



**BSI**

2429 Hyde Park Road  
Jefferson City, MO 65109



## **STOP BSI COLLABORATIVE GREATER KANSAS CITY AND NORTHWEST MISSOURI INFORMATION SHEET**

### **DESCRIPTION**

The STOP BSI Collaborative is an exciting opportunity for Greater Kansas City and Northwest Missouri hospitals to partner with patient safety experts at Johns Hopkins University to reduce Central Line Associated Bloodstream Infections, also known as CLABSIs and/or BSIs. Three years ago, researchers from Johns Hopkins developed an evidence-based program, the Comprehensive Unit-Based Safety Program (CUSP), to evaluate and improve patient safety in hospitals of all sizes and levels of complexity. Since then, CUSP has been tested in over 200 hospitals across the country, and has led to unparalleled reductions in CLABSIs but also improvements in other areas of patient safety.

**Who:** STOP BSI will be a collaborative effort among Kansas City/Northwest Missouri hospitals, Johnson and Wyandotte County hospitals in Kansas, the MHA Center for Education (MCE) and the Missouri Center for Patient Safety (MOCPS).

**What:** The collaborative will replicate CUSP to reduce CLABSIs in intensive care units or in medical/surgical units with sufficient number of central lines. CUSP was developed and tested by Johns Hopkins University researcher Peter Pronovost, M.D., Ph.D., and was later replicated by the Michigan Health & Hospital Association Keystone Center for Patient Safety & Quality.

**When:** Hospitals are invited to participate in learning sessions via conference calls throughout the summer (see attached "Stop BSI National Immersion Call and Meeting Schedule") to learn more about the collaborative. The first national call is scheduled **July 7 at 4 p.m.** The learning sessions will be facilitated by Johns Hopkins University researchers and staff. In addition, a special teleconference with MCE and MOCPS to specifically discuss the Missouri/Kansas Project is scheduled **Monday, July 13 at 12 Noon.** Those hospitals wishing to join the collaborative are asked to complete and submit the attached "Commitment Form for Participation" **by July 31, 2009.**

**Where:** The Greater Kansas City/Northwest Missouri collaborative will formally kick-off on September 2, 2009 with a face-to-face meeting. More information about this meeting will be forthcoming. All workshops and meetings thereafter will be held via conference calls. The kick-off meeting and subsequent conference calls will include partnering hospitals, MCE, MOCPS, and Johns Hopkins University researchers and staff.

**Why:** The primary focus of the two-year project is to reduce the incidence of CLABSIs in hospitals located within the Blue Cross Blue Shield of Kansas City (BCBSKC) service area, using an intervention that has proven success in Michigan hospitals. The secondary focus of the project is to test the use of the CUSP model, which combines proven patient safety techniques with a systematic focus on safety culture to reduce adverse events in hospitals.

## FUNDING

Funding for this project is provided, in part, by Blue Cross Blue Shield of Kansas City (BCBSKC). There is no fee to join the collaborative.

## BENEFITS OF JOINING THE STOP BSI COLLABORATIVE

- Access to evidence-based interventions based on the most compelling research in patient safety
- Access to practical implementation tools, which have been proven to be useful regardless of hospital size, teaching status, or case mix
- Coaching from world-renowned patient safety experts at Johns Hopkins University
- Support from MOCPS and MCE to achieve enhanced patient outcomes
- Opportunity to learn from and benchmark with other partnering hospitals in multiple states
- Opportunity to improve the culture of safety, reduce patient harm and eliminate CLABSIs in Greater Kansas City and Northwest Missouri hospitals

## PERFORMANCE EXPECTATIONS FOR PARTNERING HOSPITALS

- Each hospital must assemble a team committed to accomplishing the objectives of improving the culture of safety and reducing CLABSIs
- Hospital CEOs must sign a written commitment and designate team members prior to beginning the project
- Each team should include a minimum of a senior executive, physician leader, nurse leader, data collection and front-line nursing staff
- Each team is required to commit to collecting and submitting central line infection data and central line days
- Each team is required to commit to active and open sharing and participating in regional collaborative meetings, conference calls and other networking opportunities

## RESPONSIBILITIES OF HOSPITAL TEAMS

- Educate staff on the science of safety
- Assign an executive to adopt participating ICUs or medical/surgical units
- Identify unit defects and learn from one defect per quarter
- Implement teamwork tools
- Participate in collaborative activities
- Share experiences within their hospital and with other partnering hospitals and teams

## WHO IS ELIGIBLE TO PARTICIPATE?

- Acute care hospitals in MHA districts 1 and 2
- Acute care hospitals in Johnson and Wyandotte County, Kansas
- Participating hospitals must have a minimum of 100 central line days per year in ICUs or medical/surgical units

## WHY NOW?

- The pressures to improve quality of care and safety of patients have never been greater!
  - Payors', including Medicare, Medicaid and private payors, movement toward pay for performance: CLABSIs are on the "do not pay" list
  - The Leapfrog Group now requires CLABSI reporting
  - HHS Secretary Kathleen Sebelius announced a national goal of "75% reduction of these infections within three years."
- While most hospitals have dedicated attention and resources to patient safety initiatives, measurement of progress has been limited
- Now is the time to demonstrate that Greater Kansas City and Northwest Missouri hospitals are committed to accelerating the implementation of evidence-based interventions, rigorously measuring patient outcomes, and continuously improving hospital performance!

## MOCPS & MCE SUPPORT

The Missouri Center for Patient Safety (MOCPS) and the MHA Center for Education (MCE) are committed to supporting hospitals in improving patient safety. To that end, the two organizations will provide support to partnering hospitals in the Stop BSI Collaborative in the following ways:

- Provide education/training/tools for all levels of hospital staff on improving the culture of safety, team building, and reducing hospital-acquired infections
- Convene and facilitate sharing opportunities among partnering hospitals and teams regarding best practices, lessons learned, tools, systems, processes etc.
- Provide aggregate comparative reports and hospital-specific reports to participants

## CEO/ADMINISTRATOR COMMITMENT FORM

The enclosed formal commitment document is due by **July 31, 2009**. Please submit the completed, signed form to:

Missouri Center for Patient Safety  
Attn: Kimberly O'Brien  
2429 Hyde Park Road  
Jefferson City, MO 65109  
(573) 636-8608 – fax  
[kobrien@mocps.org](mailto:kobrien@mocps.org)



**Anesthesiology and Critical Care Medicine**  
The Johns Hopkins University School of Medicine  
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Department of Anesthesiology and Critical Care  
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1909 Thames Street – 2<sup>nd</sup> Floor  
Baltimore, MD 21231

**Peter J. Pronovost, M.D., Ph.D., F.C.C.M.**  
Professor

410-502-3231 Fax 410-502-3235  
Email: ppronovo@jhmi.edu

May 19, 2009

Dear CEO

The pressures to improve quality of care and safety of patients have never been greater. We worked with the hospital association and hundreds of ICU's in Michigan to reduce catheter line associated bloodstream infections (CLABSI) and were extremely successful. The median rate of those infections fell to zero and has been sustained at that level for nearly 4 years. These infections are estimated to cause nearly 60,000 deaths and result in nearly 3 billion in excess costs across the U.S. each year.

Thanks to generous funding from philanthropists and the Agency for Healthcare Research and Quality, we are now working with hospitals in 28 states to achieve similar improvements.

We want to be certain that you are aware of this opportunity, know with certainty your rates of these infections and are content with what they are, and have made a conscious choice whether or not to participate in your statewide project to reduce CLABSI.

Several recent announcements are bringing the importance of minimizing these infections to the forefront of safety efforts:

1. CMS pay for performance: CLABSI's are on the "do not pay" list
2. The Leapfrog Group now requires CLABSI reporting
3. Consumers Union is energizing their national activities to reduce infections
4. Health and Human Services Secretary Kathleen Sebelius announced a national goal of "75% reduction of these infections within three years". (press release attached)

The efforts of hospitals across the country to rigorously measure these infections, and then work collaboratively to reduce them, is garnering significant congressional attention. There is great expectation that this may be a model for other national healthcare improvement initiatives. More information on the national project can be found on the newly launched website, [www.safercare.net](http://www.safercare.net) . Please complete the attached form for more information about how to get involved through your state project coordinating center . We look forward to working with you.

Best regards,

Peter J. Pronovost, MD, PhD  
Director, Quality and Safety Research Group

CC: Amy Hesel, The Fund for Johns Hopkins Development  
JoAnne Duhl, The Philanthropic Initiative



JUL 30 2008

Peter J. Pronovost, M.D., Ph.D.  
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Health Policy and Management  
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Dear Dr. Pronovost:

This is in response to your request for guidance regarding your plans for activities related to improving the rate of catheter-related bloodstream infections in hospitals and compliance with the Department of Health and Human Services regulations for the protection of human subjects in research (45 CFR part 46). We appreciate your interest in advancing the quality of healthcare across the country and beyond, and your proactive efforts to take steps to prevent needless delays which might arise due to possible confusion or uncertainty related to how the regulations for the protection of human subjects in research might apply to planned activities. We are happy to cooperate with you in those efforts.

Based on your letter of April 8, 2008 to Dr. Kristina Borrer and our follow-up communications, we present below our understanding of the planned Johns Hopkins University projects.

Johns Hopkins University is going to cooperate with various state hospital associations or other institutions to implement the same five part program for reducing catheter-related bloodstream infections that was implemented in Michigan hospitals and described in the New England Journal of Medicine (NEJM) article of 12/28/06. At this point, the participating hospitals wish to adopt the program in order to improve the quality of care in their hospitals, based on their belief that the program has been shown to be effective. Johns Hopkins University is willing to provide technical assistance to the state hospital associations and the participating hospitals to accomplish this objective.

At the same time, Johns Hopkins University also plans to carry out a study to improve the understanding of how hospitals implement this program on a wide-scale basis, what factors influence the effectiveness of those efforts, and whether

rates of infection reduction found in the Michigan study are replicated in other states and settings. The data collections included in this study are as follows:

1. The participating hospitals will provide aggregate data regarding the number of infections and the number of “catheter days” occurring at the hospital over identified periods of time. These data will be collected at the hospitals for the clinical purpose of monitoring the quality of care being provided and also will be shared with Johns Hopkins University for study purposes.
2. Staff at the participating hospitals will provide information about their perceptions of the culture of safety in the Intensive Care Units (ICUs) through surveys identified by institution but not by individual respondent, using either a survey instrument developed by the Agency for Healthcare Research and Quality or an instrument used in the Michigan study. Survey results will be provided to the participating hospitals to inform hospital staff/officials about the perceived quality of ICU operations at their own hospitals. The results also will be shared with Johns Hopkins University for the study purpose of comparing those perceptions with the rates of infection across the different hospitals.
3. Staff at the participating hospitals will provide information about their perceptions of the process of implementing the infection-reduction program in their hospitals’ ICUs through surveys identified by institution but not by individual respondent, using the Team Check-Up Survey instrument developed by Johns Hopkins University. Survey results will be provided to the participating hospitals for the purpose of informing hospital staff/officials about the process of implementing the program at their hospital. The results will also be shared with Johns Hopkins University for the study purpose of relating features of the implementation process with the rates of infections across the different hospitals.

Based on this description of the Johns Hopkins University projects, our analysis of how the regulations for the protection of human subjects in research (45 CFR part 46) apply to these projects is provided below.

First, we believe that the actual implementation of the five part catheter-related bloodstream infection reduction program in the participating hospitals is a quality improvement activity that does not meet the regulatory definition of *research*. This is because none of the parties involved are implementing the program as a research intervention in order to evaluate its effectiveness. Here, the program is being implemented solely for the purpose of improving the quality of care.

Second, we believe that the activity involving the analysis of the aggregate data about the rate of catheter related infections (Point 1 above) combined with the data drawn from the two surveys (Points 2 and 3 above) does not fall under the regulations, and therefore does not need to meet regulatory requirements, including the requirement for IRB review and approval. The planned activity does meet the regulatory definition of *research* (45 CFR 46.102(d)), because it is a systematic investigation that is designed to improve the scientific understanding of how to implement this quality improvement on a wide scale. However, obtaining and analyzing the aggregated data about the rate of infections at the participating hospitals does not meet the regulatory definition of *human subjects* (45 CFR 46.102(f)), because Johns Hopkins University is not obtaining identifiable private information about any living individuals, nor is anyone intervening or interacting with living individuals for research purposes. The two surveys represent *research* involving *human subjects* under the regulatory definitions, but since the survey information is being collected anonymously, this research activity, including the comparison with the aggregate data about the rates of infections, is exempt from the regulatory requirements under 45 CFR 46.101(b)(2).

Regarding these types of projects, where the implementation of a program is being studied, an important issue is whether the regulations apply to the program itself, or only to the information collection activities used to study the program. For each hospital where the program to be studied will be implemented, the question to ask is: "Is the program implemented for a research purpose, or altered or controlled in some way to answer a research question?" If the project leaders, quality and safety leaders, and physicians implementing the program at a particular hospital answer this question "no," then the program is separable from the research for that hospital, and only the various ways in which data will be collected and analyzed are part of the research activities that may potentially need to meet the regulatory requirements. If, on the other hand, a project leader, quality and safety leader, or physician answers "yes" with respect to the implementation of the program at a particular hospital, and the delivery of the program is initiated for a research purpose, or is altered or controlled in some way to answer a research question, then the program implementation at that hospital is not separable from the research. For the Johns Hopkins University projects described above, the implementation of the program is separable from the research at all of the hospitals involved.

We understand that Johns Hopkins University may be conducting additional information collection projects related to the planned activity, and that these additional projects will be reviewed by Johns Hopkins University to determine whether or not the regulations apply and if the regulatory requirements, including IRB review and approval, need to be satisfied.

I hope this analysis is helpful. We believe that the analysis offered here is consistent with our prior analysis of the research activity reported in the NEJM article. The difference between the two analyses is that for the planned projects the implementation of the program is separate from the research activity, and so the regulations at 45 CFR Part 46 do not apply to the program implementation. If at some point you find that it would be beneficial for us to communicate directly with some state hospital associations or other collaborating partners regarding these projects, we would be willing to do so. And if you have any questions about the relationship between the regulations and this or other future projects, please do not hesitate to contact us.

Sincerely,

A handwritten signature in black ink, appearing to read "Ivor A. Pritchard". The signature is fluid and cursive, with a horizontal line drawn underneath the name.

Ivor A. Pritchard, Ph.D.  
Acting Director  
Office for Human Research Protections

cc: Dr. Daniel Ford, Vice Dean for Clinical Investigation  
John Hopkins School of Medicine  
Dr. Kristina Borrer