences. They are required by the Joint Commission on Hospital Accreditation and attended by busy practitioners who wish they were elsewhere. No one wants to sit in judgment of colleagues. Second, even if carried out assiduously, they are anecdotal and do not take advantage of national statistical norms by which medical care, and especially cardiac surgical care, is more logically appraised. Third, M and M is only one small, albeit important, aspect of comprehensive quality assurance. It does not account for several other critical aspects of the quality assurance process discussed below. Fourth, the M and M venue is too narrow in today's complex medical environment. It focuses too much on doctors when all caregivers must be involved in an interdisciplinary effort, and fifth, it does not include a mechanism to effect change. These failings are particularly troublesome for cardiac surgery because we must manage our craft by numbers and because it is ultimately a team sport – everyone must have the same playbook and the same goal.

The Mechanism

The goal of comprehensive quality assurance, not surprisingly, is identical with the goal of a cardiac surgery program: provide patients with the safest, least threatening journey through the hospital. To achieve this, we must incorporate the M and M concept into a much larger quality assurance framework to which we now turn. This framework depends on two key interrelated preconditions: leadership and an enabling environment. Leadership provides the values that encourage all team members to provide patients the journey described above. It also establishes an enabling environment that rewards ideas that strengthen those values and changes those that reduce them. Good leadership and an enabling environment rarely seek to assign blame, but rather seek better ideas to reinforce the core values. If leadership and the institution around it consistently find themselves flawless, so will individual team members. Improvement is impossible. So robust quality assurance requires leaders who transmit the core values, openly recognize and accept responsibility for failure, and encourage other team members to do the same, and it requires an institution that recognizes its own need to evolve in response to customers'

needs. This creates an environment open to change. In this environment, everyone who serves the patient in any way is in charge of quality assurance, not just the chief of service or the charge nurses, everyone. They will report difficulties and suggest solutions. Care can improve.

Cardiac Surgical QA: Standardize, Simplify, Measure

Comprehensive QA in cardiac surgery makes five ongoing assessments of the health care environment, it uses a simple recursive loop to make changes and assess progress, and it requires a regular venue and a dedicated data/QA manager to organize and focus it. The five areas that require assessment are:

- 1. Patient satisfaction
- 2. Institutional process
- 3. Outcomes
- 4. Appropriateness of care
- 5. Efficiency of resource management

First, customer satisfaction is the epicenter of most businesses, and in medicine, the patient has a dual role as the object of quality assurance and an important contributor to the QA process. We must contact patients 30 days after discharge and ask them to evaluate their hospital experience. Most are grateful to be alive, so we must specifically ask how their experience could have been improved. Furthermore when a spontaneous complaint is voiced, we must take it seriously because many other patients had the same problem but are reluctant to speak up. You can assess patient satisfaction only by asking the customer about the experience.

Second, institutional process refers to all the services that the hospital provides to patients and their caregivers including OR, nursing units, laboratories, food service etc. Any impediment to a smooth, safe, and cost effective hospital experience must be fair grounds for QA assessment. You can assess institutional process by reporting these impediments when they occur and then resolving them at a quarterly meeting. For instance, the blood bank complains that you are wasting blood products or nurses are having trouble obtaining prompt coagulation results in the ICU. In either case, invite all stakeholders to the meeting and hammer out a tentative solution right then and there, then reassess next quarter.

Third, as indicated above, the M and M concept is necessary, but not sufficient to assess results. A sufficient process must also compare quarterly and annual results to the STS national databank that provides a wealth of standards that we must strive to meet or exceed. As you are aware, risk adjustment algorithms permit reasonable comparison of your results to the national norms. In addition you must compare your complication rates to those in the national databank, including stroke rate, postop renal failure, prolonged ventilation, take back for bleeding, etc. You can assess these outcomes only by contributing to the STS databank and tracking your own morbidity and mortality data against the STS aggregates. Any outcomes worse than the STS aggregates must be relentlessly polished out of the system. The excuse that "our cases are more difficult" is presumed to be balderdash. These three assessments are easy to understand and can be fully implemented now.

The fourth and fifth are more difficult because we have yet to establish reliable mechanisms to implement their ongoing assessment. Appropriateness of care asks not whether patients were satisfied with their care, not whether hospital services delivered smoothly, and not whether outcomes met standards, but whether the treatment plan was reasonable. We have only recently recognized the importance of this aspect of QA. The Tenet facility, Redding Medical Center, in California, closed its cardiovascular program recently despite its reputation for customer services and excellent results because of allegations that its physicians inappropriately chose patients for cardiac catheterization and coronary bypass. This scandal along with some others evaporated \$11 billion of Tenet's market capitalization, so appropriateness of care has important business implications as well as the more obvious ethical ones. We need to develop a way to assess this important quality indicator. I imagine a volunteer, rotating group from the Society of Thoracic Surgeons would form to review randomly selected cases at the behest of requesting hospitals or surgical groups. I would prefer that STS form a consulting group of experienced operating members to perform such activities for a fee. Such outside review would reassure all parties that reasonable decisions were being made.

Finally, assessing resource management asks whether surgeons are making wise use of the services the hospital provides. The days when physicians could use hospital resources without regard to cost or efficiency are long over, but as far as I know, hospital managers and surgeons have done little to control what a businessman would call production costs. I predict, however, that hospitals will eventually shun surgeons who schedule cases when nurses must be paid overtime, who take too long to complete a case, and whose lengths of stay exceed norms. These are bad habits that waste money and can increase complications. I imagine that we could begin to measure this problem by assessing three numbers: total operating room time, total length of stay, and percentage of cases outside business hours. Total operating room time is probably a reasonable aggregate measurement of the efficiency of the whole operating team. Efficient units average 4-5 hours/case. If your group exceeds 7 hours/case, you may all wish to consider second careers in manuscript illumination. Percentage of cases outside normal working hours is a second overall measure of resource use, and should be low to save complications as well as money. Length of stay is probably the best measure of overall unit efficiency, and one that many hospitals are already assessing.

Although we cannot yet fully implement all five aspects of quality assurance, the first three are easily within reach. So we now turn to the more mundane aspects of organizing a strong QA program. This requires a dedicated manager to track STS databank variables within the program, trend them against national standards, assess customer satisfaction, and present results at a quarterly meeting. We schedule our meeting when operations would normally be taking place. This permits the largest number of team members to attend. All members of the team should be encouraged to report quality issues to the manager as they come up so that they can be discussed as a group during the meeting. We have a dedicated phone mail line for this purpose. Each QA issue reported should be discussed and a plan undertaken to resolve it. The issues must then be readdressed at subsequent meetings until resolved. Patient comments from the 30-day follow up should be reviewed. Deaths and serious complications must be reviewed not with an eye for absolution, but with a plan to prevent similar problems in the future.

Summary

As we all know, cardiac surgery has changed and will continue to change. Originally, intrepid academic surgeons learned to treat diseases that had always been fatal. They alone held the spotlight in hospitals because they exemplified the high tech battle to save human life. Now we share that spotlight with many other interesting new therapies. The routine success of cardiac surgery has itself gradually forged new expectations in the society. So our job as surgeons has changed. Risking people's lives will always require intrepid souls drawn to the drama of controlled, pitched battle in the operating room, but now we must temper that passion with an equal zeal for quality assurance.

Surgeons who convert to this new QA "fundamentalism" reinterpret their professional experience. They no longer see recurrent delays and inefficiencies in the operating room as "the way things are." They no longer accept the gaps in customer service visited upon our patients as part of the hospital experience. They do not view a persistent rise in the postoperative stroke rate as an expression of the increasing age of cardiac surgery patients. They view each of these issues as an opportunity to hunt down and defeat a QA problem, and they meet regularly with all members of the team to accomplish this goal. Such converts have a mantra, "simplify, standardize, measure." They recognize that most hospitals can support and enforce only one standard of care. All operating surgeons must agree on a single operating room setup, a single perfusion setup, a single prep, a single approach to anesthesia, a single set of postoperative orders, and standardized management of ventilators, blood glucose, and whatever else can be routinized. They recall as quaint and ill-advised long lists of "surgeon preferences" that serve mostly to divert attention away from the patient. They can distinguish evidence-based innovation from marketing-based glamour because their customers are counting on them. They hate lipstick.