the number of low- and especially very-low-volume programs performing CABG seems unwarranted. A solution to this problem is somewhat less obvious.

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Commentary: Safety in numbers

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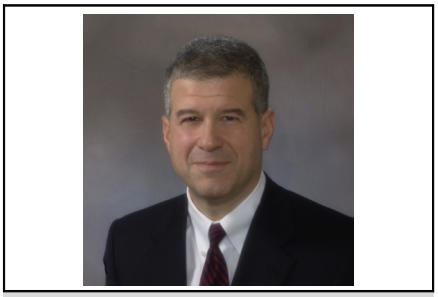

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Using publicly reported data from New York and California, Mori and colleagues[1] found substantial year-to-year variation in publicly reported, hospital-level ratios of observed to expected coronary artery bypass grafting (CABG) mortality, which they interpret as measure instability related to small sample sizes. Based on inflection point analyses, they recommend adding mortality metrics derived from a hospital's most recent 111 CABG cases (ie, a standardized denominator sample size) as a complement to traditional annual or biennial reports.

CENTRAL MESSAGE

Quality measures based on small sample sizes have low statistical power and reliability. Mitigation may include multiyear samples, standardized denominator sample sizes, composite metrics, shrinkage estimators, or graphical plots.

THE CURSE OF SMALL NUMBERS

Notwithstanding its methodological issues (eg, admixture of 2 states with markedly different cardiac surgery structures and oversight; attribution of all year-to-year variation in observed to expected mortality as random "noise") and obvious implementation challenges (eg, confusion related to simultaneous time- and sample size–specified measures), this study illustrates a pervasive challenge in health care quality measurement—small sample size.[2-7] Annual hospital discharge volumes for individual conditions and procedures are often relatively low (eg, <100 discharges), which limits accurate performance measurement. For binary outcomes such as mortality, the

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confidence and prediction intervals around point estimates widen dramatically when the number of observations is small, which is the basis for so-called "funnel plots."[8,9] This random sampling variation creates greater uncertainty regarding a hospital's true underlying performance when sample sizes for the measured condition or procedure are small.

This statistical issue has important health policy implications. Because of the volume-outcome association, the low-volume programs for whom it is most difficult to reliably measure outcomes are also those more likely to have marginal performance and for whom accurate monitoring is most crucial.[10,11]

STATISTICAL POWER AND MEASURE RELIABILITY

Small sample size is associated with low statistical power to detect outliers, a core function of risk-adjusted performance measures.[12,13] It also compromises one of the most important characteristics of any performance measure—reliability, or the proportion of measured performance variation that is due to true differences in quality.[14] Because reliability is a function of sample size and within- and between-provider variance, when sample sizes are small and within-provider random sampling error increases, reliability is lower.

Many surgical performance measures have reliabilities well below 0.40 to 0.50 at the hospital level,[15,16] which is generally considered a minimally acceptable lower limit. For its composite measures,[17-20] the Society of Thoracic Surgeons (STS) insists on average reliabilities of at least 0.50 and will not assign a performance classification to providers whose volumes are inadequate to ensure this.

MITIGATING SAMPLE SIZE CONCERNS

In addition to a fixed, minimum number of observations as advocated by Mori and colleagues,[1] numerous other strategies have been implemented to address sample size issues. For example, *multiyear time windows* that annually update by 1 year have been used by many health care report cards. The STS uses 3-year sampling periods for all its adult cardiac surgery composite measures except CABG,[21,22] currently based on 1 year of data but expanding to 3 years in 2021. Periods longer than 3 years are generally not recommended, because more remote data may not be representative of current practice. If Mori and colleagues[1] had also examined 3-year time windows, most hospitals would likely have exceeded the authors' recommended 111-case sample size threshold, and it would not have been necessary to propose a separate and possibly confusing measure.

Composite measures encompassing multiple outcomes are extremely useful and have been the basis of STS performance measurement since 2007.[17-22] Composite measures are multidimensional (eg, mortality and morbidity) and thus more comprehensive in scope, and they effectively increase the number of end points, making it possible to more reliably discriminate performance. In the development of the original STS CABG composite measure, mortality alone could classify only 1% of STS participants as better or worse then expected outliers, whereas the composite measure identified 23% as outliers.[22]

Shrinkage estimation[4,23-29] (referred to by some as "reliability adjustment"[30-32]) is a statistical technique that provides more accurate estimates when sample sizes are small, analogous to what happens naturally with regression to the mean as more observations become available. Extreme values are "shrunk" closer to the overall provider population mean, with greater shrinkage for providers with the lowest volumes and less shrinkage for those with larger volumes, whose estimates are inherently more reliable. Shrinkage estimation reduces the likelihood of false-positive outlier identification but may result in more false-negatives.[29]

Graphical methods are particularly useful to monitor performance in low-volume programs. Funnel plots explicitly demonstrate the increasing random sampling variation of point estimates derived from smaller samples and typically include specific alarm and outlier control limits.[8,9] Risk-adjusted CUSUM or VLAD plots[33-38] allow near real-time, case-by-case monitoring of observed versus expected outcomes, facilitating more timely identification of deteriorating trends in performance for low-volume programs.

SURGEON-LEVEL MEASURES

All the preceding concerns are magnified when measuring performance at the surgeon level, for which sample sizes are smaller than for hospitals. The STS individual surgeon composite measure for adult cardiac surgery[39] addresses this challenge by combining the results for 5 common procedures (isolated CABG, isolated aortic valve replacement, isolated mitral procedures, aortic valve replacement + CABG, and mitral procedures + CABG); 3 years of data; and 2 outcomes (risk-adjusted mortality and morbidity). Because of these multiple strategies to increase sample size and endpoints, it has the highest average reliability ever measured for a STS performance measure (0.81). An STS participant-level (hospital or group practice) multiprocedural composite measure with equally high reliability has been developed and will be published in 2021.

CONCLUSIONS

Small sample sizes and relatively low adverse event rates are among the greatest challenges to health care performance measurement, and numerous mitigation strategies have been suggested. Although the fixed, minimum sample size recommendation of Mori and colleagues[1] is a reasonable complement to existing time-based approaches,

longer fixed time periods (eg, 3 years of data) would likely achieve similar reliability with a single, simple, familiar, and easily understood approach.

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