

New attention on POC device disease transmission

Anne Ford

April 2013—When 19th-century Hungarian obstetrician Ignaz Semmelweis found that doctors could dramatically decrease puerperal infections by washing their hands with a chlorinated lime solution before delivering babies, his colleagues thought he was nuts. Why, everyone knew that infections were caused by noxious air!

One hundred sixty-five years after Dr. Semmelweis' discovery, hand hygiene has, of course, become accepted as one of the most important methods of preventing transmission of disease. Yet many hospitals are still struggling to convince their staff that routinely disinfecting another potential disease vector—point-of-care testing devices such as glucose meters and PT/INR meters—is both crucial and effective.

"It really hasn't been understood that even though the meter doesn't necessarily touch the patient, cleaning and disinfection is still required," says Sharon Geaghan, MD, professor of pathology and pediatrics at Stanford University School of Medicine in Palo Alto, Calif. "That's really the point that I think has to be stressed: It can be an indirect contact transmission of the infectious agent from one patient to another through an intermediate contaminated object." And we're not talking about just a few hospitals, either: "Virtually all the published audits from government and independent investigators have underscored a substantial deficiency in a variety of institutions."



Dr. Geaghan

That's why the FDA, CDC, and CMS have all recently begun issuing guidance in the form of "recommendations such as restriction of point-of-care devices to a single patient when possible, use of single-lancet devices that are auto-disabling for capillary blood sampling, strict adherence to hand hygiene, and attention to thorough disinfection and cleaning of POC devices," Dr. Geaghan says. And that's why, last July, the CAP added the following item to its point-of-care testing checklist: "There is an infection control policy in effect to prevent transmission of infection via portable or handheld testing devices."

The big potential for infection as far as POC devices are concerned? Hepatitis. "We do know that you can transmit significant bacterial pathogens, and those can lead to clinically important disease, but the majority of outbreaks in the medical literature involve hepatitis B," Dr. Geaghan says. "It's the No. 1 risk for patients undergoing point-of-care testing, for blood glucose testing in particular. There is evidence that the number of outbreaks of hepatitis B is accelerating, and so there is a sense of urgency to fix this problem, especially since outbreaks have resulted in patient deaths." The problem is bad enough, she adds, that the CDC has actually begun recommending hepatitis B vaccination for certain diabetic populations.

She points out that point-of-care devices generally rely on capillary blood sampling—"which is not a closed system; it's an open system. And when you do fingersticks, the blood flowing from that puncture site is in contact with the environment, and potentially with the hands or gloves of the testing person," she says. It's a significant source of blood and body fluid exposures. "In fact, in several published reports, it's been the most common source of exposures to health care workers."

The CAP has added a new checklist item to its point-of-care testing checklist to address this hazard and reduce transmission risk, specifying that gloves must be worn during testing events, hand hygiene must be performed,

and gloves must be changed between patients. “Standard precautions are used for point-of-care testing by testing personnel,” the requirement reads. Evidence of compliance is a written policy detailing proper hand/glove hygiene when testing patients using POC devices.

Capillary blood sampling presents another hazard: the use of multi-lancet devices on multiple patients. “This unsafe practice has been linked to hepatitis B outbreaks in a number of investigations, using molecular genotyping of highly variable regions of the hepatitis B virus to determine infection source,” Dr. Geaghan explains. The CAP has added the following checklist item to its point-of-care testing checklist to ensure safety in fingerstick and heelstick practices: “Only auto-disabling single-use finger stick devices are used for assisting monitoring of blood glucose and other point-of-care testing.”

“I have received questions in response to educational pieces about this. In some cases, there is a misunderstanding that disinfection allows the use of multi-lancet fingerstick devices on multiple patients,” Dr. Geaghan says. “However, the barrel holding the lancets is contaminated by the used blades retracted into the barrel, and blood splatter.” Published literature has even traced hepatitis B infection transmission to sharing the end cap, she says.

Dr. Geaghan points to a 2005 study that was the first to examine the prevalence of blood contamination on hospital glucose meters (Louie R, et al. *Point of Care*. 2005;4[4]:158-163). The study’s authors examined glucose meters from 12 hospitals, finding a mean blood-contamination frequency of 30.2 ± 17.5 percent. ICU meters, meters in urban hospitals, and meters used by a high number of operators were all more likely to be contaminated. Half of the hospitals in the study had no regular cleaning schedule for POC devices, and only one cleaned devices between patients. Says Dr. Geaghan: “It was a very disturbing finding.”

Part of the issue, in her view, is that POC device operators simply aren’t convinced of the risks, especially when weighed against the time it takes to thoroughly disinfect a meter. Stanford University Medical Center, which comprises Stanford Hospital and Clinics and the Lucile Packard Children’s Hospital, has attempted to address this skepticism via an educational module aimed at nurses. “This was accomplished in a fairly short time frame of several months,” Dr. Geaghan says, “and it was overseen by our collaborative infectious disease integrated program. It was a great way for us to ensure that there was a good understanding of the infectious risks associated with point-of-care testing, and what’s required to eliminate or reduce them.” In conjunction with the educational effort, she says, “we established auditing at regular intervals to ensure that we reach our infection control goals and have sustainable practices.”



Coyle

Another barrier to proper disinfection: using the right disinfectant. “Conventionally, alcohol wipes have been used to wipe down the meters, but those are not adequate,” Dr. Geaghan says. “Only bleach solutions are effective in killing viruses such as hepatitis B. And yet bleach is corrosive to many point-of-care instruments. So for the time being, there’s a problem with using the disinfectant that’s most effective and maintaining integrity of the instrumentation.”

At least one manufacturer concurs that bleach and other disinfecting wipes are a problem where device integrity is concerned. “Most meters are designed with an outer plastic shell,” says Mary C. Coyle, MS, MT(ASCP), director of POC hospital marketing for Roche Diagnostics. “The disinfectants that are used to kill the bugs take the elasticity out of that plastic, and you now have brittle plastic. So the area where the plastic would come into contact with the base unit would look like a windshield shatter—it would show cracks.”

The FDA has taken notice of this issue, Dr. Geaghan says. “They’ve written a letter to manufacturers, telling them that for the next generation of point-of-care instruments, they will be required to demonstrate in a more rigorous fashion that their disinfection protocols address these issues, and that their instrument design also takes these issues into account.”

As for the vendors themselves, they’re responding to infection transmission concerns in different ways. For example, Nova, which manufactures the StatStrip Connectivity and StatStrip Xpress point-of-care glucose analyzers, emphasizes the design of its glucose strip. “As long as one follows the procedures recommended in the instructions, the amount of blood obtained by skin puncture should be minimal, and therefore the risk of contamination is minimal,” says medical and scientific affairs vice president Jeffrey A. DuBois, PhD. “In our case, it’s 1.2 mL that’s metered into the strip. That’s not a lot of blood. And so the risk of transferring the patient’s blood to the meter is actually minimal. If the user follows procedure by wiping the meter down between each patient, there should be minimal risk.”

What about device degradation due to disinfection? “We don’t get a high number of returns due to disinfecting with bleach,” Dr. DuBois says. “Some products have that problem. I don’t think ours have had that problem.”

He adds that Nova manufactures a disposable cover that can be used with the StatStrip on patients in isolation: “So the risk of transmitting an infectious agent is minimal, because you use the protective overlay. The user should dispose of that and the strip in the patient’s room, to leave all the potentially biohazardous material within that patient’s isolation space.”

Meanwhile, Abbott, which manufactures the Precision Xceed Pro Blood Glucose and b-Ketone Monitoring System, stresses the role of its individually packaged testing strips in preventing the transmission of infection. “The test strips for the Precision Xceed Pro System are individually foil-wrapped to reduce the chances of test strips becoming contaminated by bacteria commonly found in hospitals,” says Mani Gopal, PhD, general manager of Point-of-Care for Abbott Diabetes Care. “In fact, they are the only individually packaged test strips in the POC glucose testing industry.”

Test strips that are packaged in quantity and stored in opened vials, Dr. Gopal says, have a higher risk of contamination. He points to a letter to the editor in the *American Journal of Infection Control* that said an investigation of vial-packaged test strips found that 25.7 percent of them tested positive for bacteria (Vanhaeren S, et al. *Am J Infect Control*. 2011;39:611–613). In this study, dedicating a vial to a single patient did not change the strip contamination rate.

As for Roche, in October it launched the Accu-Chek Inform II POC blood glucose meter, which, Coyle says, was designed to resist degradation by bleach and other disinfecting wipes. For example, to prevent the bar-code scanner window from falling off, it’s been attached to the inside of the device rather than clipping on from the outside. In addition, says Coyle, “We took out every possible opening that would allow liquid ingress into the meter, so that it’s not accumulating body fluid.” Finally, she adds, the top of this instrument has been made completely flat: “Previous generations had an indent where the screen was, and so to get disinfectant into those corners was sometimes a cause for concern. By making it a fully flat meter, it’s easier to clean.”

Regardless of the brand and type of POC devices they use, hospitals must consider the CDC’s recommendation that they assign each patient a single POC device, to be used exclusively on that patient during the entire length of stay and to be disinfected upon that patient’s discharge. In Dr. Geaghan’s view, most hospitals are reluctant to do this. “What I’m hearing is that they do not think this is realistic due to the capital investment required,” she says. “In addition, the cost of running additional controls for each additional meter is a recurring incremental cost.” On the other hand, she points out, “There are many unforeseen costs to the transmission of disease, which is the written position of the CDC in response to the increased-cost-of-care argument.” There are also the potential legal ramifications. “So I think it remains to be seen what level of adoption is really going to occur. At this point, it does not seem that the majority of institutions are heeding this recommendation.”□

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