The Contribution of Epidemiology to CQI: a Commentary

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“What is fate?” Nasruddin was asked by a scholar.

“An endless succession of intertwined events, each influencing the other.”

“That is hardly a satisfactory answer. I believe in cause and effect.”

“Very well,” said the Mulla, “look at that.” He pointed to a procession passing in the street.

“That man is being taken to be hanged. Is that because someone gave him a silver piece and enabled him to buy the knife with which he committed the murder; or because someone saw him to do it; or because nobody stopped him?”

Anonymous

The discovery of epidemiological methods by health care providers has “evolutionized” the management of health care delivery. In an era of re-structuring, re-engineering, re-positioning, and research, the health care delivery system is trying to uncover the aspects of its own functioning most amenable to amelioration. The purpose is simple: only the creatively responsive to external questioning (purchasers, payers, researchers, and the public at large) will continue to exist, albeit in a modified capacity. Answering to external questions, however, presupposes knowing the answers. Such a tautological argument leads to the common ailment of today’s health care provision field: that is, its propensity to answering questions before knowing the answers. Often, the eagerness to demonstrate that the care provided to enrollees of a plan or the community at large is appropriate, overshadows the requirements for scientific robustness.

The purpose of this commentary is threefold:

1) to review the evolution similarities between quality assessment, quality assurance, quality improvement, and epidemiology; 2) to discuss the usefulness of epidemiological thinking during institutional performance improvement efforts; and 3) to construct a practical framework where theory and applications of performance improvement can co-exist.

PRECURSORS OF PERFORMANCE EVALUATION, QUALITY ASSURANCE AND EPIDEMIOLOGY

Perhaps the first written mandate linking aspects of epidemiology to performance evaluation could be found in Hammurabi’s Code [1]. The explicit relationship between performance and its evaluation is apparent through “…if a physician shall make a severe wound with an operating knife and kill [the patient] or shall open an abscess with an operating knife and destroy the eye, [the surgeon’s] hand shall be cut off.” In Hammurabi’s Babylon, the choosing of a good surgeon might have been easy: any surgeon who still has both of his hands. Unfortunately, that study would not qualify as epidemiological, since it did not deal with rates, but only numerators i.e. did not ask what proportion of all Babylonian surgeons still have both of their hands after “x” years of practice.

An early statement of epidemiological principles is found in Dr. W. Guy’s [2] legacy, who in 1856, showed a 325-fold variation in hospitalization rates between two communities in England. In explaining the disparity he characterized the high hospitalization rate prone residents “…as an increasing class of working men, in receipt of good wages, who are in the habit of applying to hospitals as a matter of course, even for trifling attacks of illness, to say nothing of those which sometimes
follow immediately on expensive acts of self-indulgence". In this case, not only rates were calculated to compare the prevalence of medical services utilization across two populations, but it also discussed the variation across the geographic areas. Further, Dr. Guy interpreted the variation focusing on patient behavior and not necessarily on provider propensity to hospitalize. The implications of this statement for the future merger of epidemiological and geographical analyses under the insignia of Small Area Variation Analysis is critical: patient preferences and lifestyle, not provider proclivities, may explain much of the variation across areas.

But first, the history of health care research had to proceed. Physicians, as gatekeepers of the venerable art of healing and comforting, remained the pinnacle of medicine well into the mid-1900s. No aberrant event could have been detected, evaluated, or reported by physicians, since such self-policing seemed unlikely. After all, who was questioning the knowledge or abilities of physicians? Few indeed are the historical evidences where physician's knowledge has been challenged. The most popular literary work from Europe belongs to Molière. In his last satirical comedy "The Imaginary Invalid" [3] (1673), the maid, playing the role of a doctor, asks the patient about his attending physician. Upon receipt of the name, she takes a very large book from the top of a pile she was carrying, and flips through it, kneeling on the floor center, "He is not listed among the important doctors", she says. It is hard to believe that Molière had introduced the physician report card back in 1673!

Early in the 1900s, E. Codman, a surgeon at the Massachusetts General Hospital changed the rules. He suggested that physicians should subject themselves to peer, and eventually public, evaluation. "We must formulate some method of hospital report showing as nearly as possible what are the results of the treatment obtained at different institutions. This report must be made out and published by each hospital in a uniform manner, so that comparison will be possible. With such a report as a starting-point, those interested can begin to ask questions as to management and efficiency" [4]. Dr. Codman was also a visionary regarding the future of the "health care system" — a concept unknown to his time. In effect, during an address read before the Philadelphia County Medical Society, 1913, he may have made the fundamental distinction between "industrial production management" and health care provision. In his words, "...In various manufacturing businesses I imagine that it is not difficult to render an exact account of the product of a factory. So many dozen tin cans, cakes of soap, toothpicks, or pickled pigs' feet are readily figured up. With educational institutions and hospitals the problem is very different. The statement of the number of patients treated or of students graduated gives but a fraction of the products of such institutions. What, then, are the products of a large hospital, whether in the forms of healed wounds, healthy babies, faithful nurses, promising young surgeons and physicians, or in the more abstract forms of original ideas on pathology or treatment, model methods of administration, or such intangible things as enthusiasm and ideals?" [4]. The epidemiological concept of correlation, the strength of the correlation as a predictor of the outcome may be deduced from the above statement. Placed in a specific context, Dr. Codman's argument may still be at the heart of our struggle in trying to "fit" industrial models into healthcare — in essence, our struggle to superimpose public health epidemiology and CQI/TQM philosophies. In one sentence, Dr. Codman may have captured the essence of CQI, namely "...As a rule, standards are raised by stimulating the best — not by whipping up the laggards" [4]. Thus, the historical emphasis placed upon these ignominious laggards deserves particular attention, especially since outlier analysis of the 1980s shaped much of health services research.

ON EPIDEMICS AND OUTLIERS (LAGGARDS)

An epidemic can simply be defined as an event happening more frequently than expected. When further refined, a qualified definition may elaborate on the term "more frequently". Three key concepts are imbedded in these definitions: event, frequency, and expectation. Thus, the establishment of an epidemic first requires quantification — a perception is not enough. Second, the quantified event has to be placed with a context and, third, interpreted. The context is the "expected" frequency of that event, thus it is a conceptual context as much as
a physical one. For example, was the event different from an expected rate irrespective of where it happened? How often was it different? Was it notably different from other frequencies, previously noted in reference environments? Thus, the interpretation of that rate takes into account both its magnitude and its placement within an "accepted/acceptable" range, or even geographic location.

The definition of "epidemic" is similar to that of "outlier", both in the methods of discovery as well as interpretation of the findings. An outlier is an observation (person or event) that is significantly different from the average observation. The labelling of an epidemic follows therefore, the same steps as agreeing on the insignia about outliers. Since the study of outliers has been the hallmark of Quality Assurance (QA) in health care, an understanding of the similarities between the management of an epidemic and an outlier event in health care delivery, seems a delightful challenge.

THE SYNCHRONIZED EVOLUTIONARY PATHS OF EPIDEMIOLOGY AND QUALITY ASSURANCE

Over its evolution as a scientific method of investigation, epidemiological inquiry focused on both epidemic and endemic events. An endemic event is one that happens on an ongoing basis, thus, does not stand out as a rare event. It is possible that a sudden "surge" in the endemic profile may qualify it as an epidemic. Or, that an event happens in epidemic proportion as a new and previously undetected event within the system under analysis, e.g. population, or geographic area.

Prior to discussing the similarities between QA and epidemiological methods, it is important to place QA within the spectrum of inquiry types.

Specifically, the Institute of Medicine (IOM) defines three distinct types of inquiry: Quality Assessment, Quality Assurance, and Quality Improvement [5].

(1) Quality Assessment encompasses problems of detection and measurement. As such, QA does not result in corrective action, and does not propose solutions.

(2) Quality Assurance (QA) comprises a set of activities not aimed at achieving "error-free" health care, but maintaining quality at an acceptable level in order to engender the confidence and faith of participants. Thus, QA does not deal with improving what is not grossly aberrant.

(3) Quality improvement, in contrast, knows no permanent threshold for performance goodness: what is good according to QA can be better through continuous study and process improvement.

Quality assurance in health care and the analysis of outliers seem to have followed a similar conceptual path to epidemiology to reach the limits of "Quality Improvement". Technically, both approaches measure the happening of the event through a proportion i.e. numerator and denominator. In all situations, there is a quantitative assessment of the variability, or deviance, of the measured happening relative to the expected. Thus, the epidemic and the outlier are of special interest because they happen more frequently than expected. In epidemiological terms, the epidemic can happen out of no previous existing pool of happenings i.e., zero expected rate; or, an endemic situation may become an epidemic. In that case, there is a reference rate to establish a baseline. In quality assurance, the expected is the "acceptable" frequency upon which a review screen is based.

For example, if the review screen is based on 4% bacteremia rate, only rates higher than 4% will be flagged and eventually reviewed. Why? Because the concept of quality assurance follows the same logic as when investigating an epidemic — find out why it happened and control it. Unfortunately, since in biological sciences many distributions approximate normality [6], a very small proportion of events end up as statistical outliers. Thus, QA "legitimizes" the extent to which 90 or 95 per cent of the events happen, instead of promoting their review and evaluation.

NOTEWORTHY EVOLUTIONARY STEPS

In epidemiology

Infectious disease epidemiology and outlier analysis. Historically, infectious disease epidemiology focused on outliers. That is, the
rates of infectious diseases were not investigated unless they became higher than expected, or an epidemic. As was discussed at the outset, an epidemic is an outlier situation. The tools, statistical and clinical, used during the investigative process always aim at answering the basic Ws: What, Who, Where, When and Why. Fortunately, these Ws can be claimed by any systematic inquiry, other than epidemiology. Therefore, the study of mortality rates, delays in the receipt of lab reports, barriers to 100% child immunization rate in a community, can all be investigated using the five Ws. The critical similarity between the analysis of a Diphtheria epidemic and an "epidemic" of patient dissatisfaction with the care is that both phenomena are expressed as rates, placed within a distinct time and place context, and the affected populations strictly identified. What remains is the conduct of the investigation, to understand what happened, how serious it was, and what caused it. The goal? To stop the epidemic, and learn how to prevent it from happening again.

Chronic disease epidemiology and inlier analysis. Outlier events are controlled, the remaining pool of events becomes "chronic" to the environment under study. The science underlying the study of these events also changes. Epidemiological sciences have progressed from the study of infectious disease epidemics to the study of chronic diseases, which often do not manifest themselves as epidemics. In distributional analogy, such a change in focus could be called "from outlier to inlier".

The conceptual underpinnings of such a change in focus are also distinctly interesting. The association between the one or few factors can be causally established in infectious disease epidemiology, whereas the association is highly probabilistic in the multi-factorial correlation established in the study of chronic conditions. And, in the case of a probabilistic association (correlation) the identification of the factors is much more tentative and the improvement process more experimental.

In quality assurance

Adverse output analysis. That the term "assurance" is imprecise, over-promised, and unpromoting of improvement [5], is now well accepted among health care providers. The term was borrowed from industry where it is possible to assure the goodness of the product. The reason for the differential success between two seemingly comparable organizations is that in materials-producing industries the environment and the input can be kept constant and well measured. As such, any change in the output could be attributed to some aspect of the process. In health care, the environment is variable and fluid and the input (the patient) is partially known regarding her/his structure (e.g. genetic heritage) and reaction to intervention (e.g. treatment.)

Therefore, the QA professionals turned to the identification of adverse outcomes. Through screens and cut off points, they identified the rare events that happen when there is interaction between the provider and the recipient of a service. But that was not all, for QA also focused on the study of the rare and sometimes unavoidable adverse outcomes: mortality being the crown jewel of such a credo. The 1990s were the awakening years for health services research and quality assurance. It became clear that if the true profile of performance had to be evaluated, it would be through an understanding of the processes of the care triggered by the variation in the output rates observed at discharge from hospital.

Process analysis. Why did an epidemic happen? Why are there outlier performers? Both questions are answered through the same strategy. In epidemiological and medical terminology, the "why" is addressed through analysis of aetiology going through differential diagnosis steps. In other words, the causative factors are investigated to identify which ones are the most probable and substantial a contribution to the befall of an epidemic. The differential diagnosis is a logical, step by step approach to the description and subsequent elimination of the least important contributing factors.

In performance evaluation methodologies e.g. CQI, the equivalent activity is called a process analysis. In this case, all the processes that could have contributed to the observed output profile, e.g. nosocomial infection rate, would be
mapped, described, and studied. The purpose is to identify the most prominent of the processes that, when improved, would substantially improve the output profile. The stepwise approach of the differential diagnosis is followed attentively, using such statistical strategies as a Pareto Analysis, or a fish-bone diagram. In the epidemiological and statistical parlance, the former is referred to as aetiological analysis, while the latter is none other than a regression analysis. Indeed, the head of the fish is the dependent variable and the bones are the independent variables. There is no causality analysis as the fish bone diagram is often misleadingly proposed to perform: the relationship between the bones and the head of the fish is probabilistic, not deterministic i.e. a true causality would be depicted through a fish-bone diagram where the fish has one head and only one bone.

**CQI and TQM: application of epidemiology to performance analysis.** The evolution in health care management brought about by the CQI mentality is not through the shift from outlier to inlier analysis, but in considering both distributions simultaneously. That was, indeed, a fundamental change in health care and medical care providers: that a person, institution, or group of institutions do not need to be outliers in performance before they (or others) decide to ameliorate that performance. In some ways, the CQI approach is mainly a synthesis of epidemiological tools, to a wider topic: that of the production of a good or service. Indeed, the successful applications of the CQI tools to performance gauging in industry show how the analysis of rates, patterns, associations, and causation are the generic bricks and mortar of any decision-making framework.

The contribution of TQM to the health care field has been less immediate compared to the effect CQI techniques had on demonstrating performance change and improvement [7]. The reason may be in the more encompassing nature of TQM. For example, in a hospital, unless line management and clinical staff work together, on the same goal, for a long time [8], no organization-wide performance improvement can be achieved [9]. The common "tree-or-forest" analogy may be used to explain the disparity of successes between the seemingly different approaches. Consider the trees to be the CQI techniques. The Forest is the sum of those approaches, but placed within an ecosystem. That ecosystem will vary depending on where the organization exists and functions. The relationship between the trees, the forest and the ecosystem is measured through epidemiological tools. Specifically, TQM describes the ecosystem within which trees exist, epidemiology describes what happens to the trees, and CQI identifies why it happens. In that sense, TQM is the more encompassing concept where the philosophy of CQI is incorporated as one strategy for performance amelioration [10,11]. Thus, although the health care professional is interested in knowing why things are, there may be structural and functional attributes to the organization that inhibit the providers from studying the larger picture.

In both epidemiology and quality assurance

No matter what tools are used to study what befalls populations, the reasons for the study are identical in QA and epidemiology: to measure, evaluate, and improve. That improvement in health can be achieved through the elimination of causative agents of ill-health (pathogens, carcinogens and mutagens among others) or by promoting access to appropriate, effective, health care. The strikingly similar steps in the evolution of epidemiology and QA towards health or performance improvement is shown in Table 1. Perhaps it is possible to make a prediction as to the future paths of these two disciplinary approaches, such as: epidemiology and QA will increasingly converge as methods of inquiry to study population health status. Also, the purpose of each discipline toward this goal is different: QA will pave the way toward performance improvement, whereas epidemiology will demonstrate the impact of the improved care delivery on population health status. Both activities will result in real outcomes research with all its caveats [12,13] (Table 1).

A FRAMEWORK FOR PRACTICAL AND CONCEPTUAL COEXISTENCE

Which of the three approaches is most useful to the health care professional? There are no differences in the methods used across epide-
TABLE 1. Evolutionary pathways in epidemiology and performance evaluation in health care (also a prediction)

<table>
<thead>
<tr>
<th>Epidemiology</th>
<th>Performance Evaluation</th>
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</thead>
<tbody>
<tr>
<td>A) History</td>
<td>A) History</td>
</tr>
<tr>
<td>1. Focus on diseases when they reach epidemic proportions within a population.</td>
<td>1. Focus on individuals as part of a group (e.g. physicians as part of physician community).</td>
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<tr>
<td>2. Focus on individuals as part of a group (e.g. scrotal sac cancer among chimney sweepers in England).</td>
<td>2. Focus on patients as recipients of services and evaluators of their goodness.</td>
</tr>
<tr>
<td>3. Focus on populations and their chronic diseases.</td>
<td>3. Focus on the environment/system within which providers provide care and recipients receive it.</td>
</tr>
<tr>
<td>B) Actiological Analysis</td>
<td>B) Process Analysis</td>
</tr>
<tr>
<td>1. Find the cause of an infectious disease epidemic.</td>
<td>1. Find the cause of adverse events (e.g. a &quot;bad&quot; physician and mortality).</td>
</tr>
<tr>
<td>2. Identify the causes of chronic behavior in groups (e.g. addictions, violence, etc.).</td>
<td>2. Identify the causes of chronic behavior among health care providers (e.g. is the system the cause of aberrant behavior?).</td>
</tr>
<tr>
<td>3. Identify the correlates of chronic disease and behavior prevalence (e.g. heredity, environmental exposures, etc.).</td>
<td>3. Identify the correlates of chronic under-performance (e.g. state of science, level of performer knowledge, recipient expectation, system's rewards, etc.).</td>
</tr>
<tr>
<td>C) Outcome Analysis</td>
<td>C) Output Analysis</td>
</tr>
<tr>
<td>1. Describe the temporal and spatial distribution of disease in communities (e.g. &quot;mad cow&quot; disease, osteoarthritis, ischemic heart disease, etc.).</td>
<td>1. Focus on what happens during a hospitalization episode (e.g. mortality, nosocomial infections, cesarean sections, etc.).</td>
</tr>
<tr>
<td>D) Outcome Analysis</td>
<td>D) Outcome Analysis</td>
</tr>
<tr>
<td>1. Focus on the continuum of care after discharge from a hospital or end of an ambulatory care episode (e.g. define community-based measures of functional status changes as real outcomes).</td>
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Prediction

Epidemiology and Epinosocomiology will complement as well as output and outcome analysis. The result: a re-emphasis on population-based measures where the incidence/prevalence of health is correlated with health care, among others.

Historically, the hospital-based health care system took the epidemiological concepts and tools and applied them to its own "population" — those who already had access to the hospital and were classified as patients. In that sense, the "science of what befalls people" became the "study of what happens to hospitalized patients". Perhaps that modified version of epidemiology can more accurately be called "epinosocomiology" or, the study of what befalls hospitals. Indeed, when epidemiological tools and methods are used to compare the hip replacement rates across hospitals in a region, the unit of the analysis becomes the hospital not the population. The attractiveness of this argument lies in its generic applicability across sites of analysis. If epidemiological tools are useful during the analysis of hospital or provider
The contribution of epidemiology to CQI: a commentary performance assessment and evaluation, hence quality, then the integration of epidemiology into CQI and other similar philosophies of inquiry becomes a natural evolution [14] and the conceptual and practical framework of the interchangibility between population and organization-based approaches becomes reality.

REFERENCES