

Safe Use of Fingerstick Devices

Ty Reidhead, MD, MPH
CMO, Phoenix Area IHS

John T. Redd, MD, MPH, FACP
Santa Fe Indian Hospital

Carol Dahozy, RN, MSN
Phoenix Area IHS



CDC Clinical Reminder: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens

2010 – “The Centers for Disease Control and Prevention (CDC) has become increasingly concerned about the risks for transmitting hepatitis B virus (HBV) and other bloodborne pathogens to persons undergoing fingertick procedures for blood sampling -- for instance, persons with diabetes who require assistance monitoring their blood glucose levels. Reports of HBV infection outbreaks linked to diabetes care have been increasing. This notice serves as a reminder that fingertick devices should never be used for more than one person.”

CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens (cont.)

The screenshot shows a web browser window displaying the CDC website. The address bar shows the URL: <http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>. The page title is "CDC - CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens". The page content includes a navigation menu with "Injection Safety" selected, a sidebar with "Injection Safety" and "CDC Clinical Reminder: Fingerstick Devices", and a main content area with the title "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens". The main content area also includes a "Summary" section and a "Background" section. The "Summary" section states: "The Centers for Disease Control and Prevention (CDC) has become increasingly concerned about the risks for transmitting hepatitis B virus (HBV) and other bloodborne pathogens to persons undergoing fingerstick procedures for blood sampling -- for instance, persons with diabetes who require assistance monitoring their blood glucose levels. Reports of HBV infection outbreaks linked to diabetes care have been increasing [1, 2, 3]. This notice serves as a reminder that fingerstick devices should never be used for more than one person." The "Background" section is partially visible. The page also features social media sharing options (Recommend, Tweet, Share), a "Contact Us" section, and a "Print page" button.

<http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>

IHS Priorities

- To renew and strengthen the partnership with Tribes and improve the tribal consultation process.
- To bring reform to the IHS in the context of national health insurance reform.
- To improve the quality of and access to care.
- To have everything we do be as transparent, accountable, fair, and inclusive as possible.

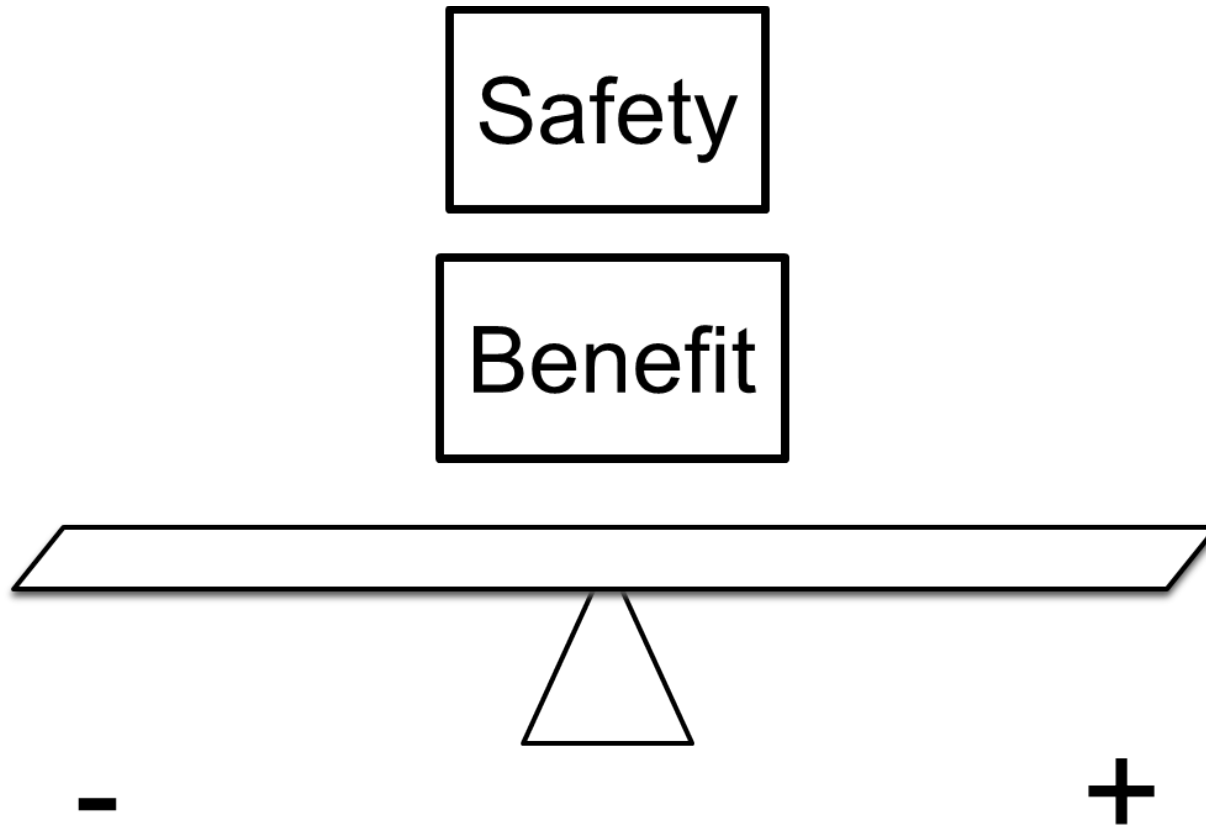
Patient Safety

“First, Do No Harm” – Safe Care

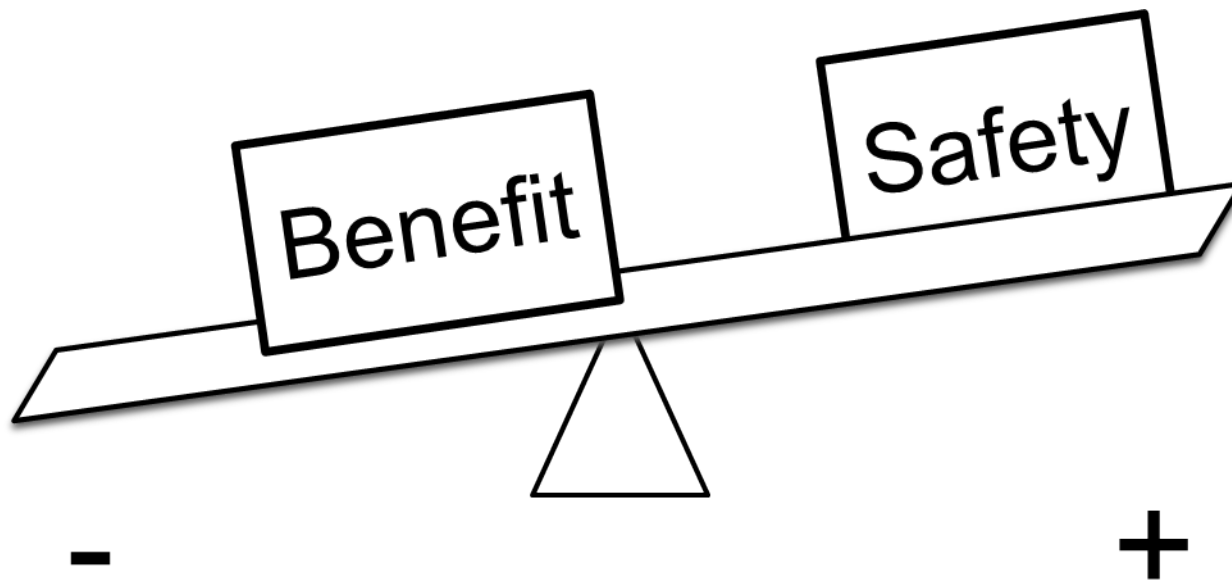
Primum non nocere!

-Hippocrates?

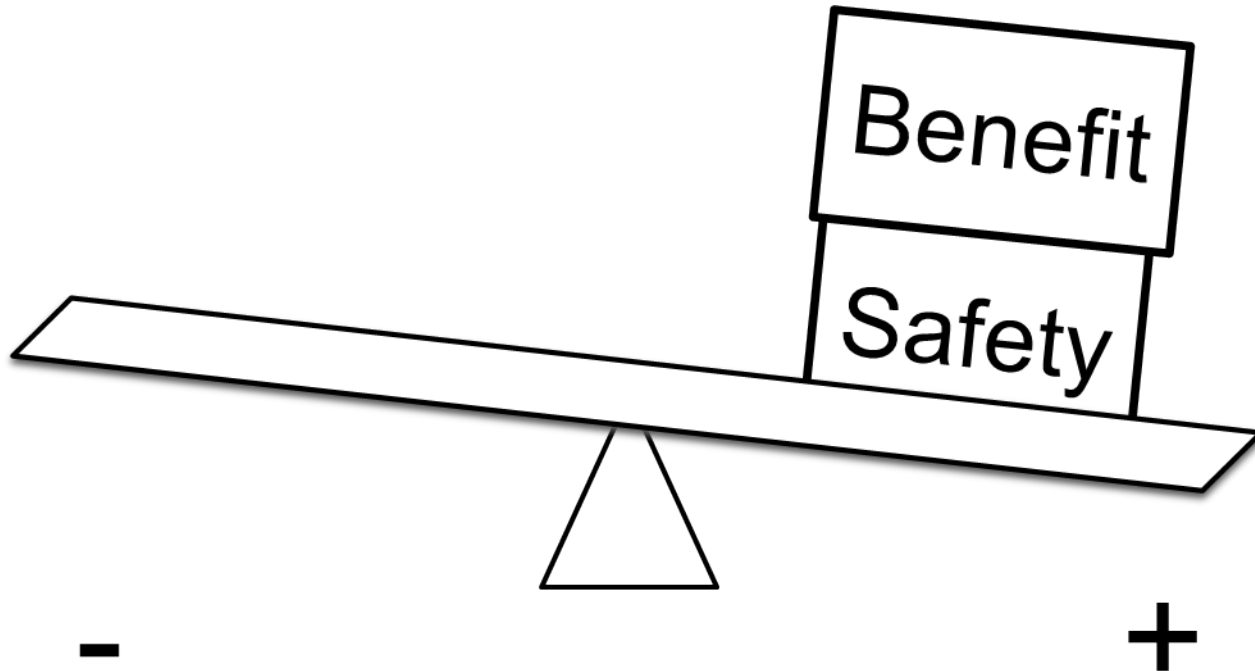
Utility of a Test



Utility of a Test (cont.)



Utility of a Test (more)



Self Monitoring of Blood Glucose: A Crucial Tool

- Aids in adjustment of therapeutic regimen in response to blood glucose.
- Helps individuals adjust their dietary intake, physical activity, and insulin doses to improve glycemic control.
- AACE, ADA, AADE

Where is Glucose Monitoring Taking Place?



Q#1

Assisted Monitoring of Blood Glucose (AMBG)

- Blood glucose monitoring performed for one or more persons by either a healthcare provider or other caregiver.
- Typically performed serially for multiple persons.
- Risk of infection transmission (HIV, HCV, HBV) if those performing AMBG fail to select the appropriate equipment and follow basic infection control.

AMBG: One Meter for Multiple People

- Therapeutic reasons
- Screening/Educational venues

Locations: Living Facilities

- Individual: Consider use by multiple family members
- Living facilities: Group homes, nursing homes, prisons, dorms, camps

Locations: Medical Venues

- Hospitals
- Clinics
- Physicians' offices: CLIA waived test indicative of common practice
- Pharmacies: Pharmacist-directed diabetes self-management and education programs

Other Locations

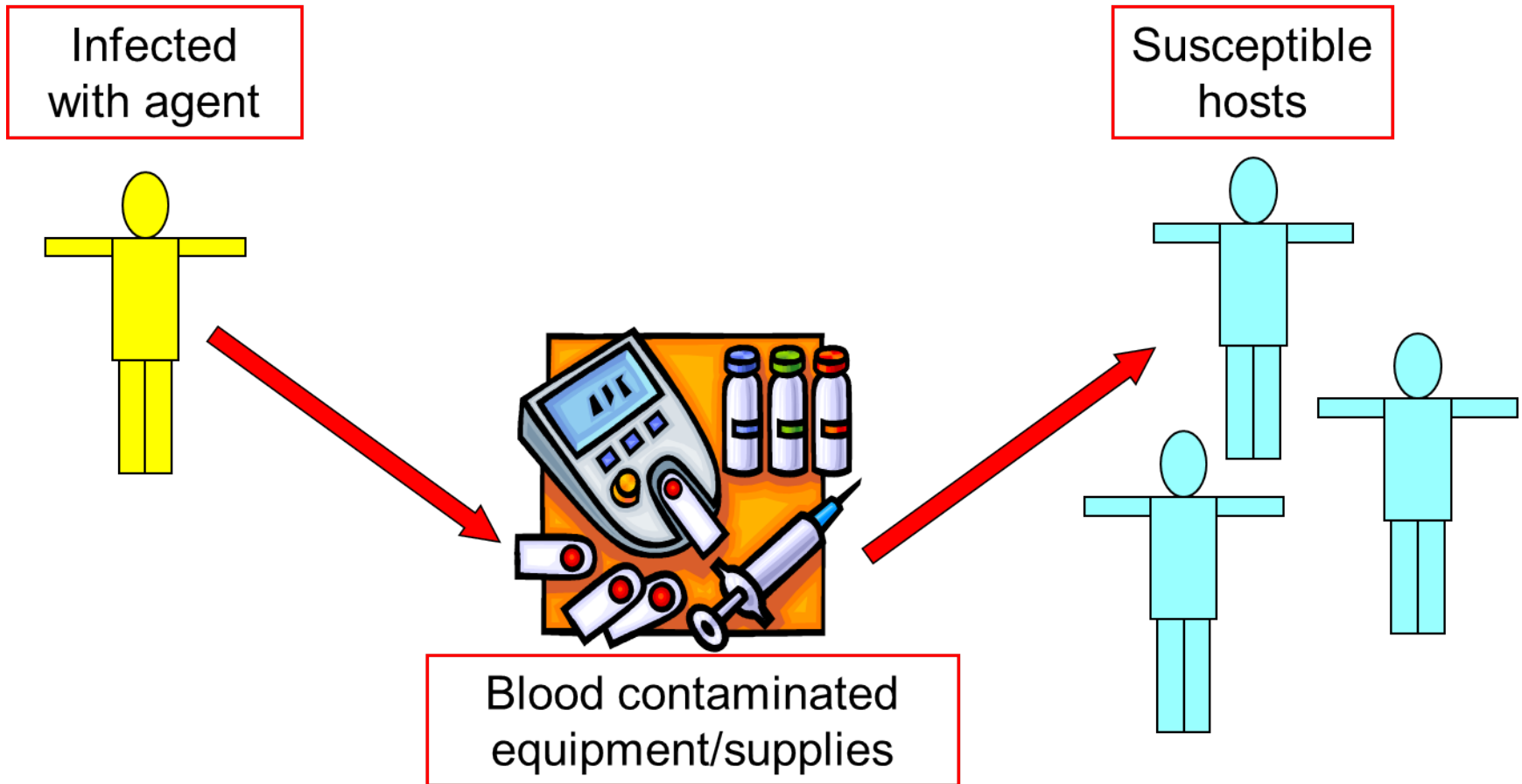
- Worksites: Screening, education, therapeutic decision making
- Schools: Usually therapeutic decision making (but student may have personal meter)
- Diabetes Education/Screening programs: Malls, convention centers, faith-based locations, community centers

Indirect Contact Transmission

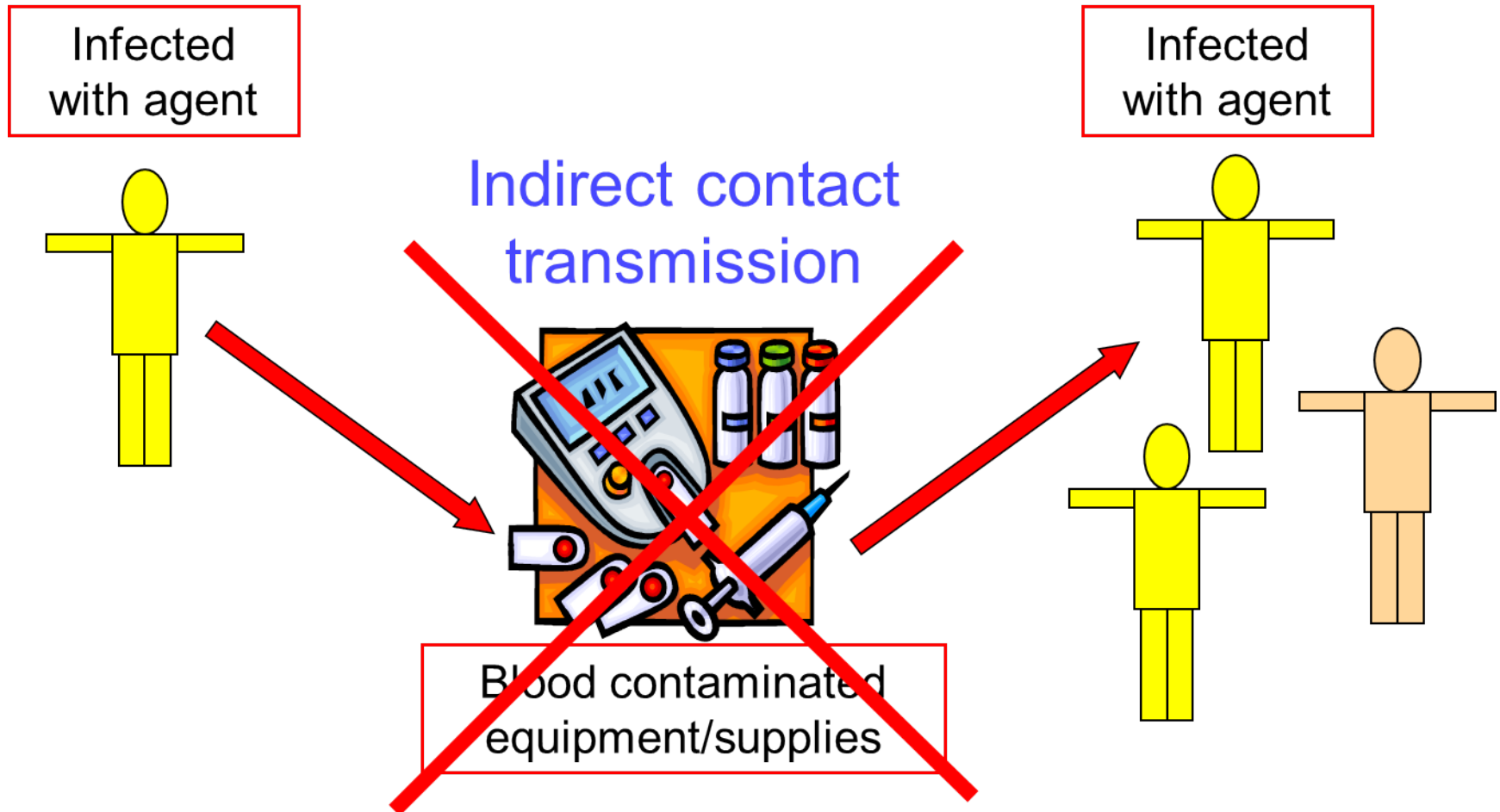
The transfer of an infectious agent (e.g., HBV) from one patient to another through:

- A contaminated intermediate object
 - Blood glucose meter
 - Reusable fingerstick devices
- Or person
 - Healthcare personnel hands

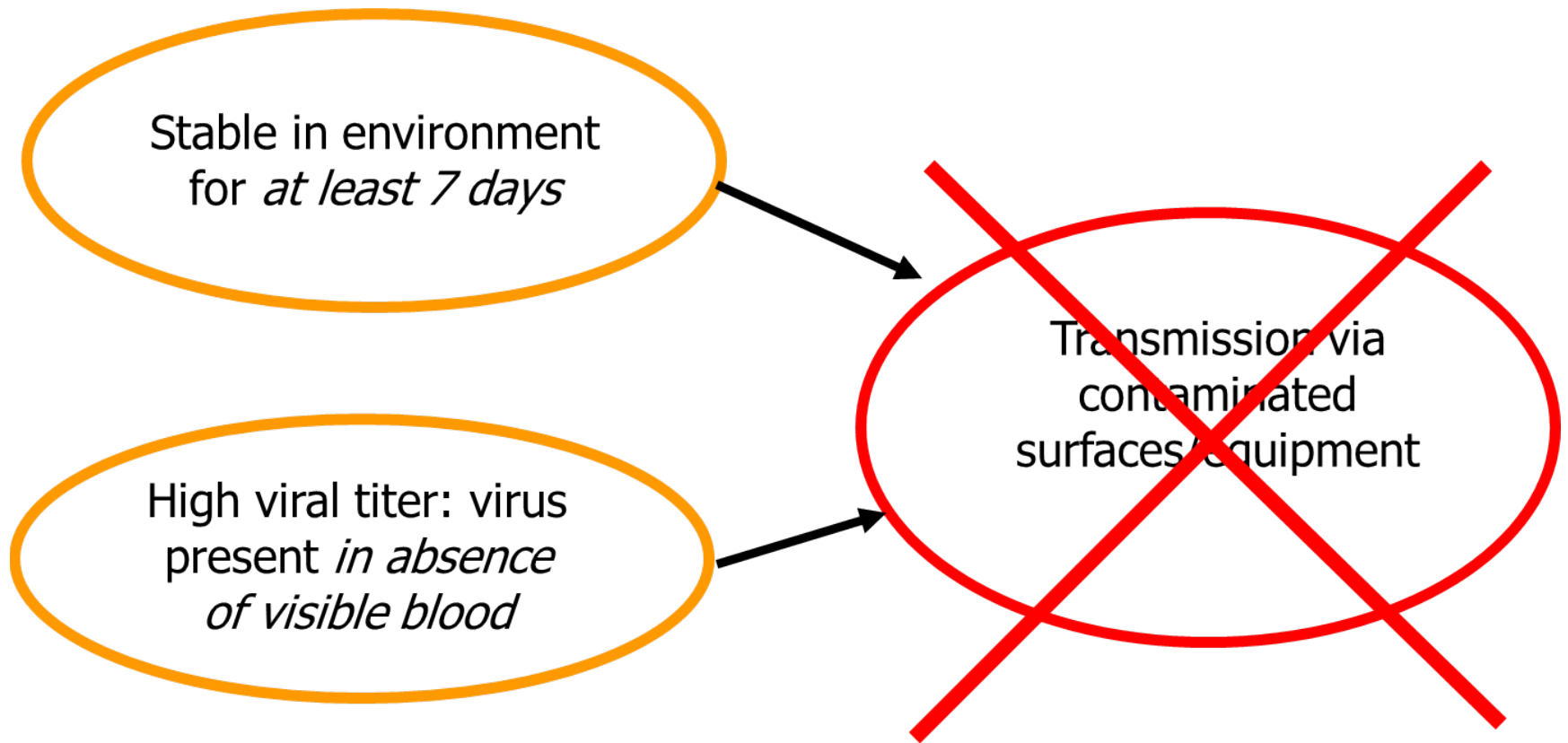
Person-to-Person Transmission of Bloodborne Viruses (or Other Pathogens) During Blood Glucose Monitoring



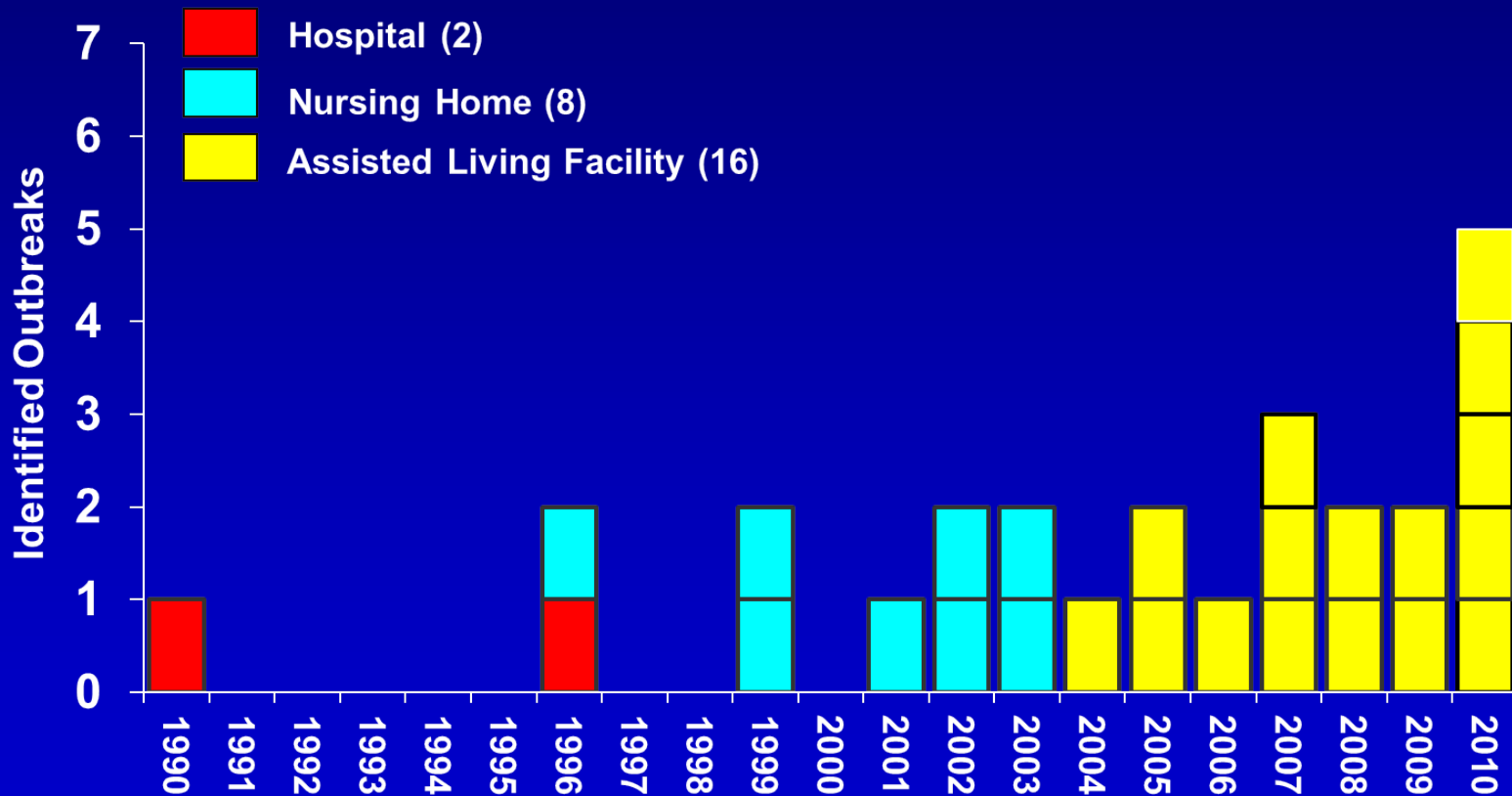
Person-to-Person Transmission of Bloodborne Viruses (or Other Pathogens) During Blood Glucose Monitoring (cont.)



Indirect Transmission of HBV During Diabetes Care



Outbreaks of HBV infection associated with blood glucose monitoring - 1990 to 2010, US



Reported Outbreaks: Tip of an Iceberg

- Under-reporting of cases
 - Long incubation period for HBV (up to 6 months)
 - Most (50-70%) infections are asymptomatic
 - Many persons go undiagnosed
- Under-recognition of healthcare as a risk for viral hepatitis
 - Traditionally, thought to be rare events in the US

Reported Outbreaks: Tip of an Iceberg (cont.)

- Older adults have multiple healthcare exposures
 - Identification of a single healthcare encounter as the venue of transmission is difficult
- Under-investigation of cases
 - Limited resources at health department level
 - Time consuming, expensive (patient notification, screening)

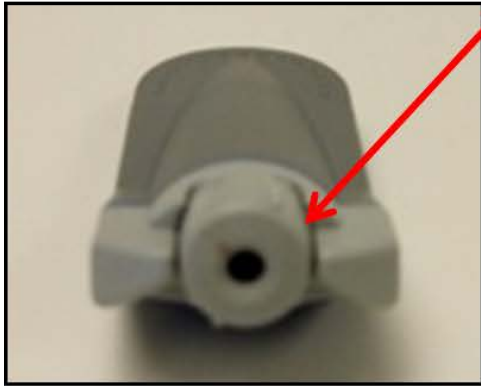
Can the Meter *Really* be a Source of Transmission?

- NC Nursing Home, 2003
 - Only single-use lancets were used and insulin vials were not shared
 - Single blood glucose meter was used for all patients and was not routinely cleaned between patients

Can the Meter *Really* be a Source of Transmission (cont.)

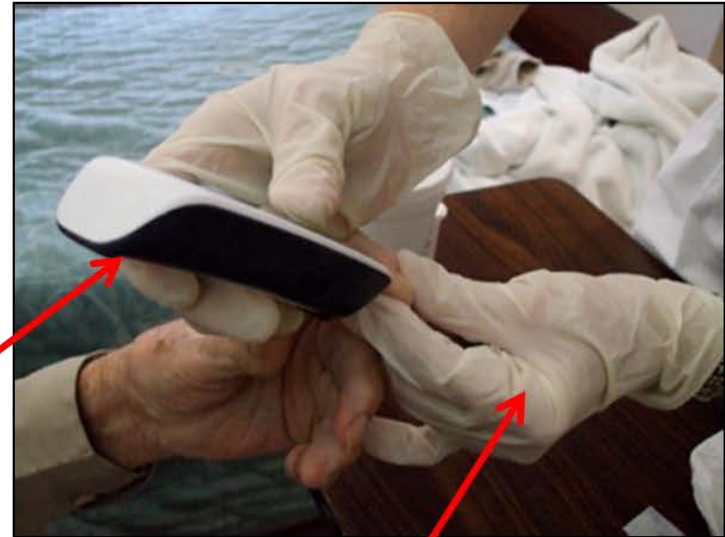
- High prevalence of blood contamination of meters
 - Survey of 12 hospitals
 - 609 blood glucose meters tested for presence of hemoglobin
 - 30.2% (range 0 - 60.6%) meters had blood contamination
 - 31.4% for on-meter vs. 26.6% for off-meter test strip dosing
 - Multiple outbreak examples where fingerstick devices were not shared

Practices Associated with HBV Transmission During Assisted Monitoring of Blood Glucose



1. Use of fingerstick devices on multiple persons

2. Failure to clean and disinfect blood glucose testing meters between each use



3. Failure to change or use gloves, or perform hand hygiene between procedures

An Emerging Problem: New Devices



Multi-lancet
fingerstick device

Sharing of multi-lancet fingerstick devices reported as cause of HBV infection outbreak in nursing home

Sharing of multidose insulin pens reported



Multidose Insulin Pen

Q#2&3



CDC INFECTION PREVENTION RECOMMENDATIONS

Hand Hygiene

- Wear gloves during blood glucose monitoring (or any other procedure that involves potential exposure to blood or body fluids)
- Change gloves between patient contacts

Hand Hygiene (cont.)

- Change gloves that have touched potentially blood-contaminated objects or fingerstick wounds before touching clean surfaces.
- Perform hand hygiene immediately after removal of gloves and before touching other medical supplies intended for use on other patients.

Fingerstick Devices

- Fingerstick devices (including lancet and lancet holder devices) should NEVER be used for more than one person
- Facilities should select and use single-use, auto-disabling lancing devices for each patient

<http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html>



Q4&5

Insulin Pens Must NEVER Be Used for More than One Person

CDC Clinical Reminder: Insulin Pens Must Never Be Used for More than One Person

Summary

The Centers for Disease Control and Prevention (CDC) has become increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV). This notice serves as a reminder that insulin pens must **never** be used on more than one person.

On this Page

- [Summary](#)
- [Background](#)
- [Recommendations](#)
- [References](#)

Background

Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use. In healthcare settings, these devices are often used by healthcare personnel to administer insulin to patients. Insulin pens are designed to be used multiple times, for a single person, using a new needle for each injection. Insulin pens must **never** be used for more than one person. Regurgitation of blood into the insulin cartridge can occur after injection [1] creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed.

In 2009, in response to reports of improper use of insulin pens in

Blood Glucose Meters

- Whenever possible, blood glucose meters should be assigned to an individual patient and NOT be shared.
- If blood glucose meters must be shared, the device should be cleaned and disinfected after every use, per the manufacturer's instructions.

Blood Glucose Meters (cont.)

- Select a device intended for use in healthcare settings and capable of withstanding frequent cleaning and disinfection.
- If the manufacturer does not specify how the device should be cleaned and disinfected, then it should not be shared.

Summary: Education is Key

- Increase awareness of the history of outbreaks related to assisted monitoring of Blood Glucose and the CDC Infection Prevention Recommendations.
- Review Infection Control and FDA recommendations for infection prevention with Point-of-Care Blood Testing Devices in settings where multiple use may occur (not just nursing homes).
- Review Centers for Medicare and Medicaid Services recommendations for cleaning and disinfection of glucometers: Learn about the correct cleaning agents.

Q#6&7

CDC Infection Prevention Resources

Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care

<http://www.cdc.gov/HAI/settings/outpatient/outpatient-settings.html>

4. Point-of-Care Testing (e.g., blood glucose meters, INR monitor)	Practice Performed	If answer is No, document plan for remediation
a. New single-use, auto-disabling lancing device is used for each patient <i>(Note: Lancet holder devices are not suitable for multi-patient use.)</i>	Yes No	
b. If used for more than one patient, the point-of-care testing meter is cleaned and disinfected after every use according to manufacturer's instructions <i>(Note: If the manufacturer does not provide instructions for cleaning and disinfection, then the testing meter should not be used for >1 patient.)</i>	Yes No	
<p><i>For additional guidance on infection prevention during point-of-care testing consult the following resource(s):</i></p> <ul style="list-style-type: none"> • Infection Prevention during Blood Glucose Monitoring and Insulin Administration • Frequently Asked Questions (FAQs) regarding Assisted Blood Glucose Monitoring and Insulin Administration 		

CDC Infection Prevention Resources (cont.)

Infection Prevention during Blood Glucose

[Monitoring and Insulin Administration](http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html)

<http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html>

FAQs regarding AMBG and Insulin
Administration

http://www.cdc.gov/injectionsafety/providers/blood-glucose-monitoring_faqs.html

Acknowledgments

- CDC Division of Diabetes Translation
 - Dr. Pamela Allweiss
- CDC Division of Viral Hepatitis
 - Dr. Trudy Murphy
- CDC Division of Healthcare Quality Promotion
 - Dr. Melissa Schaefer

Assessing Benefits

Community Screening for Diabetes

Education

- Increase awareness of Diabetes
- Encourage screening
- Behavior change
- Hepatitis B Vaccination

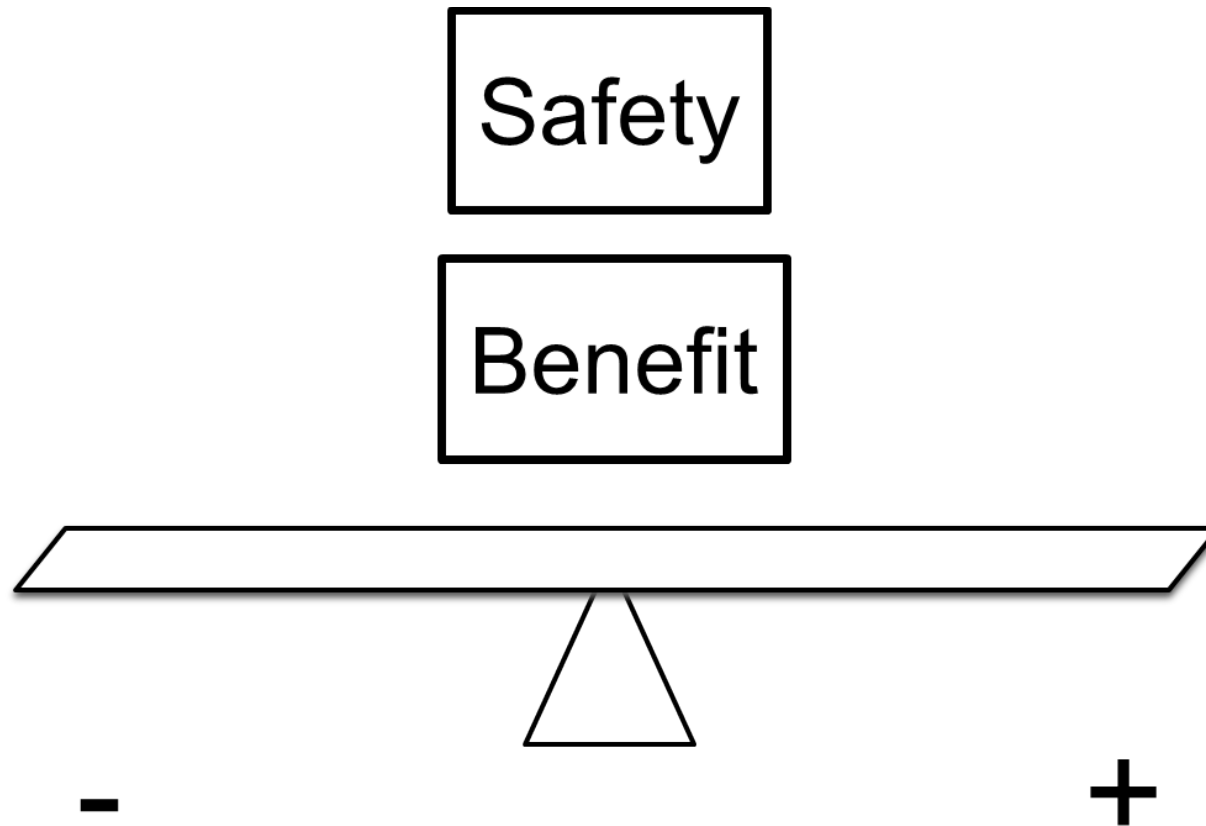
Interpretation of Results

- Identify appropriate people for testing
- Published standards are plasma glucose
- Quality Control

Follow-up

- Abnormal test results
- Retesting of people with normal results
- Inclusion in continuum of care
- Confidentiality

Utility of Assisted Monitoring of Blood Glucose in the Community?



Limitation of Fingertick Blood Glucose for Screening

- Meters are not designed for this purpose
- Inconsistencies and Challenges:
 - Identification of appropriate people for testing
 - Use of proper technique and infection control practice
 - Ensuring confidentiality of results
 - Following accepted guidelines for interpretation
 - Ability to provide adequate follow-up testing

Community Diabetes Screening Key Recommendations

- The American Diabetes Association (ADA) does NOT recommend random blood glucose screening even in high-risk populations.
- Testing should be carried out within the health care setting because of the need for follow-up and discussion of abnormal results.
- Some American Indian and Alaska Native communities feel that fingerstick screening is an important or useful strategy in their community based diabetes programs.
- If you perform community based fingerstick testing:
 - Understand this is not a diagnostic test
 - Understand the limitations of the use of fingerstick for screening
 - Ensure that proper infection control practice is used
 - Have mechanism for referrals for follow-up in a timely manner.

Indian Health Diabetes Best Practice: Community Diabetes Screening
Diabetes Care Volume 37, Supplement 1, January 2014

<http://www.oneandonlycampaign.org/>

1 ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.
Safe Injection Practices Coalition
www.ONEandONLYcampaign.org

About the Campaign | Safe Injection Practices | Healthcare Provider Information | Patient Information | Campaign Resources | News | Contact Us

ONLY ONCE.

Safe injection practices are a set of measures to perform injections in an optimally safe manner for patients, healthcare providers and others.
[Learn about Safe Injection Practices >](#)

About the Campaign

The One & Only Campaign is a public health campaign, led by the Centers for Disease Control and Prevention (CDC) and the Safe Injection Practices Coalition (SIPC), to raise awareness among patients and healthcare providers about safe injection practices. The campaign aims to eradicate outbreaks resulting from unsafe injection practices.

Enhancing the Campaign

To better protect patients from unsafe injection practices, the CDC Foundation partnered with [Eli Lilly and Company](#) to support and expand CDC's Safe Injection Practices Coalition for the next three years. Read more about this exciting expansion on the [CDC Foundation Blog](#).

Featured Content

- [CDC Foundation and Lilly to Address Unsafe Injection Practices in U.S. Healthcare Settings](#)
- [CDC releases toolkit to assist with patient notification](#)

Campaign Resources

The SIPC has many resources on safe injections, including an award-winning video that shows the correct way to use a single-dose vial.

Become a Member

Help us promote safe injection practices to healthcare professionals, patients and/or the public. Become a One & Only Campaign member today.

Hepatitis B Vaccination

- All children
- Adults if you:
 - have sex with or live in the same house as a person with hepatitis B virus infection.
 - have sex with more than one partner.
 - seek care in a clinic for STDs, HIV testing or treatment, or drug treatment.
 - are a man who has sex with other men.
 - inject drugs.
 - have a job that involves contact with human blood*.
 - are on the staff of, or a client in, an institution for the developmentally disabled.
 - are a hemodialysis patient or have end-stage renal disease.
 - have HIV infection.
 - are a dialysis patient.
 - have chronic liver disease.
 - have diabetes and are under age 60... “consider for > 60”
 - live or travel for more than 6 months a year in countries where hepatitis B is common.
 - seek care in a clinic for sexually transmitted diseases, HIV testing, or drug treatment.
 - are a prisoner in a correctional facility.

<http://www.cdc.gov/Vaccines/vpd-vac/hepb/in-short-adult.htm#who>

<http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=SOImmunizations>

Training & Competency



Carol Dahozy, RN, MSN
Nurse Consultant
Phoenix Area IHS

Training & Competency

- Did staff receive adequate training?
- Are you sure your staff is using the device and performing the test correctly?

Training

- Owner's Manual
- First time Guide
- Quick Reference Guide
- Instructional video's
- Instructional DVD's
- Onsite training by vendor

Competency

Competence

An individual's capacity to perform his or her job functions.

Competency

An individual's **ACTUAL** performance in a particular situation

Competency Assessment

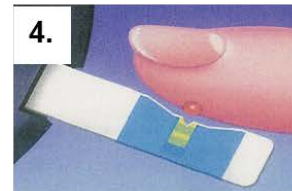
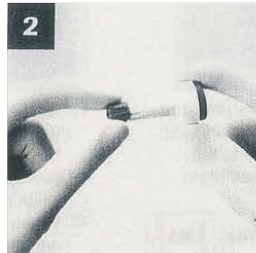
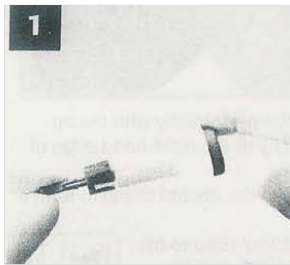
- Verifying “Competence”
 - Capability to perform up to defined ***expectations!***
 - Competency Verification Methods
 - Demonstration
 - Verbalization
 - Policy Review
 - Written tests

Competency Skill Checklist

- Skills checklists outline the required skills for employees and the level of performance expected for each skill

Objective:	Participant will demonstrate performing controls & patient tests on the Accu-Chek Inform® Glucometer per PIMC policy.		
A. Reason for selection:	<input type="checkbox"/> ↑ Risk ↑ Volume <input type="checkbox"/> Regulatory Requirement <input checked="" type="checkbox"/> New/Changed <input type="checkbox"/> Safety Issue <input checked="" type="checkbox"/> Critical Skill <input type="checkbox"/> ↑ Risk ↓ Volume <input type="checkbox"/> PI Data <input type="checkbox"/> IC finding <input type="checkbox"/> Problematic <input type="checkbox"/> other (identify) _____		
B. References:	<input type="checkbox"/> Standards of Care Manual <input checked="" type="checkbox"/> Policy and Procedure Manual <input checked="" type="checkbox"/> Other (Identify) Manufacturer's Instructions		
C. Behavioral Criteria:	D. Dimensions	E. Competent	F. Validation Method
	C-Critical Thinking I-Interpersonal Skills T-Technical skills	Yes/No/NA	1. Direct Observation 2. Documented results of written test 3. Accurate documentation of results 4. Skills checklist 5. Other (specify) _____
C. Behavioral Criteria:	D. Dimensions	E. Competent	F. Validation Method
Coding (calibrating)			
States when coding is necessary (when new vial of strips is opened or code displayed on Accu-Chek Inform® System display does not match code on strip vial in use)	C, T		1, 4
States how to code (calibrate) the glucose meter (insert correct code key before programming the test)	C, T		1, 4
Quality Control			
States when controls are routinely run (once every 24 hrs)	C		1, 4
States when to discard control solution (at exp. date or 3 months after opening)	C		1, 4
States what to do when control result fails to fall within the acceptable range (repeat the test and document remedial action with a comment).	C, T		1, 4
Demonstrates correct application of control solution to test strip: holds bottle horizontally, touches drop to edge of yellow window until window is filled, adds a drop if window not completely filled. (as shown in picture 5 below)	C, T		1, 4
Patient Testing			
Put on gloves	T		1, 4
Turn on meter, input operator ID and select patient test	T		1, 4
Have patient wash hand or clean with alcohol and allow to completely dry	T, I		1, 4
Perform finger puncture using single-use lancet (Demonstrates correct use of lancet: removes cap by twisting, adjusts depth setting, & avoids squeezing finger at puncture site. See pictures 1-3 below)	T		1, 4
Apply drop to yellow window. Must be filled completely for accurate result. (the "beep" sound does not indicate window is completely filled only that blood has been applied.) Can redose within 15 seconds (as shown in picture 4 below)	C, T		1, 4
After test result appears, enter comments, if necessary	C, T		1, 4

C. Behavioral Criteria:	D. Dimensions	E. Competency Score	F. Validation Method
After test result appears, enter comments, if necessary	C, T	1 2 3 4 5	1, 4
Dispose of lancet in sharps disposal	T	1 2 3 4 5	1, 4
Discard strip in biohazard receptacle	T	1 2 3 4 5	1, 4
State where result is recorded (in patient record)	C	1 2 3 4 5	1, 3, 4
<i>Hospital Critical Limits and Follow-up</i>			
State critical values (<40 or >400 mg/Dl); notify provider of critical results	C	1 2 3 4 5	1, 4
State when venous sample is sent to central laboratory for confirmation (<40 or >400 mg/dL) unless there is a unit specific policy that supercedes	C	1 2 3 4 5	1, 4
<i>Cleaning</i>			
State cleaning procedure (wearing gloves, wipe Accu-Chek Inform® Meter with a disinfectant of choice)	T	1 2 3 4 5	1, 4
State minimum cleaning frequency (once every 24 hours at time of QC check)	T	1 2 3 4 5	1, 4



G. If any of the behavioral criteria cannot be validated, document the reason and the corrective action below

Employee Signature: _____

Date: _____

Evaluator: _____

Date: _____

1. Quality Control tests should be performed:
 - a. Daily
 - b. When a new vial of test strips is opened
 - c. If the meter is dropped
 - d. All of the above**
2. When is it necessary to code the Accu-Chek Inform® System?
 - a. When a new vial of strips is opened
 - b. When the code displayed on the meter does not match the code on the strip vial in use
 - c. a & b**
 - d. None of the above
3. Gloves do not need to be worn when running the Quality Controls.
 - a. True**
 - b. False
4. A possible reason why the glucose control result is not within the acceptable range would be:
 - a. The system is not coded for the test strips you are using
 - b. The test strip is damaged from exposure to humidity or extreme temperatures
 - c. The test strips have expired
 - d. All of the above**
5. Glucose control solutions should be dated when they are first opened and they remain stable for:
 - a. 3 months**
 - b. 6 months
 - c. 12 months
6. When obtaining a blood sample or dropping the control solution on the test strip you should:
 - a. Apply the drop on the top of the test strip
 - b. Apply the drop on the edge of the test strip**
 - c. Submerge the strip in the blood or control solution
7. An RRLO or RRHI message after a patient test indicates:
 - a. There may have been an operator error and the test should be repeated
 - b. The blood glucose level is at a critical level (<40mg/Dl or >400mg/Dl)
 - c. A venous sample should be obtained and sent to central laboratory for confirmation
 - d. All of the above**
8. If the blood drop is not large enough to fill the strip window, another drop may be added within:
 - a. 3 seconds
 - b. 5 seconds
 - c. 15 seconds**
9. The meter should be cleaned (circle all that apply):
 - a. Daily, at the time of QC Check**
 - b. When visibly soiled or used with a patient on contact precautions**
 - c. With Chlorine bleach**
 - d. With Cavi-Wipes
10. After running a patient test, the used test strip should be discarded in the biohazard receptacle
 - a. True**
 - b. False

Accreditation Requirement

- The Joint Commission
 - HR.01.06.01 – Staff are competent to perform their responsibilities
- AAAHC
 - 3.B-4 – File contains evidence of periodic performance appraisals Including current competence
- CMS
 - §482.13(f)(4) - The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed.

Risk Management

- Adverse outcome
- Reviewers/investigators will look for
 - Training
 - Competency