

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 ¹

Blood glucose monitoring (BGM) remains key to diabetes management

86% of diabetics test their glucose monthly or more often ²

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

1.CDC .Diabetes Data and Trends: National Diabetes Surveillance System. www.cdc.gov/diabetes/statistics_Accessed February 14, 2013.

2.CDC. <http://www.cdc.gov/diabetes/pubs/estimates11.htm#1>. Accessed February 14, 2013.

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 ¹
- 33% of respondents reported the potential spread of HIV ¹

1. Louie RF,

MJ, Tran NK et al. National survey on biohazard control for point-of-care testing. Point of Care 2003; 23:338-41.

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 ¹

CDC data suggests that HBV morbidity & mortality may be higher in
diabetics than in non-diabetics ¹

1. Unpublished data, Trudy V. Murphy, CDC, Division of Viral Hepatitis, Advisory Committee on Immunization Practices, October 24, 2011.
<http://www.cdc.gov/vaccines/recs/acip/downloads/mtg-slides-oct11/03-HepatitisMurphy.pdf>

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

CDC. Diabetes Data and Trends: National Diabetes Surveillance System, www.cdc.gov/diabetes/statistics Accessed January 21, 2010.

CDC. Self-monitoring of blood glucose among adults with diabetes-United States 1997-2006. MMWR Morb Mortal Wkly Rep 2007; 56: 1133-7.

CDC. Blood Glucose Monitoring Frequently Asked Questions (FAQs) regarding Assisted Blood Glucose Monitoring and Insulin Administration. March 8, 2011. www.cdc.gov/injectionsafety/providers/blood-glucose-monitoring_faqs.html

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 ¹

1. FDA Patient Safety News. Show #105. Preventing Infections While Monitoring Glucose. December 2010. <http://www.accessdata.fda.gov/psn/printer-full.cfm?id=164>. Accessed February 14, 2013.

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

1.Guh et al. Patient notifications for blood borne pathogen testing due to unsafe injection practices in U.S. healthcare settings,1999-2009. (Abstract 633). Presented at International Conference on Healthcare-associated Infections 2010. Atlanta, GA.

2.Thompson ND, Schaefer MK. "Never Events" : Hepatitis outbreaks and patient notifications resulting from unsafe practices during assisted monitoring of blood glucose, 2009-2010.J Diab Sci Tech 2011; 5: 1396-1402

3.Thompson ND, Perz JF. Eliminating the blood: ongoing outbreaks of hepatitis virus infection and the need for innovative glucose monitoring technologies. J DiabSci Technol 2009; 3: 283-8.

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.

5.Schaefer MK, Jhung M, Dahl M, Schillie S, Simpson C, Llata E. Infection control assessment of ambulatory surgical centers.JAMA 2010; 303:2273-9.

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

1. Patel AS, White-Comstock MB, Woolard CD, Perz JF. Infection control practices in assisted living facilities: A response to hepatitis B outbreaks. *Infect Control Hosp Epidemiol.* 2009; 30:209-214.
2. Southwick KL, Clement EJ, Konings F, VanZetta S, Johnson S, Schaffzin JK. Cluster of hepatitis B infection among residents of an assisted living facility—New York, 2007 [Abstract]. Presented at the International Conference on Emerging Infectious Diseases. Atlanta, Georgia. 17 March 2008.
3. Thompson ND, Perz JF, Moorman AC, Holmberg SD. Nonhospital Health Care–Associated Hepatitis B and C Virus Transmission: United States, 1998–2008. *Ann Intern Med.* 2009;150:33-39.
4. Schaffzin JK, Southwick KL, Clement EJ, Konings F, Ganova-Raeva L, Xia G et al. Transmission of hepatitis B virus associated with assisted monitoring of blood glucose at an assisted living facility in New York State. *American Journal of Infection Control* 2012; 40:726-31.
5. Bender TJ, Wise ME, Utah O, Moorman AC, Sharapov U, et al. Outbreak of Hepatitis B Virus Infections Associated with Assisted Monitoring of Blood Glucose in an Assisted Living Facility—Virginia, 2010. *PLoS ONE* 2012; 7: e50012. doi:10.1371/journal.pone.0050012

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 ¹
- Benefit of routine vaccination for adults aged >60 years is reduced - vaccine immunogenicity appears to decrease w/ increasing age ²

1. Centers for Disease Control and Prevention. Use of hepatitis B vaccination for adults with diabetes mellitus: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2011;60:1709-11.

2. Zimmerman RK, Middleton DB, Burns IT, Clover RD, Kimmel SR. Routine vaccines across the life span, 2007. J Fam Pract 2007;56:S18-37.

Strategies to address cross-contamination



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

Neely AN, Maley MP. Survival of enterococci and staphylococci on hospital fabrics and plastics. J Clin Microbiol 2000; 38:724-6.

Bond W, Favero M, Petersen N, Gravelle C, Ebert J, Maynard J. Survival of hepatitis B virus after drying and storage for one week. Lancet 1981; 550-1.

CDC. Recommendations for identification and public health management persons with chronic Hepatitis B virus infection. MMWR 2008; 57(No. RR-8).

Shikata T, Karasawa T, Abe K, Uzawa T, Suzuki H, Oda T, et al. Hepatitis Be antigen and infectivity of hepatitis B virus. J Inf Dis 1977; 136: 571-6.

Beltrami E, Williams I, Shapiro C, Chamberland M. Risk and management of blood-borne infections in health care workers.

Clin Microbiol Rev 2000;13:385-407.

Best practice: Mandatory change of gloves and hand washing after each and every testing event



CAP checklist requirement

POC.09180	Standard Precautions - Hand Hygiene	Phase II
	<p>Standard precautions are used for point-of-care testing by testing personnel.</p> <p>NOTE: Gloves must be worn during testing events, hand hygiene performed, and gloves changed between patients, according to Standard Precautions.</p> <p>Evidence of Compliance:</p> <ul style="list-style-type: none">✓ Written policy detailing proper hand/glove hygiene when testing patients using point-of-care devices	

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

High rate of blood contamination of glucose meters raises the risk of blood-borne pathogen transmission

Multicenter study meter contamination : 12 institutions , 609 meters , variety of care units

Presence of blood evaluated first by visual inspection; then by reduced phenolphthalein test for hgb

12 hospitals surveyed, only 1 routinely cleaned meters between patients

Mean meter contamination rate = **30.2 % ($\pm 17.5\%$)** ¹

1.Louie RF, Lau MJ, Lee JH, Tang Z, Kost GJ. Multicenter study of the prevalence of blood contamination on point of care glucose meters and recommendations for controlling contamination. Point of Care 2005; 4:158-63.

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 ¹

Increased utilization may offer more opportunities for infectious agent transmission

1. Hellinger WC, Grant RL, Hernke DA, Shalev JA, Barber BW, Meek SE, et al. Glucose meters and opportunities for in-hospital transmission of infection: Quantitative assessment and management with and without patient assignment. Am J Infect Control 2011; 39:752-6.

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

1.FDA Website.

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm227935.htm>

Accessed February 14, 2013.

CAP checklist requirement

POC. 09190	Testing Devices - Disinfection	Phase II
	<p>There is an infection control policy in effect to prevent transmission of infection via portable or handheld testing devices.</p> <p>NOTE: Compliance with the manufacturer's guidelines when provided is required. Handheld or portable testing devices must be disinfected after each patient use.</p> <p>REFERENCES</p>	
¹⁾	<p>U.S. Department of Health and Human Services, U.S. Food and Drug Administration. Use of Fingerstick Devices on More Than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication: Update 11/29/2010. Access at http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm224025.htm</p>	

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 ¹

1.CDC. Blood Glucose Monitoring Frequently Asked Questions (FAQs) regarding Assisted Blood Glucose Monitoring and Insulin Administration. March 8, 2011

www.cdc.gov/injectionsafety/providers/blood-glucose-monitoring_faqs.html. Accessed February 14, 2013.

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% ¹

1. Hellinger WC, Grant RL, Hernke DA, Shalev JA, Barber BW, Meek SE, et al. Glucose meters and opportunities for in-hospital transmission of infection: Quantitative assessment and management with and without patient assignment. Am J Infect Control 2011; 39:752-6.

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

1.Hellinger WC,Grant RL, Hernke DA, Shalev JA, Barber BW, Meek SE,et al.Glucose meters and opportunities for in-hospital transmission of infection: Quantitative assessment and management with and without patient assignment. Am J Infect Control 2011; 39:752-6.

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 ¹

1.Louie RF, Lau MJ, Lee JH, Tang Z, Kost GJ. Multicenter study of the prevalence of blood contamination on point of care glucose meters and recommendations for controlling contamination. Point of Care 2005; 4:158-63.

CAP checklist requirement

POC.09172	Safety Manual	Phase II
	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 ¹

1.Lanini S, Garbuglia AR, Puro V, Solmone M, Martini L, et al. Hospital Cluster of HBV Infection: Molecular Evidence of Patient-to-Patient Transmission through Lancing Device. PLoS ONE 2012; 7: e33122. doi:10.1371/journal.pone.0033122

CAP checklist requirement

POC.09185	Single-Use Devices - Fingerstick	Phase II
	<p>Only auto-disabling single-use fingerstick devices are used for assisted monitoring of blood glucose and other point-of-care testing.</p> <p>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.</p> <p>Evidence of Compliance:</p> <p>✓ Written policy detailing requirement of limitation of single-use devices to one patient</p> <p>REFERENCES</p>	
1)	<p>http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html accessed 1/30/2012\</p> <p>http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm224025.htm accessed 1/30/2012</p> <p>U.S. Department of Health and Human Services, U.S. Food and Drug Administration. Use of Fingerstick Devices on More Than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication: Update 11/29/2010. Access at</p> <p>http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm224025.htm</p>	

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. ¹

1. CDC. Blood Glucose Monitoring Frequently Asked Questions (FAQs) regarding Assisted Blood Glucose Monitoring and Insulin Administration .March 8,2011.
http://www.cdc.gov/injectionsafety/providers/blood-glucose-monitoring_faqs.html

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



1. Diabetes and Viral Hepatitis: Important Information on Glucose Monitoring, Centers for Disease Control: <http://www.cdc.gov/hepatitis/Settings/GlucoseMonitoring.htm>. Accessed February 14, 2013.

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

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 ¹

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

1.Nichols JH. Estimated strip wastage from glucose meter infection control recommendations. Clin Chem Acta 2012 Dec 24;414:91-2. doi: 10.1016/j.cca.2012.08.007. Epub 2012 Aug 16.

Pennsylvania Department of Human Services Bulletin March 17, 2015:

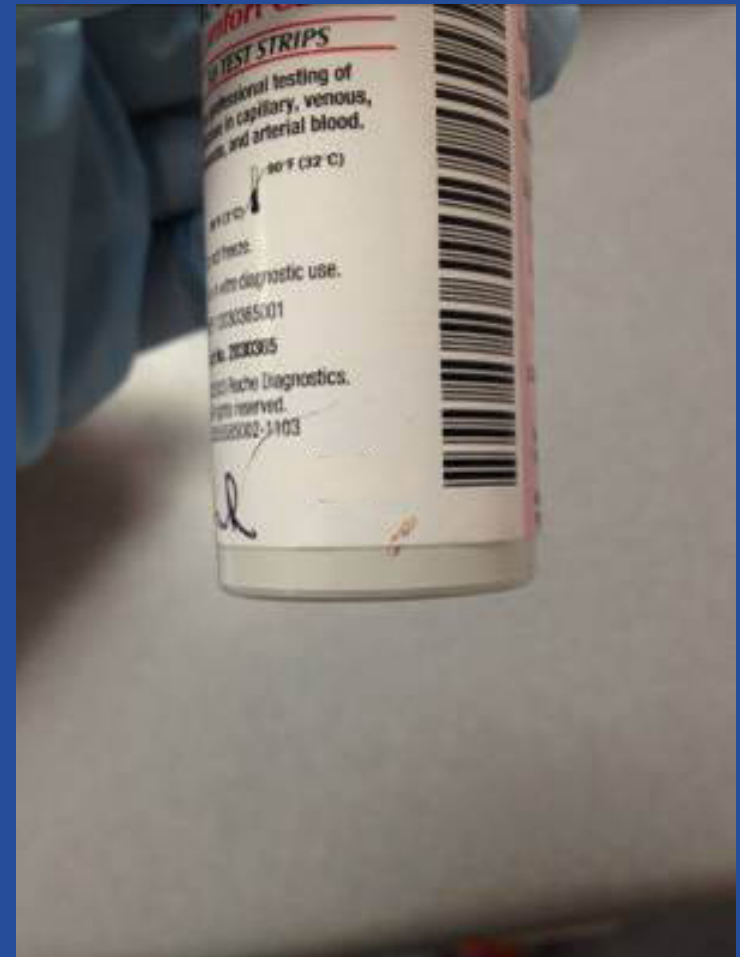
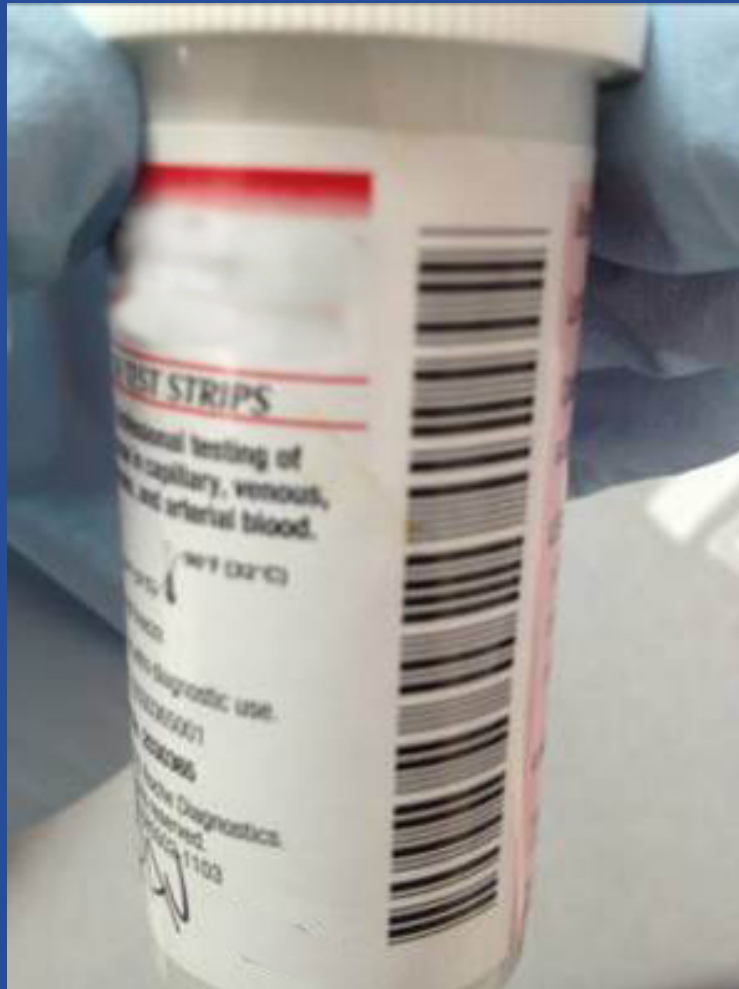
“Ensure that each resident has his or her own working glucometer, lancets, lancet device, test strips, syringes, and insulin vial or pen.”

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 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.

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



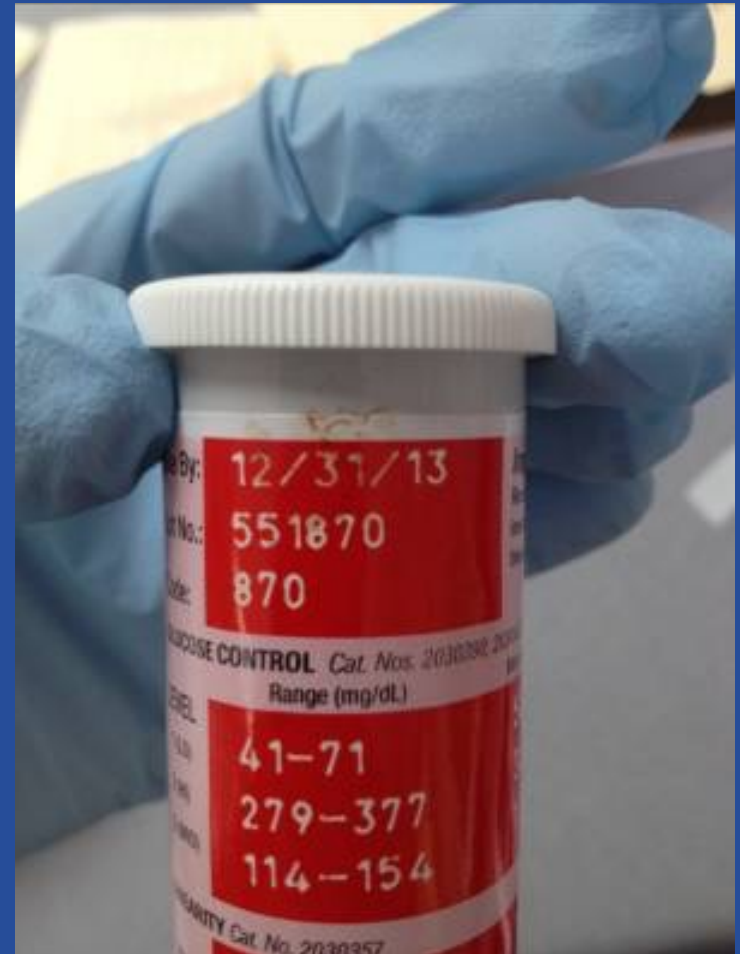
Abbott sponsored study data July 2013.

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*

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An Interview with Sharon M. Geaghan, MD

Thank you

*Follow up questions?
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