



***An important message from ASQ's Healthcare Division
Jan. 29, 2008***

Saving Lives vs. Enshrining Bureaucracy

A number of popular press and blog editorials recently brought a serious impasse to public attention. The impasse centers on action taken by the [Office for Human Research Protections](#) (OHRP) relative to a program initiated by Johns Hopkins that demonstrates measurable and significant infection control results. The program was also deployed in nearly all Michigan hospitals ([See New Yorker, The Checklist](#)).

While the OHRP ruling did nothing to directly stop individual hospitals from using the simple and highly effective checklist designed to prevent catheter-related bloodstream infections, the OHRP action has the potential to threaten other initiatives that have typically been driven by collaborative efforts of healthcare quality improvement professionals, epidemiologists and dedicated clinicians.

This potential threat comes in the form of inappropriately forcing quality improvement activities into an experimental clinical research mode; erecting unnecessary hurdles that will slow down the pace of quality improvement activity; having the potential to choke off observational studies and collaborations that are routinely used to improve care and enhance patient safety.

For additional articles and stories on this issue, see:

- [A Lifesaving Checklist, an op-ed from the New York Times](#).
- [The Dec. 31 entry on the Health Care Renewal blog](#).
- [The Jan. 3 entry on the Technology in Medicine blog](#).
- [The Jan. 4 entry on the Healthbeat Blog](#).

In short, a team at Johns Hopkins initiated a quality improvement program at its hospital to reduce the risk of IV-catheter-associated bloodstream infections. Essentially, it involved:

- Creating a short checklist that translates established evidence based recommendations to simply implement guideline actions already recommended by respected authorities.
- Gathering all required supplies in one central dispensing location convenient to the point of use.
- Empowering unit nurses to do what operating room nurses have long been empowered to do (namely, call for correction of lapses in antisepsis or asepsis immediately upon notice).
- Evaluating the relationship to infection rate outcome in a before-and-after-time-series manner.

The team's project is typical of the sort of quality improvement or infection control program surveillance applied research activity that historically doesn't require informed consent of patients or staff members¹.

Unlike typical experimental clinical research trials—which involve randomization to potentially hazardous or less effective treatments, experimental treatments and deception or revelation of person-specific information—audit and quality improvement projects typically involve observational research and process improvement plan-do-

check-act studies which are consistent with the Health Insurance Portability and Accountability Act (HIPAA).

The success of the Johns Hopkins initiative, documented as a five-year prospective cohort study, was published by *Critical Care Medicine*.²

The Agency for Healthcare Research and Quality then funded an expansion of this approach throughout all Michigan hospitals, including smaller rural hospitals—where clinical research and institutional review boards are rare—without challenging the quality improvement nature of the work. Success across Michigan's hospitals similarly was published in the *New England Journal of Medicine*.³

The question, and now controversy, of distinguishing auditing and quality improvement applied research from experimental clinical trials research seems to stem from a query from an anonymous "concerned citizen" who wrote to the OHRP and complained that the research violated federal regulations to protect subjects in human experimentation. The citizen wrote that the research should have required ethical approval by an institutional review board in every participating Michigan hospital and informed consent of each individual involved.

The OHRP responded in support of the one anonymous complaint, maintaining a narrow interpretation of regulations governing experimental research in clinical trials.

Applying regulations that appropriately protect human subjects in true experimental research is ethical and proper. Applying them to the observational research and process improvement methods forming the foundation of hospital or healthcare epidemiology effectively stifles increasing the effectiveness of infection surveillance and control among other aspects of patient safety improvement, threatens operation of regional and national surveillance collaborations, such as the Center for Disease Control and Prevention's National Healthcare Safety Network.

This also sets bureaucratic paperwork burdens incompatible with the efficient, adaptive, rapid cycle protocol change pace common in a continuous quality improvement process. Failing to distinguish between experimental clinical trials research versus audit and quality improvement applied research can lock all of us into a status quo of patient safety that will be less safe than what is possible. Informed consent to treatment, not informed consent to individual process quality overviews historically conducted by hospital safety and quality assurance committees or programs is more appropriate.

This unprecedented impasse has already impeded further expansion of a cost-effective approach to markedly reduce the risk of potentially life-threatening bloodstream infections throughout American hospitals. It threatens established surveillance based applied research necessary to further increase our understanding of how best to prevent adverse outcomes in healthcare. Lastly, it presents so fundamental an impediment without justifying benefits that many deem the OHRP decision as defying reasonable logic.

Indeed, several prominent professional associations in the United States have already written in protest to Health and Human Services Secretary Leavitt, and have issued press releases, such as this [Healthcare Association of New York State](#) release, which calls the ruling an "absurd policy and a dangerous threat to patient safety." Other organizations outside the United States are taking notice, and ASQ's Healthcare Division is presently recommending a course of action for our Society.

Read the background information hypertext-linked above. Decide for yourself whether this OHRP decision appears to be based on blind enforcement of narrowly-interpreted bureaucratic procedure rather than appropriate recognition of important distinctions between experimental research (that ethically puts subjects at potential risk

so requires informed consent) versus healthcare epidemiology's long tradition of infection control and quality improvement program surveillance activity.

The latter observational studies, which are consistent with HIPAA, validly have a long history of not requiring informed consent of individual patients beyond their general consent to treatment. Watch for further messages from ASQ that will provide you with a convenient, effective way to both register disapproval of this OHRP decision and advocate for better approaches to such federal regulation. The safety of your own healthcare might depend upon it.

Written with, and on behalf of, the ASQ Healthcare Division Leadership Council, Douglas Dotan, Healthcare Division Chair.

References

1. Sarah L. Hill and Neil Small, "Differentiating Between Research, Audit and Quality Improvement: Governance Implications," *Clinical Governance: An International Journal*, Vol. 11, No. 2, 2006, pp. 98-107. [View abstract](#).
2. Sean M. Berenholtz, Peter J. Pronovost, P.A. Lipsett et al, "Eliminating Catheter-Related Bloodstream Infections in the Intensive Care Unit," *Critical Care Medicine*, Vol. 32, No. 10, 2004, pp. 2014-2020.
3. Peter J. Pronovost, Sean M. Berenholtz, Dale Needham, et al, "An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU," *New England Journal of Medicine*, Vol. 355, No. 26, 2006, pp. 2725-2732. [View article](#).

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