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Commentary

The value of monitoring outcomes should be measured by the appropriateness of the response

Timothy P Hofer

VA Health Services Research & Development Center of Excellence, and Department of Internal Medicine, University of Michigan, Ann Arbor, MI, USA

Corresponding author: Tim Hofer, thofer@umich.edu

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See related research by Cockings *et al*. in issue 10.1 [http://ccforum.com/content/10/1/R28]

Abstract

Real-time monitoring of outcomes is becoming increasingly feasible in health care, and with it the hope of early detection of problems and the ability to tell whether interventions are having their desired effect. The next step should be to try to demonstrate that the reports of such monitoring systems lead to reasonable responses and valid inferences about causality, and that we are not chasing red herrings.

A high-profile patient managed by a high-profile doctor has a bad outcome. Within the same month, but at different geographical locations within a medical center, two surgical procedures are conducted at the wrong anatomical site. In a monitoring programme it is noted that an intensive care unit (ICU) has ‘more deaths than expected’ for the second quarter in a row. How should an organization react to such findings? At what point should leaders convene special meetings to evaluate organizational performance. How does one decide whether and when to make sweeping changes to established operating procedures, which almost invariably increase the number of steps involved in caring for patients? Although we have all experienced how the first example can galvanize an institution into possibly ill considered responses, there is hope that feedback from careful analyses of large databases will improve patient care.

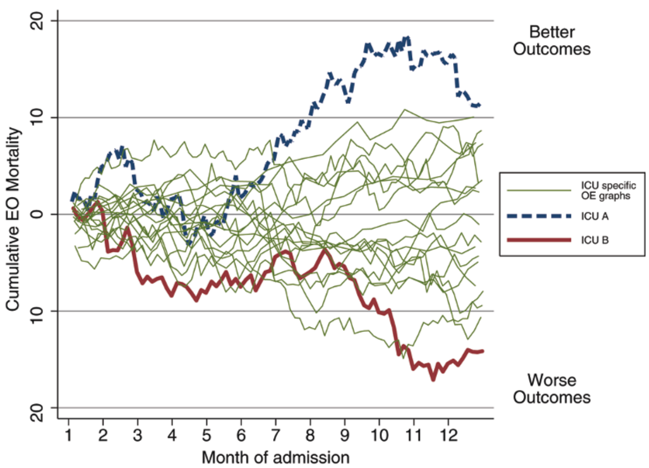
The report by Cockings and coworkers in the previous issue of *Critical Care* [1] describes a method that allows individual ICUs to monitor mortality outcomes graphically, and more easily and rapidly than is possible using the quarterly standardized mortality ratios received from an ICU national audit programme, as already exists in England. The goal is to minimize delays in recognizing significant deterioration in performance and to provide this expedited feedback locally to ‘management and clinicians [who] are well placed to respond rapidly with suitable investigation and corrective strategies if necessary.’

The real allure of these methods is that we may be able to achieve a new level of insight by linking trends in outcomes to specific calendar dates and sequences of patients. It is believed that this will allow local personnel to utilize their knowledge of what is going on day-to-day in a particular organizational unit as an additional explanatory factor for the observed temporal variations in outcomes. It is acknowledged by some of these same authors elsewhere [2] that, given the small numbers of patients with any particular clinical diagnosis in an ICU patient population, these methods are necessarily ‘more suited to monitoring changes that affect all patients or the entire clinical process.’

The use of real-time process monitoring is of course not new. Statistical process control achieved widespread acceptance after it was described in practical operational terms in Western Electric’s *Statistical Quality Control Handbook* in 1958 [3], and it remains an essential tool in highly structured manufacturing systems today. These methods have also been applied across a variety of the much less structured settings found in medicine, as summarized in the report by Cockings and coworkers [1]. Their contribution in that article is to illustrate, through a practical example in one ICU, two of the simpler forms of process control charts: a ‘CRAM chart’ or a plot of the cumlative difference between expected and observed number of deaths, along with a ‘p-chart’ that uses control limits based on statistical testing at monthly intervals to look for mortality that exceeds expected levels. While both of these methods have some disadvantages relative to more complex methods, Cockings and coworkers argue that their ease of use and accessibility to a nonstatistical audience outweigh potential disadvantages.

E-O = expected-observed; ICU = intensive care unit.

Figure 1



Simulated expected-observed tracings. OE, observed-expected; ICU, intensive care unit.

For those who are interested in the relative advantages and disadvantages of different methods of real-time process monitoring methods, the cited report by Grigg and coworkers [4] provides additional discussion. However, there is perhaps another important point to be made. Statistical process control as practiced in industrial settings is conceived of as having three parts [5], monitoring the process, identifying the reasons for deviations in the process and taking corrective action. However much we manage to improve the monitoring step, the success of the undertaking still depends on how well the causes of the problems are identified and remedied. These latter two steps have received much less attention. It is still an open question as to whether the widespread use of these monitoring methods will lead to valid inferences about cause and effect relationships that affect mortality in ICUs. Even if valid causal relationships are correctly inferred, then determining the appropriate response can be an enormous challenge and one that is sometimes better suited to multicentre trials than local improvization.

As correctly noted by Cockings and coworkers, 'care must be taken not to over interpret the E-O [expected-observed] chart as fluctuations may represent random variations, or real but transient and reversible changes in the quality of care.' Figure 1 shows a simulated series of E-O tracings that could be produced simply by random variation (given the relationships between and distributions of mortality rates, numbers of admissions and severity seen in a large cohort of ICU patients in the USA [6]). One could imagine that in this sample of identically performing ICUs, ICU A might feel quite smug whereas ICU B would be instituting all kinds of new procedures in an effort to remedy their apparently disastrous trend. Even if the *P* charts revealed no statistically significant monthly difference, an institution might be hard pressed to ignore such a trend. Furthermore, apart from false alarms due to random variation, Cook and coworkers [2] pointed out that all types of control charts, 'are as much a form of continuous assessment of [a risk adjustment] tool calibration as of the clinical process of care. Where a change is signaled, either the model fit or the clinical milieu may have changed.'

Real-time monitoring of outcomes is becoming increasingly feasible in health care, and with it the hope of early detection of problems and the ability to tell whether interventions are having their desired effect. What are really needed at this point are some concrete examples of how ICUs use this more timely signalling of outcome trends to identify and rectify changes in performance, and some assurance that ICUs will not end up spending too much time chasing red herrings as a consequence of random variation in outcomes.

Competing interests

The author declares that they have no competing interests.

References

1. Cockings JGL, Cook DA, Iqbal RK: **Process monitoring in intensive care using cumulative expected minus observed mortality and risk-adjusted *p* charts.** *Crit Care* 2006, **10:**R28.
2. Cook DA, Steiner SH, Cook RJ, Farewell VT, Morton AP: **Monitoring the evolutionary process of quality: risk-adjusted charting to track outcomes in intensive care.** *Crit Care Med* 2003, **31:** 1676-1682.
3. Western Electric. *Statistical Quality Control Handbook*. New York, NY: Western Electric Company; 1958.
4. Grigg OA, Farewell VT, Spiegelhalter DJ: **Use of risk-adjusted CUSUM and RSPRT charts for monitoring in medical contexts.** *Stat Methods Med Res* 2003, **12:**147-170.
5. Guh RS: **Integrating artificial intelligence into on-line statistical process control.** *Qual Reliabil Eng Int* 2003, **19:**1-20.
6. Render ML, Kim HM, Deddens J, Sivaganesin S, Welsh DE, Bickel K, Freyberg R, Timmons S, Johnston J, Connors AF Jr, *et al.*: **Variation in outcomes in Veterans Affairs intensive care units with a computerized severity measure.** *Crit Care Med* 2005, **33:**930-939.