

Infection transmission associated with point of care testing and the laboratory's role in risk reduction

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ABSTRACT

Lack of knowledge and confusion exists regarding safe and appropriate use of blood glucose monitoring equipment. Increasing numbers of diabetics, and exponential growth in blood glucose monitoring presents increased opportunities for infection transmission between patients. Diabetics have increased exposure to blood and blood borne pathogens from frequent blood glucose monitoring.

Risk factors have been identified in infectious outbreaks and by analysis of testing practice. Point of care blood glucose meters are frequently contaminated by blood. Bacterial and viral organisms survive on surfaces and in dried blood. Instrumentation is shared between patients, and is heavily utilized in institutional settings, so that serial testing is performed on multiple patients within a short timeframe. Hand hygiene, glove changes and meter disinfection between testing events has been found to be inconsistent. Time pressure for meter usage competes with proper cleaning and disinfection procedures. Meter storage areas are frequently contaminated by blood. Multi-use lancets, improperly used for serial patient blood sampling, are a source for infection transmission. Test strips in vials, frequently contaminated by bacterial organisms, present potential hazard. The responsibility of the clinical laboratory is to insure successful implementation of practices that insure patient safety.

Risk reduction strategies include single-use auto-disabling skin

puncture devices for blood sampling; hand hygiene and glove change for every testing event; effective meter cleaning and disinfection for every testing event; meter use restriction to a single patient; safe practices for glucose meter storage; infection control practices to reduce contamination of blood glucose test strips or changes in test strip packaging and test strip dispensing.

POINT OF CARE GLUCOSE MONITORING IS ON THE RISE

Increasing numbers of newly diagnosed diabetics and increasing overall prevalence of diabetes in the U.S. population herald an increasing number of individuals for who point of care (POC) blood glucose monitoring is performed. Current United States Centers for Disease Control and Prevention (U.S.CDC) estimates are that 25.8 million people in the United States, or 8.3 % of the population, have undiagnosed or diagnosed diabetes¹. Whether the diabetic patient is prescribed nutritional modification, oral medications or insulin therapies, blood glucose monitoring (BGM) continues to be the foundation of diabetes management. The vast majority of diabetics -for example, approximately 86% of diabetics in the U.S. – are monitored monthly or more often². Point of care glucose testing is therefore one of the most common tests performed in hospital, ambulatory and home settings.

If diabetics perform self-monitoring why are they at increased risk for hepatitis B?

Patient-to-patient transmission of infections such as hepatitis B can be transmitted through point of care devices, such as blood glucose meters. In self-monitoring of blood glucose (SBGM), an individual performs the entire testing process for themselves³. Two-thirds of diabetics perform SBGM⁴. The great majority of health care institution-associated hepatitis b

outbreaks have been associated with assisted blood glucose monitoring (ABGM)⁵. In ABGM, the steps of blood glucose testing are performed by a caregiver for an individual or a group of individuals³. ABGM occurs in a variety of patient care settings: acute care hospitals, clinics, skilled nursing facilities, long term care and residential care settings. ABGM is also provided to self-monitoring diabetics at school or camp, during acute hospitalizations, in rehabilitation facilities, and at ambulatory care visits. The risk for infection transmission exists wherever blood glucose monitoring equipment is shared, and/or where those performing tests do not follow consistently follow basic infection control practices: long-term care facilities; acute care facilities; clinics; health fairs; shelters; prisons; senior centers; and schools and camps.

Bacterial and viral pathogens can be transmitted from equipment to patients. The primary focus on infection transmission linked to point-of-care testing is viral disease, most notably hepatitis B (HBV), hepatitis C (HCV), and human immunodeficiency virus (HIV), though bacterial transmission is also of concern. The emphasis on hepatitis B risk in particular is based on epidemiology of outbreaks⁶, as well as a higher infectivity rate (approximately 30% attack rate following exposure, versus 0.2% for HIV, and 3% for HC)⁷.

Quantifying the risk of hepatitis B in diabetics

Adult diabetic individuals are at significantly higher risk for hepatitis B infections than non-diabetic individuals. The increase in risk of hepatitis B infection for diabetics is associated with blood exposure. An investigation of the relative risk of acquiring hepatitis B in 865 adult diabetics who did not harbor other risk factors for hepatitis B demonstrated the odds of contracting acute hepatitis B were 2.0 times higher for diabetics less than 60 years of age; and 1.5 times higher for diabetics greater than or equal to 60 years

of age⁸. Seroprevalence studies demonstrated a 60% increase in antibody to hepatitis B core antigen, or anti-HBc, among non-institutionalized adults with diabetes, compared with non-diabetics ($p < 0.001$). The risk differed by age group: at 18-59 years of age, diabetics showed a 70% increase ($p < 0.001$) of hepatitis B exposure compared to non-diabetics, whereas diabetics greater than or equal to 60 years of age showed a 30% increase ($p = 0.032$)⁸. In the United States, this increased risk has prompted public health agency epidemiologic investigations, outreach efforts promoting best practices by public health agencies and public health initiatives such as a hepatitis B vaccination campaign for diabetics⁸.

Analysis of U.S. outbreaks of hepatitis B associated with blood glucose monitoring reveal that outbreaks have occurred with increasing frequency over the twenty years audited (1990 through 2009)⁹. Outbreaks have resulted in patient deaths¹⁰. The unsafe practices most frequently implicated in these outbreaks at this time are spring-loaded finger stick lancet devices used on multiple individuals, and omission of cleaning and disinfection of blood glucose meters between patient testing events⁶. Other supplies and components of the testing process have not been noted or as well studied.

Proper choice and use of single-use, auto-disabling skin puncture or lancet devices for blood sampling

One of the most serious biohazard risks to patients undergoing point of care testing is the use of finger stick devices on multiple patients. Molecular genotyping has even provided evidence of disease transmission in a hepatitis B outbreak by a lancet cap¹¹. Because of this risk, the CDC and United States Food and Drug Administration (FDA) recommend that finger stick devices should never be used for more than one patient¹². It is further recommended that patients and health care professionals adopt the immediate precaution of using auto-disabling,

single-use finger stick devices for assisted monitoring of blood glucose. These devices are designed to be used only once, after which the blade is retracted, capped or otherwise made unusable. These are sometimes called "safety" lancets¹³. Design of safe practices for residential and other similar settings where a patient will be using their own reusable finger stick device is also critically important, such as proper labeling with the patients name and securing the lancet in a safe place (such as in their room) to protect from inadvertent use by or for others.

Hand hygiene and glove change requirement for every testing event

Best practice, according to public health agencies, is a mandatory change of gloves and hand washing after each and every testing event¹⁴. Even in the absence of visible blood, infectious pathogens can be transmitted through indirect contact transmission. Gloves, like hands, carry flora or blood from surfaces and from patients touched. As is required for venipunctures, when performing finger sticks, gloves should be changed between patients³. If hand hygiene and glove changes are not consistently performed between patients, device contamination and disease transmission (e.g., hepatitis B) can occur. The FDA advises "Change gloves between patients, even when using patient-dedicated POC blood testing devices and single-use, auto-disabling finger stick devices."¹³

Effective meter cleaning and disinfection requirement for every testing event

Best practice is to clean and disinfect the meter after each and every use, for meters designated for multi-patient use. A high rate of blood contamination of glucose meters raises the risk of blood-borne pathogen transmission. A multicenter study assessed meter contamination in institutions by evaluating 609 meters across a variety of care units. Presence of blood was evaluated first by visual inspection; followed by

a reduced phenolphthalein test for hgb. Overall, mean meter contamination rate was 30.2% ($\pm 17.5\%$)¹⁴. Of 12 hospitals surveyed, only one routinely cleaned meters between patients. Sharing of blood glucose meters should be avoided, if possible. If shared, the device must be cleaned and disinfected after every use according to manufacturer's instructions. If there are no manufacturer's instructions, the device must not be shared¹².

Selection of appropriate products and use of recommended procedures for cleaning and disinfection of point of care devices is critical to reduce risk of infectious cross-contamination. The use of 70% alcohol wipes is inadequate for disinfection. According to the FDA: "The disinfection solvent you choose should be effective against HIV, Hepatitis C, and Hepatitis B viruses ... Please note that 70% ethanol solutions are not effective against viral blood borne pathogens and the use of 10% bleach solutions may lead to physical degradation of your device."¹⁵

Identify patterns of use of point of care devices which pose hazard to patients

Risk factors for patient safety have been identified by analysis of testing practice. Instrumentation is shared between patients, and is heavily utilized in institutional settings, so that serial testing is performed on multiple patients within a short timeframe. A study of blood glucose meter use in a 214-bed acute care hospital demonstrated that, over a 31-day baseline period, 11,665 glucose measurements were performed on 803 patients using 38 glucose meters. Sequential tests were performed on different patients using the same meter within 24 hours in 9302 of 11,665 (79.7%) tests: 99.9% were performed within 24 hours and 60.9% were within 1 hour¹⁶. Time pressure for meter usage competes with proper cleaning and disinfection procedures. Inadequate time for thorough cleaning and disinfection between patients

poses a safety risk. Clearly, if multiple point-of-care devices are used on a single patient, and without a use restriction, all patients on a unit could be tested with all the meters over a short time interval. As previously cited, independent published literature indicates inconsistent and/or ineffective meter cleaning practices. Without appropriate and consistent meter cleaning and disinfection, increases risk for blood borne pathogen exposures.

Dedicated meter assignment to an individual patient

To reduce the risks associated with point of care testing, The CDC and FDA recommend that each glucose meter should be assigned to a single patient whenever possible. This guidance extends also to other point of care devices also¹². If dedicating POC blood testing devices to a single patient is not possible, the devices should be properly cleaned and disinfected after every use as described in the manufacturers' product device labeling and instructions¹².

Safe practices for glucose meter labeling and storage

If meters are not effectively cleaned and disinfected after every use, storage may present additional risk of cross-contamination by blood. In a survey of blood contamination of glucose meters, a mean of 20% of hospital meter storage areas were contaminated. Up to 52.7% of storage areas in institutions were contaminated by blood¹⁴. Analysis of meter labeling storage procedures is good practice to protect patients from cross-contamination. If a dedicated meter for single-patient use is provided, such measures can help protect patients from inadvertent use of their meter by others¹².

Recent evidence indicates bacterial contamination of blood glucose test strips requires intervention

In a study conducted over six weeks in four United Kingdom hospital wards, the bacterial load on 148 glucose test strips was quantified by culture. The overall test strip contamination rate ranged from 16.6% - 35.7%. Enteric and skin flora were the bacterial species identified. The authors noted that the narrow test strip vial opening requires repeated manual touching to pull a strip out, under non-sterile conditions. Investigators' recommendation was to "dispense single units that can be used in a 'no-touch' procedure"¹⁷ A second, multicenter evaluation of glucose test strip contamination found that the majority of open vials in use in five hospitals had contaminated glucose test strips. In this U.S.-based study, between 27-70% of opened vials tested positive for bacteria, regardless of vendor, versus only 0-4% of individually foil-wrapped strips. Test strips were culture-positive for a variety of bacterial (enteric and skin flora) species¹⁸. A third study, based in three hospitals in Spain, tested 423 test strips which had an overall contamination rate of 34% (146/423). Comparing contamination rate and differences in test strip packaging, the authors found that 7% of individually-wrapped strips were contaminated, versus 45% of strips from multi-use vials ($p < 0.001$). Pathogenic organisms such as methicillin-resistant *Staphylococcus epidemidis* and *Staphylococcus hemolyticus* were recovered from multi-use vials but not from the individually-wrapped strips¹⁹. The latter two studies were industry-sponsored studies. Confirmation by independent investigators would be a valuable addition to this growing literature.

Relevant CDC guidance is the following general recommendation: "Unused supplies and medications taken to a patient's bedside during finger stick monitoring or insulin administration

should not be used for another patient because of possible inadvertent contamination".²⁰

The proposal to address test strip contamination by dedicating individual vials to single patients clearly adds cost, due to the mandatory discard of unused test strips upon patient discharge. In addition to increasing health care cost, assignment of a test strip vial to an individual patient may not eliminate contamination risk. Noteworthy is the U.K. finding, where (independent) investigators found that opened vials that stayed with a single patient had same contamination rate as those that moved from room to room¹⁷. What are the financial consequences of discarding unused strips from common-use testing vials? A real-life estimate of the financial impact of strip vial wastage was undertaken to answer this question. Based on a set of assumptions of patient census, glucose test workload and hospital length of stay, such estimates may be calculated for a given institution. In this independent published study, the author estimated the annual cost of test strip wastage to range from \$80,000 USD with 25-strip vials to more than \$170,000 USD with 50-strip vials. This study highlights that – if single-use test strip vial is adopted - choosing glucose vendors and/or test vial count (e.g., 25 versus 50 count test strip vials, or single-use packaging versus multi-strip vials) has potentially substantial, largely unrecognized, financial impact²¹. Individually foil wrapped test strips additionally protect against moisture and environmental contamination, considerations outside the scope of this paper. However, not all vendors have offered this product as yet, and a solution to this problem must be found across multiple vendor products.

Bacterial test strip contamination may be addressed risk by sterile handling protocols, albeit with addition of time and inconvenience to the overall testing process. Alternatively, test strip contamination could possibly be reduced in the future by single-unit, "on demand" test strip

dispensers (e.g. a “touch less” technology) and/or industry-wide transition to single test strip packaging. The principle of single-unit dispensing and/or packaging has become the norm of pharmaceuticals, health care supplies and other patient equipment.

SUMMARY

The number and scope of infectious outbreaks associated with blood glucose testing points to knowledge gaps and confusion regarding the appropriate, safe use of blood glucose monitoring equipment. Educational campaigns by public health agencies (e.g. CDC and FDA) and professional societies such as the IFCC and College of American Pathologists serve to inform responsible parties in health care settings. Device manufacturers are responsible for improved, effective, validated cleaning and disinfection protocols, product labeling, and package instructions. The following strategies can help reduce the risk of infection transmission between patients during point of care testing: using only single-use auto-disabling skin puncture/lancet devices for blood sampling; requiring hand hygiene and change of gloves between patients for each testing event ; effective meter cleaning and disinfection for every testing event; advocating for restriction of meter use to a single patient, when possible; properly labeling and storing meters, such that risk of inadvertent use for/by other patients is eliminated; and reducing contamination rate of glucose test strips in vials by employing sterile practices entering and removing test strips from vials, or by making changes in test strip packaging and dispensing., It is our responsibility to use these best practices to help protect patient safety.

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