Editorial

The Tools of Quality Improvement: CQI Versus Epidemiology

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When Your Only Tool Is a Hammer, Everything Looks Like a Nail

In this issue, Burnett and Chesher describe how they applied tools developed for continuous quality improvement (CQI) to reduce the risk of sharps injuries in their hospital.[1] They charted the number of syringes received in the lab with the needle still attached, then contacted the medical officers involved in these instances to determine the reason why. In most cases, the needle was left on because the medical officers could not find the syringe cap. Using this information, the hospital changed to preheparinized syringes that were prepackaged with their caps. Subsequently, the number of syringes returned with attached needles fell significantly.

Burnett and Chesher found the solution to their quality problem by using the tools of CQI. Why didn't they use the tools of epidemiology? Although epidemiology long has been used to solve quality problems in the hospital, especially in infection control, it probably wouldn't have been efficient for solving Burnett and Chesher's problem. On the other hand, CQI cannot be used to solve many hospital quality problems, such as finding a staphylococcal disseminator or a healthcare worker purposely killing patients.[2] Given the variety of quality problems encountered in healthcare, it is important to ask: When is it more advantageous to use the tools of CQI versus those of epidemiology to improve quality?

There are clear instances when epidemiology is superior to CQI and vice versa. To understand the strengths of each set of tools, one first should understand their historical development. CQI developed out of industrial management science to improve the quality and efficiency of manufacturing processes.[3] Manufacturing processes are explicitly designed. Every step of the process is known, and the desired result of every process step is specified. In this situation, one can examine the process to see if each process step is capable of producing the desired output. If it is not, the process can be redesigned until it is capable of performing to expectations. The tools of CQI are geared to assist in this endeavor. What aspect of the process should receive attention? That depends on the kinds of defects the overall process is producing. A Pareto chart displays the relative frequency with which certain kinds of defects occur. Burnett and Chesher's Pareto chart shows the relative frequency of various reasons why the syringes were not capped properly. Knowing how the process was failing allowed the hospital to select a process redesign (in this case changing to syringes prepackaged with their caps) that reduced the opportunity for the process failures to occur.

The tools of epidemiology have a very different lineage from those of CQI. The science of epidemiology developed because there were outcomes—infectious illnesses—with unknown processes generating them. Epidemiology seeks to deduce the processes generating outcomes. It does this by examining patterns of occurrence of putative causes in association with the events of interest. When applied to the case-control study, this logic leads to the systematic comparison of the frequency of putative causes between two groups: those with the outcome and those without the outcome. When applied to the

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TABLE
SELECTING STRATEGIES FOR QUALITY IMPROVEMENT

Prefer CQI when:
A well-defined process is not performing as required
A problem's solution is known but difficult to implement
Prefer epidemiology when:
The problem is an epidemic (ie, a sudden increase over historical experience in the rate of outcomes)
The process by which outcomes occur is not known (especially clinical outcomes influenced by severity of illness or other external factors)
Consider combining the two when:
Multiple processes are in place to achieve the same outcome, and it is not clear which process is better
A clinical process is to be changed

cohort study, this logic leads to the selection of two groups, one exposed to the putative cause and another unexposed, and follows them through time to determine whether there is a greater rate of outcome in the exposed group compared to the unexposed. The epidemiologic approach assumes that, when outcomes vary, there is some associated variation in process. Epidemiologic approaches would not have made a very useful contribution to Burnett and Chesher's research because they understood the primary process involved in their problem and identified where it was breaking down simply by asking those involved in the process failures.

Epidemiologic methods are superior to CQI methods for addressing some situations commonly faced in the hospital. An epidemic of staphylococcal wound infections is an excellent example. In this situation, a new unknown cause of wound infections has been introduced in the hospital. Many of CQI's tools, such as process flow diagrams, cause and effect diagrams, and Pareto charts, contribute little in this situation.[4] A process flow diagram is a step-by-step representation of a process. It is useful for identifying duplication, unnecessary complexity, and areas of process weakness. Precisely because these diagrams are intended to represent a process as it is routinely executed, they simply do not address the introduction of new causes into a system. The cause-and-effect diagram, or fishbone diagram, is a tool for generating hypotheses about how defects occur. This tool lists components of a process to organize thinking about how failures in certain areas might lead to the undesired outcomes. This diagram might indeed be helpful in generating hypotheses concerning the cause of an epidemic in the hospital, but CQI lacks the tools to test the hypotheses efficiently. In manufacturing, these hypotheses can be tested by changing the process and observing changes in outcome. In the case of the epidemic, it would be very time-consuming and inefficient to have some physicians continue operating and some refrain from operating, and then wait to see whether the epidemic subsides. The Pareto chart already has been described. As a way of documenting the relative importance of problems or opportunities for improvement, it is quite useful; but, as a tool to understand causality, it is inadequate. In the epidemic situation, listing the doctors involved in operations on cases might indicate that 75% of the cases were operated on by Dr. A. The significance of this fact is unclear until the percentage of noncases operated on by Dr. A. also is known. The Pareto chart represents a series of cases (numerator data), the causal significance of which need to be established by reference to a series of comparable controls.

CQI, with its focus on process, and epidemiology, with its focus on outcome, complement each other. Because of their complementary natures, CQI and epidemiology can work synergistically. When there are multiple processes at work to achieve the same goal, the important question for quality improvement is: which process is superior? Epidemiological techniques can be used to document the differences in outcomes associated with different process variants. For example, there is striking variation in many aspects of the delivery of clinical care.[5] Each physician has an internalized set of rules concerning what decisions to make in certain situations. These rules form the basis of a decision-making process that can vary tremendously among physicians.[6] When addressing this variation, CQI tools can help to make explicit these internalized processes, so that they can be rationally examined. In part, critical pathways and clinical practice guidelines attempt to address the variation in clinical processes by making the processes explicit.[7] However, the decision regarding which process to adopt must depend on the ability of the chosen process to give better outcomes than the alternatives. The role of epidemiology in providing the link between process and outcome is clear. It provides the method for comparing the rates of outcomes among alternative care processes. If there are not differences in outcomes, the most efficient process should be preferred.

In other situations, CQI can help inform epidemiology. Epidemiology works especially well for epidemics, but it works less well for endemic problems, especially if the solutions to the problem are

known already but are difficult to implement. Consider the hospital with a clean wound infection rate of 5% with no obvious pattern of infection, ie, no clustering of infections by surgeon, time of day, ward, or other definable pattern. When all the odds ratios generated by case-control studies are 1.0, does this mean that one cannot reduce the infection rate? In the hospital, there is a constellation of factors involving the patient, the microbial environment, and the processes of care. These factors converge in such a way as to lead to a recognizable infection in 5% of patients. It is a basic tenet of CQI that to change the endemic rate, the overall processes must be changed. But how? Here the tools of CQI may be quite useful. Consider antibiotic prophylaxis, for example. Epidemiology has demonstrated that when prophylaxis is delivered well, the infection rate is reduced.[8] In a given hospital, all patients are exposed to the same antibiotic delivery process. The endemic infection rate is determined, in part, by the extent to which this process performs as required. Process flow diagrams can describe how antibiotic prophylaxis is delivered, cause and effect diagrams can help organize hypotheses regarding how that process fails, and a Pareto chart can indicate the most common modes of failure.[9] In addition to these diagnostic techniques, CQI also provides methodologies to help drive change. Unless process changes occur, there is no reason to expect the endemic rate of infection will be affected.

Several epidemiologists have experienced great difficulty convincing those tutored in CQI that epidemiology is important to quality improvement within the hospital. As CQI has developed to be an important cultural force within the hospital, its proponents largely have ignored the contributions that epidemiology could make. This lack of appreciation may be fueled by hospital epidemiologists' reluctance to venture far from their traditional focus in infectious disease.

CQI ignores epidemiology to its own detriment. Epidemiology's experience with surveillance and measurement in the hospital environment could make a valuable and immediate contribution to CQI. In many nonclinical areas, processes are sufficiently understood for CQI to work well. In clinical areas, however, the processes by which some patients get well are not understood so clearly. When the processes are unclear, CQI tools may not be so useful. Benchmarking, for example, is a CQI method for comparing aspects of organizational performance to that of a superior organization. When applied to a well-defined process, benchmarking can bring substantial improvement very quickly. The desire to benchmark outcomes of care seems nearly irresistible. However, the ability to compare outcomes usefully between institutions requires that sources of variation that are not under the control of the hospital do not influence the comparison. Thus, comparisons of outcomes that ignore differences in patients are all but uninterpretable.[10] Unfortunately, the concepts of confounding and risk adjustment are not well established in CQI methodologies, as commonly employed in hospitals.

Furthermore, changing clinical processes without an eye to outcomes of care is imprudent. At the very least, sufficient surveillance should be in place to detect coincident changes in the occurrence of adverse events. The delivery of clinical care is a complex enterprise, and a change in one area may have unintended negative ramifications in other parts of the process. Because these processes directly affect patients, there is potential for harm. In many instances, a trial (either randomized or not) could be staged within the hospital to verify that the planned change has both the desired effect and tolerable adverse consequences. Epidemiology provides the methods for linking process changes to outcomes.

On the other hand, epidemiologists can gain by a better appreciation of what CQI has to offer. Epidemiology often seems to stop at the point where the culprit has been found. Epidemiology generated the evidence that antibiotic prophylaxis was important, but that knowledge has to be put into action by redesigning the processes by which antibiotics are delivered. The tools of CQI are well suited for putting knowledge into action.

Both the hospital epidemiologist and those interested in CQI want to improve the quality of patient care. Both epidemiology and CQI provide tools for achieving that goal. Therefore, those interested in improving quality should be versed in both disciplines. Every day, quality improvement personnel use various tools to study and solve problems. The strategies chosen to assist in these endeavors are those with which people are familiar, not necessarily the ones that best fit the problem at hand: when your only tool is a hammer, everything looks like a nail. Finding solutions efficiently depends upon the nature of the problem at hand. It is important to maintain a toolbox that contains the right tools to address the variety of problems faced in healthcare.

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by Gina Pugliese, RN, MS
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