



The Status of the HCD/ASQ Hospital Acquired Infection (HAI) Data Validation Initiative

Almost a year and a half ago, the HCD was approached by the Chief Epidemiologist at the Washington State Health Department, David Birnbaum (a former HCD member), with a request to assist in his quest to rationalize the collection, evaluation and reporting on data having to do with Hospital Acquired Infections. He demonstrated how the now mandatory systems for collecting and processing this data are based on antiquated data validation methods and that there are now more efficient and accurate methods.

Some in HCD (Kay Brown, Bill Dunwoody, and others) believed that within ASQ Divisions there is the requisite team experience and expertise to address the issues that Dave Birnbaum raised.

Pursuant to that belief, we partnered with the Stats Division (including William Brenneman, Connie Borrer, and Gordon Clark), the Audit Division (Sandy Storli) and the QMD (Grace Duffy) to research the issue. In addition, we communicated with some in CDC for whom the quality of this process is a responsibility.

We also wrote a considered response to a number of questions that had been posed by the CDC about how they planned to address this issue (see additional information below). It was received politely and we were thanked for our effort.

Another response was that we wrote an article on the dilemma entitled "The Current State of Validating the Accuracy of Clinical Data Reporting: Lessons to Be Learned from Quality and Process Improvement Scientists." The article was published in the June 2013 issue of the very prestigious juried medical journal, "Infection Control and Hospital Epidemiology (ICHE)." <http://www.jstor.org/stable/10.1086/670636>

We are now exploring additional ways to communicate the problems with HAI data validation and how they can be more effectively addressed.

We believe that this effort has demonstrated the utility and potential of cross-Divisional efforts within ASQ and are looking for other similar opportunities in the future.

If you have questions, please contact Joe Fortuna (jaf@prism1.org<<mailto:jaf@prism1.org>>)

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Dear Dan,

Thank you for the opportunity to review a presentation by your NHSN staff and the validation guidance/toolkit document they explained. As you know, most of our review team are leading members of several divisions of the American Society for Quality. Some members of the team have greater first-hand familiarity with healthcare setting or government agency operations than others; all have expertise in statistical theory, audit and validation methodology and related standards. They were asked to address six specific questions:

1. What sources of variation in CLABSI and other HAI reporting to CDC's National Healthcare Safety Network (NHSN) should be the focus of validation efforts?
2. Should numerator and denominator data that comprise CLABSI and other HAI measures be included in validation programs or should validating numerator data, i.e., case finding, be the sole focus, at least initially?
3. How should CDC take into account the wide range of resources—human and material—for CLABSI and other HAI data validation in state health departments as CDC develops, publishes, and refines its validation methodology?
4. What considerations should CDC use to decide when to move from targeted validation to representative validation sampling?
5. What are best practices to maximize inter-validator reliability?
6. What are the best ways to evaluate pass-fail standards for validation, e.g., should the bar be set high or low?

When reflecting on what they heard and saw, team members diverged between thoughts related to quality control and thoughts related to quality improvement. I suspect this relates to lack of clarity as to whether your approach is intended as quality control (your document is entitled validation but it lacks many of the hallmarks typical of validation as applied in other industries to ensure a work process produces reliable product or service quality) or as quality improvement (e.g. any starting level of performance is fine and your intent is to bring it up by discovering improvement opportunities). In one way or another team members also recognized that not only is validation important, but verification of submitted data is as well. Aspects of these distinctions are discussed in an article by several members which should appear in the next few months (Fortuna JA, Brenneman W, Storli S, Birnbaum D, Brown KL. "The Current State of Validating the Accuracy of Clinical Data Reporting: Lessons to Be Learned from Quality and Process Improvement Scientists" *INFECT CONTROL HOSP EPIDEMIOL in press*).

This summary will start with the quality control perspective comments, then give the quality improvement perspective comments, and end with some thoughts on how we might be able to work together on this and other quality issues. While some members of this review team are more familiar than others with steps that can be taken to prevent these healthcare-associated infections, all share a common understanding that the purpose of validated infection reporting is to produce information that can guide prevention actions. We share that goal with you.

In terms of the specific questions and overall impressions, from a quality control perspective some of the members:

- Expressed concern about your sampling strategy. Some noted that it will over-expose certain types of hospitals (likely the largest ones) while almost ignoring other types rather than expose all to validation, so is not optimal to ensure your entire data supply chain consistently produces quality data.
 - Related to this, it was noted that a focus solely on CMS IQR participating facilities (excluding facilities that are in a state reporting network but not participating in CMS IQR), and focus only on ICU, are troubling. It also was noted that the sequence of first sampling from all facilities, then checking if a selected facility is an IQR and removing it if not to be replaced by another chosen until all of the facilities are IQR seems inefficient.
 - Another similarly thought that a stratified random sampling procedure should be considered (vs. the 5% random sample) and evaluated to insure that a more representative sample is obtained.
 - Another found puzzling your lack of connection between internal self-assessment results and prioritization of external validation on-site assessment site selections.
- Noted lack of an explicit pass/fail standard, operating characteristic curves, etc. (which we usually see in the design of industrial validation programs).
- Recommended benchmarking to find an achievable low yet acceptable for intended purpose pass/fail level; while this must be low enough to be achievable it may be unwise given current public opinion to simply say “low” or “minimum” instead of good enough for intended purpose.
- Most if not all felt that you need to validate both the numerator and denominator reporting process, but the relative importance of these two components may be different for different agencies.
- Standardized tools, “round robin” testing along with clear definitions and instructions, and engaging state partners all can help improve inter-rater reliability, but pertinent literature also was identified showing number of years of experience counts in terms of rater qualification. One questioned the need for sending more than one person to each hospital; another suggested the data collection process and scoring parameters may need to be better defined if variability in scoring is to be kept within acceptable limits (which could be assessed by kappa, weighted kappa or intraclass correlation coefficient).
- In terms of what sources of variation in reporting should be validated, one member commented that “Being an engineer, my first thoughts are to validate the process and then focus on what part of the data needs to be validated.”. Another expressed this in a different way, noting that validation is a pass/fail decision as to whether the end product of a work process is of sufficient quality for its intended purpose; if not, then sources of variation can be investigated. Further discussion between our teams might be helpful in clarifying whether your starting intent is to research all possible sources of variation (a task which might not be within the capacity of all state health departments) or to confirm whether hospital reporting reliably meets quality requirements for each state health department (a much simpler task with analogous precedents in many other industries). If hospital processes for detection and reporting are not in statistical control, or lack critical elements, perhaps a separate guidance for hospitals as to best practices might be considered apart from this guidance/toolkit on validation steps for health departments. Please see the next section for further thoughts regarding quality improvement within hospital detection and reporting programs.

In terms of the specific questions and overall impressions, from a quality improvement perspective some of the members suggested:

- We must recall that data reporting is a process. While training can be helpful, Dr. Juran taught us that problems with processes are typically 85% due to the process and 15% due to the people working in the process. Accordingly training will only address 15% of the data validity problem.
 - This relates well to another’s comment that validation should assess whether the process produces an end result of suitable quality or not (a pass/fail decision), and if not then process step deficiencies can be investigated and corrected.

- Also helpful to identify IPs that lack resources to analyze data and performance improvement skills (i.e., separating issues of skill versus will). Supportive organizations like state-based improvement collaboratives or state health department consultants may assist in shoring up IP knowledge and skills, but other remedies are needed where resources to do the work are insufficient. Where a process improvement view is needed it seems that CDC should take a major leadership role in this regard.
- To define the highest a threshold level can be set at some point in time, don't believe this can be estimated until the validation program has been in place and achieved some stability over time. At that time, the level may become clear and could be a combination of expert opinion and statistical analysis. Benchmarking may be helpful too. What do other enterprises that employ sampling do to change from one sampling method to another - I would recommend publications by Dr. Sharon Lohr of WeStat (she is one of the foremost experts in sampling methods and emeritus professor of Arizona State University. Dr. Lohr has papers and textbooks that may be helpful here).
- Use of Statistical Process Control (SPC) charts might be helpful. For rare events, time between events might be helpful to determine whether a process is in control or not and to detect adverse trends due to common versus special cause variation. There is literature on risk-adjusted control charts.
- It would be helpful to have some agreement between what is documented and coded versus what is interpreted by IPs/ID physicians. For example, there may be variation in evaluation between a hospitalist, a surgeon, the attending and the infectious disease physician; if a physician documents or denies presumptive UTI, pneumonia, etc., it is coded as such and may not be an actual infection. A period of time is needed to review and correct erroneous coding and HAI data to ensure performance improvement is directed where it needs to be.
- In SIR where the denominator uses a logistic regression model to predict risk, one of our members recommended keeping and improving that model, suggesting the example given appears simplistic however the statement is made that it is only an example. To evaluate the model that member indicating needing to examine plots and control charts in different situations.
- Standardized data collection and interpretation tools are important (our team members haven't seen yours inside of NHSN so cannot comment further).
- One member assumed you've already benchmarked with other data gathering organizations such as Press Ganey and PRC subscription services for healthcare customer satisfaction. Another asked what types of validation are they after -- Construct, Content, Criterion -- they also need to look at both validity and reliability. Another, who had a seasoned IP in the room during the call brought up a clinical concern that IP had heard about: mid-line vs. central-line use to avoid the definition of infection reporting in NHSN. The IP had been told by vendors that people are using this alternative method as line infections in ML are not part of NHSN, and after the call sent this information: <http://digital.infectioncontrolday.com/i/108409/42>

Several of the members identified literature they thought pertinent to some of their suggestions. You might already have considered those resources, but in case not here are their suggestions:

- Regarding qualification of those who conduct validations (questions 3 & 5):
 - Experience counts and for this problem there is a pertinent finding in the research literature (Ehrenkranz NJ, Shultz JM, Richter EI, "Recorded Criteria as a "Gold Standard" for Sensitivity and Specificity Estimates of Surveillance of Nosocomial Infection: A Novel Method to Measure Job Performance" INFECTION CONTROL HOSP EPIDEMIOL 1995;16(12):697-702). Ehrenkranz et al. found that significantly more infection control professionals with 4 or more years of coding experience achieved the target level of accuracy in applying NHSN coding conventions than those with less than 4 years of experience among a regional collaborative organization. Supportive findings by Kahn MG, et al. J AM MED INFORM ASSOC 1996;3(3):216-23 indicates that performance improved among a team of infection control professionals through

regular opportunity to compare their results with computer-generated expert-system classifications. Thus, one best practice is to define as a state validator hiring requirement a minimum number of years of practice in a setting wherein one has an opportunity to learn from mentoring.

- Inter-validator agreement (as kappa or intraclass correlation coefficient) indicates they agree but not necessarily that they got the answer correct. ASQ offers certification by examination for quality auditors, managers and engineers. Testing on both theoretical and practical aspects should be considered, and the test material should span both simple and complex case coding since some parts of NHSN criteria are easier to apply consistently than others. We would be happy to assist CDC in developing a national certification for state validators.
- Regarding establishment of measurement process control:
 - NBS Monographs (now NIST) on Measurement Assurance Programs (e.g. the Volt Transfer Program) could be a natural here. The methods require computers and statistics, but they are right in the wheelhouse for our Statistics Division. We'd be glad to discuss the concept further and run down current references if you'd like.
 - The second area is in the area of Big Data (Data Mining, Scrubbing, Reporting, and Predictive Analytics). This field offers the biggest potential for discovering and predicting the critical cause/effect relationships between data collected in real-time EMRs and the kind of predictive diagnoses that CDC is seeking. Again, some on our team believe our software group would be all over this angle.
- Regarding risk-adjusted control charts:
 - Alemi, Farrokh and Douglas W. Oliver (2001). "Tutorial on Risk-Adjusted P-Charts", *Quality Management in Health Care*, Vol. 10, No. 1, pp 1-9.
 - Grigg, O. and V. Farewell (2004). "An Overview of Risk-adjusted Charts", *Journal of the Royal Statistical Society*, Vol. 167, No. 3, pp 523-539.
 - Paynabar, Kamran and Jionghula Jin and Arthur Yeh (2012). "Phase 1 Risk-Adjusted Control Charts for Monitoring Surgical Performance by Considering Categorical Covariates", *Journal of Quality Technology*, Vol. 44, No. 1, pp 39-53
 - Woodall, William H. (2006). "The Use of Control Charts in Health-Care and Public-Health Surveillance", *Journal of Quality Technology*, Vol. 38, No. 2, pp 89-104.
 - Montgomery, Douglas C. (2005). *Introduction to Statistical Quality Control*, 5th Edition, John Wiley & Sons, Inc.
 - Montgomery, Douglas C. (2005). *Introduction to Statistical Quality Control*, 5th Edition, John Wiley & Sons, Inc.
 - Wheeler, Donald J. (1995). *Advanced Topics in Statistical Process Control*, SPC Press.
- Regarding other aspects in which ASQ members might aid CDC and its partners in improving healthcare safety and quality through techniques originating in the quality sciences:
 - Shreyas Limaye, Christina Mastrangelo, Danielle Zerr and Howard Jeffries (2008). "A Statistical Approach to Reduce Hospital-Associated Infections", *Quality Engineering*, Vol. 20, pp 414-425.
 - Ehie, I. and C. Sheu (2005). "Integrating Six Sigma and Theory of Constraints for Continuous Improvement: A Case Study." *Journal of Manufacturing Technology Management* 16(5): 542-553.
 - Pirasteh, R. M. and K. S. Farah (2006). "Continuous Improvement Trio: The top elements of TOC, lean and six sigma (TLS) make beautiful music together." *APICS Magazine*: 31-36.
 - Some reference books they may want to review (if they don't have these already) would be Dr. Don Wheeler's books. One is on evaluating the measurement process and there were a couple on data collection and data validation. His books are very good and easy to use. SPC Press offers today's best books on Statistical Process Control, Six Sigma, Data Analysis, Quality Improvement... (<http://www.spcpress.com/books.php>)

ASQ has a long history of providing simple and efficient tools for validation. These include “sampling by attributes” (which would be appropriate for this HAI problem) and “sampling by variables” which have found wide acceptance across many manufacturing and service industries where there are similar concerns about workload or available expertise. These tools have been codified into national and international standard methods since the 1940s. These methods are relatively easy to teach, certification by examination already is available for quality auditors and quality managers, and members of ASQ located across the nation could assist in educating state health departments in use of these methods. Many data quality issues are discovered when data are analyzed statistically using both graphical and numeric techniques. This suggests that both graphical and numeric analytical procedures should be recommended for use, another aspect in which ASQ’s members could provide examples and assistance.

Our review team members were glad to see CDC taking first steps in this important direction, and hope our constructive criticism will enable you to refine the guidance you’re providing to your partners at the state level. Please let me know what you see as the next step in building a collaborative relationship between our two organizations.

Sincerely,

A handwritten signature in blue ink that reads "Joseph A. Fortuna, MD". The signature is written in a cursive style with a large initial 'J' and a distinct 'M' at the end.

Joseph A. Fortuna, MD, Chair
ASQ Healthcare Division



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The Current State of Validating the Accuracy of Clinical Data Reporting: Lessons to Be Learned from Quality and Process Improvement Scientists

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