Infectious Risks of Point of Care Testing and Strategies to Reduce Risk to Patient and Healthcare Worker Safety

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Key Objectives

- Identify point of care testing practices which pose risk to patient safety today

- Review infection risks in self-monitoring versus assisted monitoring of blood glucose

- Review hepatitis B and C transmission from patient to patient through glucose meters and other point of care equipment used in health care facilities & current FDA, CDC guidance for prevention

- Consider how to insure safe practices for point-of-care testing: *proper hand hygiene, effective and consistent meter disinfection, appropriate storage of meters and test strips, restriction of multi-use finger stick devices, and other single-use strategies*
Point-of-care blood glucose monitoring on the rise

25.8 million diabetics in U.S.—8.3% of population

Blood glucose monitoring (BGM) remains key to diabetes management

86% of diabetics test their glucose monthly or more often

Point-of-care glucose testing is one of the most frequent tests performed on a global scale

Testing safety is a major public health issue

Survey: Infection control and point-of-care personnel share concern for infection transmission

- 63% of respondents reported the hazard of potential transmission of hepatitis B and C

- 33% of respondents reported the potential spread of HIV

Diabetics have increased risk for hepatitis exposure

- More capillary blood sampling than other patient groups
- Odds of contracting Hepatitis B in 865 adult diabetics = 2x higher < 60 yrs
- Studies of institutionalized diabetics showed 70% increase in HBV exposure risk
- CDC data suggests that HBV morbidity & mortality may be higher in diabetics than in non-diabetics

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

Assisted blood glucose monitoring (ABGM): steps of blood glucose testing are performed by a caregiver for an individual or a group of individuals

Self blood glucose monitoring (SBGM): an individual performs the entire testing process for themselves

ABGM is also provided to self-monitoring diabetics outside the home

Where does the risk exist?

Wherever blood glucose monitoring equipment is shared and/or where those performing tests do not follow basic infection control practices, including:

- Long-term care facilities
- Acute care facilities
- Clinics
- Health fairs
- Shelters
- Prisons
- Senior centers
- Schools and Camps

Infection outbreaks due to unsafe diabetic equipment: a rising tide 1-5

- U.S. HBV outbreaks associated with BGM increasing in frequency—outbreaks resulted in deaths
- 88% of patients with HBV infection associated with BGM 1
- U.S. patient notifications due to unsafe injection practices > 5000 patients / 3 yrs 2
- Unsafe practices 1-5 include, to date:
  - Finger stick devices used on multiple individuals
  - Failing to clean/disinfect blood glucose meters between uses

4. CDC. Notes from the field: deaths from acute hepatitis B virus infection associated with assisted blood glucose monitoring in an assisted living facility – North Carolina, August –October 2010. MMWR Morb Mortal Wkly Rep 2011; 60:182.
HBV outbreaks: why numbers are underestimated 1-5

Most acquired HCV and HBV infections are asymptomatic

Elderly briskly progress to chronic infection (not recognized as part of acute outbreak)

Many outbreaks may go undetected or uninvestigated - financial, legal, and personnel barriers

Hepatitis B vaccine recommended for diabetics

- HBV vaccination is a safe, effective means of prevention
- Key criteria for HBV vaccination recommendation:
  - Evaluation of vaccine efficacy
  - Impact of age at diabetes diagnosis
  - Vaccine cost-effectiveness
- Advisory Committee on Immunization Practices (ACIP) recommend adults aged < 60 years w/ diabetes be vaccinated for HBV
- Benefit of routine vaccination for adults aged >60 years is reduced - vaccine immunogenicity appears to decrease w/ increasing age

Strategies to address cross-contamination

A Multi-dimensional Approach
Bacterial and viral organisms survive on surfaces and pose nosocomial risk

- Bacterial pathogens can be transmitted from equipment to patients
- Primary focus on infection transmission linked to point-of-care testing is viral disease: HBV, HCV, HIV
- Most notable risk is HBV because:
  - Higher infectivity rate (approx. 30% c/w est. 0.2% HIV, 3% HC)
  - Higher titer (acutely infected patient): $10^8$ c/w : $10^6$ HC, $10^{3-6}$ HIV
  - Greater reservoir of infectivity - est. 800,000-1.4 mill people in U.S. (diabetics figure importantly in contributing risk of infection to fellow diabetics)
  - Extraordinary environmental stability – min. 7 day survival in surface dried blood

CDC. Recommendations for identification and public health management persons with chronic Hepatitis B virus infection. MMWR 2008; 57(No. RR-8).
Best practice: Mandatory change of gloves and hand washing after each and every testing event
<table>
<thead>
<tr>
<th>POC.09180</th>
<th>Standard Precautions - Hand Hygiene</th>
<th>Phase II</th>
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<tbody>
<tr>
<td></td>
<td>Standard precautions are used for point-of-care testing by testing personnel.</td>
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<tr>
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<td>NOTE: Gloves must be worn during testing events, hand hygiene performed, and gloves changed between patients, according to Standard Precautions.</td>
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<td>Evidence of Compliance:</td>
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<td></td>
<td>✓ Written policy detailing proper hand/glove hygiene when testing patients using point-of-care devices</td>
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Best practice: Clean and disinfect the meter after each and every use, for meters designated for multi-patient use.
A key obstacle to best practice: “If the meter does not touch the patient, why is cleaning and disinfection required after every use?”

Indirect contact transmission of infectious agents can occur from through:

- Intermediate contaminated objects
- Provider’s hands

Even in the absence of visible blood, infectious pathogens can be transmitted through indirect contact transmission.
Point-of-care blood glucose meters are frequently contaminated by blood

<table>
<thead>
<tr>
<th>High rate of blood contamination of glucose meters raises the risk of blood-borne pathogen transmission</th>
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<tr>
<td>Multicenter study meter contamination: 12 institutions, 609 meters, variety of care units</td>
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<td>Presence of blood evaluated first by visual inspection; then by reduced phenolphthalein test for hgb</td>
</tr>
<tr>
<td>12 hospitals surveyed, only 1 routinely cleaned meters between patients</td>
</tr>
<tr>
<td>Mean meter contamination rate = 30.2% (±17.5%)</td>
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Analyze the practice pattern: Point-of-care devices are frequently shared among patients in health care facilities

Multiple point-of-care devices used on a single patient

Without a use restriction, all patients on a unit could be tested with all the meters over a short time interval

Without appropriate and consistent meter cleaning and disinfection, this increases risk for pathogen exposures
Multiplicity of meters used on patients: most meters shared within one hour

- Glucose meter use in a 214-bed acute care hospital over 31-day period:
  - 11,665 glucose measurements; 803 patients; 38 meters
  - Sequential tests on different patients, same meter within 24 hours
    - 99.9% performed within 24 hours
    - 60.9% were within 1 hour

*Increased utilization may offer more opportunities for infectious agent transmission*

Current FDA guidance: Disinfection of blood glucose meters assigned for multi-patient use

Blood glucose meters should be cleaned and disinfected per manufacturer’s instructions after each and every use, unless assigned to a single patient and protected by specific precautions.

FDA guidance for manufacturers:

“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.”

1. FDA Website. 
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm227935.htm
<table>
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<tr>
<th>POC. 09190 Testing Devices - Disinfection</th>
<th>Phase II</th>
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<tbody>
<tr>
<td></td>
<td>There is an infection control policy in effect to prevent transmission of infection via portable or handheld testing devices.</td>
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<td></td>
<td>NOTE: Compliance with the manufacturer's guidelines when provided is required. Handheld or portable testing devices must be disinfected after each patient use.</td>
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CDC Guidance: Avoid sharing of blood glucose meters

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 shared.

Does assignment of equipment to individual patients *really* affect risk?

- Increased # meters from 22 to 87: AND meters assigned to individual patients
- Increased # meters from 16 to 28: NO meter assignments to individual patients
- **Without** individual assignment of meters: sequential glucose meter use on multiple patients within 24 hours *increased by 17%*
- **With** individual meter assignments: sequential glucose meter use on different patients within 24 hours *decreased by 95.1%*

Point-of-care meter disinfection requires staff time and labor

When meters assigned to individual patients in high-use patient units:

• Labor requirement for disinfection and cleaning of dedicated devices was **reduced from 1.9 to 1.0 full time equivalent**

• Reduction in labor offers an “offset” to capital costs of additional meter inventory, **BUT QC remains burdensome for large # instruments**

Disinfection of blood glucose meters dedicated for single-patient use

For meters assigned to a single patient:

- Meter must be cleaned and disinfected per manufacturer’s instructions at a minimum when reassigned to a new patient *
- Meters must be stored to prevent accidental use by others or contamination by others’ blood
- Removal of gloves, hand hygiene, disinfecting meters after testing is required for handling single-patient use meters ¹

*If manufacturer’s instructions for device cleaning and disinfecting are not available, meter cannot be shared or reassigned

Question for you
Blood glucose meter storage: potential patient safety risk

If meters are not effectively cleaned and disinfected after every use, storage areas present risk of blood cross-contamination.
Meter storage: Studying the risk

- In a study of glucose meter blood contamination:
  - Up to 52.7% of storage areas were contaminated by blood.
  - On average, 20% of hospital meter storage areas were contaminated.
  - Institutions had no infection control protocols nor biohazard elimination protocol for POCT instrumentation: 30% of total.

The POCT program has a program to assure the safety of patients and health care personnel commensurate with the scope of its activities.
Best practice: Never use fingerstick devices on more than one patient.

Reusable lancets present biohazard risks and are NOT appropriate for multi-patient testing.
Molecular genotyping provides evidence of disease transmission by lancet

- Capillary blood sampling by non-disposable lancing device brings unacceptable risk of HBV infection
- Molecular evidence linking infection cluster to multi-patient lancing device
- Authors recommend: BAN multi-patient lancing devices from healthcare facilities — replace with disposable safety lancets that permanently retract to prevent reuse of device on multiple patients

Only auto-disabling single-use fingerstick devices are used for assisted monitoring of blood glucose and other point-of-care testing.

NOTE: These devices are designed to be used only once, after which the blade is retracted, capped or otherwise made unusable. All waste sharps are discarded in compliance with the Laboratory General Checklist in puncture resistant containers that are easily accessible, located in areas where needles are commonly used, and properly labeled to warn handlers of the potential hazard.

Evidence of Compliance:

✓ Written policy detailing requirement of limitation of single-use devices to one patient

REFERENCES

1) http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html accessed 1/30/2012
http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm224025.htm accessed 1/30/2012
http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm224025.htm
Question for you
Is it safe for patients in institutions who perform self-monitoring of blood glucose to use their own reusable finger stick devices?

Yes.

Safe practices recommended by the CDC include:

- Individually labeling the multi-use lancet devices with patient’s name
- Patient training to handle these as personal care equipment like toothbrushes and razors, which are not to be shared.  

What goes where? Clean and Dirty cannot mix!
Additional single-use strategies in diabetic supplies

Individually packaged supplies for patient safety
Dedicating individual vials to single patient use: CDC recommendation

CDC recommends:

“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” 1

Evidence of bacterial contamination of glucose test strips: 2011 report

- Bacterial load on 148 strips, 4 wards, was quantified by culture over 6 wks
- **Strip contamination rate: 16.6% - 35.7%**
- Authors concluded: narrow strip vial opening requires repeated manual touching to pull a strip out, under non-sterile conditions
- Investigators’ recommendation:

  “Dispense single units that can be used in a ‘no-touch’ procedure” ¹

¹ Vanhaeren s, Duport C, Magneney M. Bacterial Contamination of glucose test strips: Not to be neglected. Am J Inf Control 2011;39: 611-613.
Individually wrapped packaging for glucose test strips?

- Individually foil wrapped test strips aids in protecting strips from potential cross-contamination by testing personnel
- Also protects against moisture and environmental contamination
- Not all vendors have offered this product as yet
European study confirms high rate of strip contamination in multi-use vials vs. single-use packaged strips

Prospective observational study 423 strips in use, 2 CFU/strip considered positive; 3 lg hospitals

High contamination rate (45%) multi-use vials -including pathogenic organisms MRSA; S.hemolyticus

Only 7% individually packed strips contaminated - low CFUs (2-6/strip) with no pathogenic organisms (p<.001)

Recommend single-use packaging in hospital settings for financial & clinical reasons; or at a minimum, assignment one vial -one patient

Contamination in opened vials

- Multicenter evaluation of strip contamination found majority of open vials in use have contaminated strips:
  
  **27-70% of opened vials tested positive for bacteria**

- Regardless of vendor vs. 0-4% of individually foil-wrapped strips
  
  Five hospitals sampled, test strips culture-positive for a variety of bacterial (enteric and skin flora) species

Real-life estimate of strip vial wastage when assigned single-patient use

• **Question:** What are the financial consequences of switching from common-use testing vials to single patient-use testing vials, discarding unused strips in open vials?

• Based on a set of assumptions of patient census, glucose test workload and hospital LOS: estimated annual cost of test strip waste: $80,000 w/ 25-strip vials; > $170,000 w/ 50-strip vials

• If switching glucose vendors, minor differences in vial count (25 vs 50 – count, or single-use packaging versus multi-strip vials) — potentially substantial financial impact ¹

• Individually-wrapped test strips do not require strip wastage to become compliant w/ CDC & CLSI guidelines

Pennsylvania Department of Human Services
Bulletin March 17, 2015:

“Ensure that each resident has his or her own working glucometer, lancets, lancet device, test strips, syringes, and insulin vial or pen.”

http://www.dhs.state.pa.us/cs/groups/webcontent/documents/document/c_157443.pdf
Dedicating individual vials to single patients adds cost may not eliminate contamination risk

Study found that opened vials stayed with a single patient had same contamination rate as those that moved from room to room.

New finding: Bloody contamination of glucose test strip vials in acute care institutions

Abbott sponsored study data July 2013.
Question for you
Multi-test strip vials in use at acute care facilities can pose health risk due to blood contamination

- 81 vials in active use w/ ≤ 10 strips remaining, submitted by users
- Blood contamination on outside (2) & inside (1) of vials, confirmed by 3 sensitive test methodologies
- 2 of 3 institutions pos. findings
- Vial disinfection may expose unused test strips to bleach-based agents, add staff time, not FDA-cleared or validated
- Additional study required to establish true incidence

Abbott sponsored study data, July 2013.
Question for you
Summary Points

Confusion and lack of knowledge is evident regarding safe and appropriate use of finger stick devices, blood glucose meters, strips & vials

Public health efforts (CDC & U.S. FDA) serve to educate & inform accountable parties in health care settings

Manufacturers responsibility: provision of improved product labeling, package instructions, improved, effective validated cleaning & disinfection protocols
Question for you
A leadership opportunity

We can reduce risk of cross-contamination by:

- Using only **single-use** skin puncture/lancet devices in acute care settings—multi-use lancets not allowed
- Advocating for **restricting point-of-care meter use** to a single patient, per CDC guidance, when possible
- **Consistent meter disinfection with each patient event** with an effective disinfectant mandated
- **Properly labeling and storing meters**, such that risk of inadvertent use for/by other patients is eliminated
- **Changing gloves & washing hands** between patients for each testing event mandated
- Employ **single-use packaging or another no-touch solution** for glucose test strip use

*It is our responsibility to use best practices to help protect patient safety*
The Journal of the International Federation of Clinical Chemistry and Laboratory Medicine
An Interview with Sharon M. Geaghan, MD
Thank you

Follow up questions?
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