Understanding the Increase

A panel discussion on the risk of catheter-related bloodstream infections

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Tobi Karchmer, MD, MS is an Assistant Professor of Infectious Diseases at Wake Forest University Health Sciences, as well as the Hospital Epidemiologist at Wake Forest University Baptist Medical Center in Winston-Salem, North Carolina. She is currently an elected member of the board of the Society of Healthcare Epidemiologists of America (SHEA).

Cathryn Murphy, MPH, PhD, CIC is the Managing Director of Infection Control Plus Pty, Ltd in Australia and is an elected board member in the Association for Professionals in Infection Control and Epidemiology, Inc. (APIC), 2006-2007.

Karen Olekson, RN, CIC is an Infection Control Practitioner at the Health Sciences Centre, in Winnipeg, Manitoba, Canada, and is responsible for infection prevention and control activities involving neonatal and child health, obstetrical and gynecological programs, and psychiatric services.

Russell N. Olmsted, MPH, CIC has over 24 years experience in the field of infection control/applied epidemiology. He is Epidemiologist with Infection Control Services at Saint Joseph Mercy Health System headquartered in Ann Arbor, Michigan, and President of Applied Epidemiology Solutions, Inc., a private consulting business that covers the field of infection prevention/control and healthcare epidemiology. Over the last several years, infection control professionals (ICPs) from some institutions have begun to recognize a distinct rise in catheterrelated bloodstream infection (CRBSI) rates within their facilities. Although clinical studies are still in the early stages, there has been debate over the connection between a change in needleless-access devices and these increases in CRBSI rates. BD Medical believes this will become an increasingly important issue for ICPs across the world, and in an effort to increase awareness and encourage dialogue, we brought together six industry experts to share their unique perspectives in a frank roundtable discussion. On September 30, 2006, they convened in San Francisco to talk about the issue.



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The discussion was moderated by Geoffrey A. Dugue, MD, MPH, Director of Clinical Research for BD Medical.

What has been your exposure to the subject of needleless access devices and their impact on CRBSIs?

Tobi Karchmer At our facility, we noticed an increase in our bloodstream infection rate in 2003 and began investigating it at that time. Some of the factors we investigated included how centralvenous catheters were being inserted, how they were being cared for, and how the dressings were being maintained, but we were unable to identify any major problems with insertion, maintenance or care that would explain why our rate had increased as dramatically as it had. Then a colleague was at a meeting in 2004, and the issue of CRBSIs related to the mechanical valves was discussed. He called me from the meeting to ask which needleless device we were using and when it had been introduced. It turned out that the change had been made to mechanical valves and it temporarily related to our increase in bloodstream infection.

Eve Giannetta At the University of Virginia we had used a split-septum device and changed to a mechanical-valve device and immediately saw a jump in our house-wide bloodstream infection rate.

Lynn Hadaway I first heard the issue discussed at a meeting for another manufacturer probably a little over two years ago, and from there I followed the literature. I have seen firsthand many disconcerting practices in the hospitals where I've been in the past couple years. I've become very concerned about what's going on.

Cathryn Murphy In 2005 two Australian hospitals publicly reported and presented increases in their CRBSIs along with one New Zealand hospital. Two more Australian hospitals have anecdotally reported increases. The Australian equivalent of the FDA is now actively seeking data on devices and bloodstream infections (BSIs). It's been interesting watching the U.S. experience extrapolate across the southern hemisphere.

Russell Olmsted My initial awareness was from abstracts presented at scientific meetings in 2005 and publication of a report by Maragakis in January 2006. At our facility we've been using a split-septum system for over ten years, but we've had numerous occasions where we've been asked to consider moving to mechanical-valve devices, and because of the emerging literature we've been hesitant to switch. In addition, our facility has been participating in a central-line-associated bloodstream infection (CLABSI) prevention collaborative that has produced strikingly positive results, so we would carefully assess any proposed change in our BSI prevention program.

Building off the last question, how critical an issue is this on the radar of healthcare organizations?

Cathryn Murphy To paraphrase Al Gore, I think these reported increases in BSIs are an inconvenient truth. It is a critical issue, but unfortunately, in

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TOBI KARCHMER





Australia and New Zealand few organizations are giving it the attention that it requires. Reportedly, CLABSIs have an attributable mortality of 12 percent. There's a huge potential for increased morbidity, mortality and increased costs. We need to urgently find the truth, along with workable solutions, so we can make sure that not only are healthcare workers safe from needlesticks, but also that patients are not compromised in the process.

Russell Olmsted We're at a point, possibly, where the emphasis on protecting healthcare workers has tipped the balance to the point that we may be compromising patient safety.

Tobi Karchmer It's an extremely important issue. But it's complicated by the fact that there are many places where the infection control practitioner is fulfilling many roles in the institution, such as employee health or risk management. The part-time ICP may only have the support of a part-time hospital epidemiologist who does not have any formal training, and therefore the resources may not be available to thoroughly access changes in CRBSI rates. Lynn Hadaway My focus is more at the bedside, and most nurses at the bedside have not heard of this. Many times, needleless devices are being used in ways that they were never intended to be used. For example, I don't know of a single hospital that connects continuous infusions hub to hub anymore. They're going to put a needleless device in there regardless of whether they need it or not.





Tobi Karchmer You ask people what needleless device they use in their institution and many can't tell you unless they've been thinking about it and have gone to look. There's a huge amount of misinformation and lack of understanding related to needleless devices and an attitude that CRBSIs are part of what happens to patients in intensive care units (ICUs). I think we need to acknowledge that CRBSIs don't just happen, but represent a failure in the process of patient care. We do things that allow this to happen, and therefore we need to look at what we're doing.

Specific to catheter-related bloodstream infections, what do you feel are the recognizable contributing factors?

Cathryn Murphy Any textbook cites insertion technique, preparation of the insertion site, the way that a catheter is managed, contamination of the hub and the importance of prepping the site of administration. Prevention requires good compliance, and, unfortunately, we don't have good compliance with all those things.

Lynn Hadaway It's how we're managing that hub. I teach that you've got to look at the whole system, all

the way from the container where the flush solution is obtained, to the syringe, the needleless injection system, the flush solution itself and the catheter features. Because if you change just one component, you might not change your outcome.

Which has more of an impact on the level of CRBSIs—product design or clinical practice involving needleless connectors?

Eve Giannetta It was evident from our investigation that we had both device issues and practice issues; both have been addressed.

Lynn Hadaway I don't know that you can separate the two. I think they both go hand in hand and they both contribute to the problem. There are many times when there is no physical way to clean the device appropriately due to the grooves and crevices in the device. The nurse could be using as good a technique as humanly possible and still not overcome the deficits of the device.

Tobi Karchmer A big part of it is about clinical practice—and also about taking responsibility. We do need to improve compliance with best clinical practices such as disinfectation of the needleless





device prior to every access. In our facility we looked to see if we had technique issues. We did find problems with inconsistent disinfectation of the IV access hub, but despite documented improvement in technique, it did not significantly impact our CRBSI rates. It is very possible that a lot of this had to do with the device and how unforgiving it can be with less-than-perfect technique.

How can ICPs, along with the healthcare community in general, improve things?

Karen Olekson I think discussion, communication and dissemination of information are the keys to improvement. You also need to be able to track your bloodstream infections. A lot of us are doing manual extraction of data. There's no electronic extraction, so we wouldn't recognize the problem in a timely fashion at all. It makes no sense to get rates back nine months after the fact, so it's a lot easier if you can present that information back to the various departments in a timely manner.

Cathryn Murphy Two things I would love to see are, first of all, a cooperative effort from multiple manufacturers and unit users to undertake multisite investigations. The second would be the ability to encourage frank and fearless discussion of this issue without the fear of legal retribution, because that's one of the most difficult things. I am in the process of developing a safe, moderated, Webbased forum where clinicians and others that are independently interested can safely discuss this issue.

Tobi Karchmer We need more research. We really have a very small amount of actual data on what is happening in the devices, how they're working and why there are problems with them. Do these problems involve all mechanical-valve devices? Is there a difference between positive-pressure and neutralpressure devices? Are there differences between splitseptum and luer-activated, split-septum devices?

Lynn Hadaway Nurses want a prescriptive approach. They're saying, "Just tell me what I need to use and give me the data so I can make my decision." Nurses are frustrated when they see all these presentations and read all these reports, and they're talking in general terms. Is it the positive-displacement devices? Is it all mechanical valves? What is it about these devices that is adding to the risk?

Russell Olmsted Some facilities might have two or more different kinds of needleless devices in



different units, and I think that's a prescription for an absolute problem with patient care. Addressing that would be a good step in the right direction. Further, infection control professionals need to examine the incidence of CRBSIs at their affiliates and determine if their surveillance identifies a possible problem. If so, then multiple factors, including specific devices and patient-care practices, need to be examined.

Eve Giannetta Our facility switched to a splitseptum, luer-access device and right now things are looking good at our facility. We have almost one year of data on the new device we are using and we may publish. But right now I think ICPs should move cautiously and watch their data.

How do you feel about the role of the FDA, APIC, CDC guidelines, and SHEA, in terms of changing practices and products?

Russell Olmsted I think that those organizations will be key to getting the information disseminated and scientific meetings involving these and other stakeholders can shed light on the correlation between device design and increased risk of BSIs.

Cathryn Murphy APIC can have a key role as it can raise awareness in a fair and unbiased way. The other thing APIC could probably do is develop tools to help sites investigate these BSI increases and monitor practice surrounding the use of these devices. Perhaps APIC can be involved in businesscase preparation templates? APIC is very good at developing practical tools for ICPs.

Karen Olekson I think there may be a role for government agencies to offer manufacturers suggestions on how to properly test the products as well.



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LYNN HADAWAY

Tobi Karchmer I'm actually on the board of SHEA at the moment and we are obviously interested in the same things as APIC and other agencies, but one of the difficulties with guidelines is that it is difficult to move guidelines into practice. The other problem with guidelines and Healthcare Infection Control Practices Advisory Committee (HICPAC) recommendations is that currently there is not enough data for HICPAC to say very much, other than you should be aware that these are potential issues related to needleless devices that could lead to infection. We need data so that we can clearly show where and what the issues are in order to appropriately address change.

Do most facilities have surveillance processes in place? What needs to be a part of that process?

Tobi Karchmer Since bloodstream infections are considered a major issue, I would think that even in small facilities they're monitoring bloodstream infections, but that may be limited to just ICUs, with surveillance only happening part of the time. Beyond the acute-care-hospital setting, many systems do not have a good way of tracking infections that occur in the home-healthcare setting, long-termcare settings or other settings in which catheters are routinely used. There really is no surveillance in the outpatient setting.

Cathryn Murphy Regarding the process, most important are two things. First, whatever we find in our systems, we have to be responsive to these findings, and we need to respond in a timely and action-oriented manner. Second, we need to avoid any form of punition, because people who look hard will find bad outcomes and we don't need to punish them for that, but rather encourage them to recognize room for improvement and to find the truth of the matter.

Russell Olmsted The big question right now is whether the scope is sensitive and specific enough to pick up on these problems. The CDC's National Healthcare Safety Network looks like a very promising system in which we could at least have some convergence of standardized method and definitions so that we're using the same methodology as the person down the road or across another state. Certainly the gold standard would be an extremely technology-driven system, such as a data warehouse.

Eve Giannetta We would not have recognized our CRBSI issues as quickly if we didn't have such an aggressive surveillance program in place. Seeing an increase of one or two infections per month on a particular unit doesn't have the same impact as seeing that increase multiplied by several units. Depending on the frequency and type of surveillance other facilities are doing, there's a chance they might have issues they're missing.

Karen Olekson I admire healthcare facilities with fully integrated electronic systems—systems which capture real-time data and turn it into information. Hopefully these integrated systems will become more widely available across all healthcare facilities.

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What has been more influential when considering a change in medical device the financial data or the clinical proof?

Russell Olmsted At our facility there's a threshold. If you're going to exceed a certain capital expenditure, you need to present some justification so there's a formal process. They ask you to have certain information prepared for that particular group. It's similar to the business-case idea, but basically it looks at cost effectiveness, examines our current state and determines how much this will improve patient safety.

Eve Giannetta Our product change was driven by our infection rate. We tried education and the rate moderated, but we certainly weren't satisfied. Our administration said, "We need to do what's best for the patient so let's see what else is out there and let's go to a new device." We didn't have to absolutely quantify the clinical advantage in dollars.

Tobi Karchmer While we looked at the financial implications of changing our needleless device, once we identified that we needed to change to see if it would improve our CRBSI rates, we had the support of the institution regardless of the cost. On other

occasions, we have presented a business model where the number doesn't equal something positive, and we've said, "We still need to do this, because it's important for our patients and it's the right thing to do."

Cathryn Murphy Many ICPs feel that they have both a moral and ethical obligation to do something about this. Beyond a business point of view, those who have made the changes have also been driven by their ethical position. They feel it's unethical not to do something about it.



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