# Reclassification Discussion for Blood Lancets:

# Transmission of bloodborne pathogens related to reuse of blood lancets

*Wednesday June 26, 2013*

Nicola D. Thompson, PhD
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

# Outline

- **Background information**
  - Characteristics of bloodborne pathogens (BBP)
  - Healthcare as a mode of BBP transmission
  - BBP transmission during use of blood lancets
- **History, review of outbreaks related to use of blood lancets**
  - United States, International
- **Misuse of blood lancets**
- **Infection control recommendations and guidance regarding use of blood lancets**

# 2010 CDC Infection Control Guidance:
## Best practices for use of fingerstick devices

- Reusable Devices: the lancet blade can be removed and replaced after each use, device can be used more than once
  - Some devices previously approved and marketed for multi-patient use
- But, due to
  - Failures to change the disposable components
  - Difficulties with cleaning and disinfection equipment after use
  - Reusable devices linked to multiple HBV infection outbreaks
- CDC recommends that reusable fingerstick devices are never to be used for more than one person

www.cdc.gov/injectionsafety/blood-glucose-monitoring.html

# BACKGROUND INFORMATION

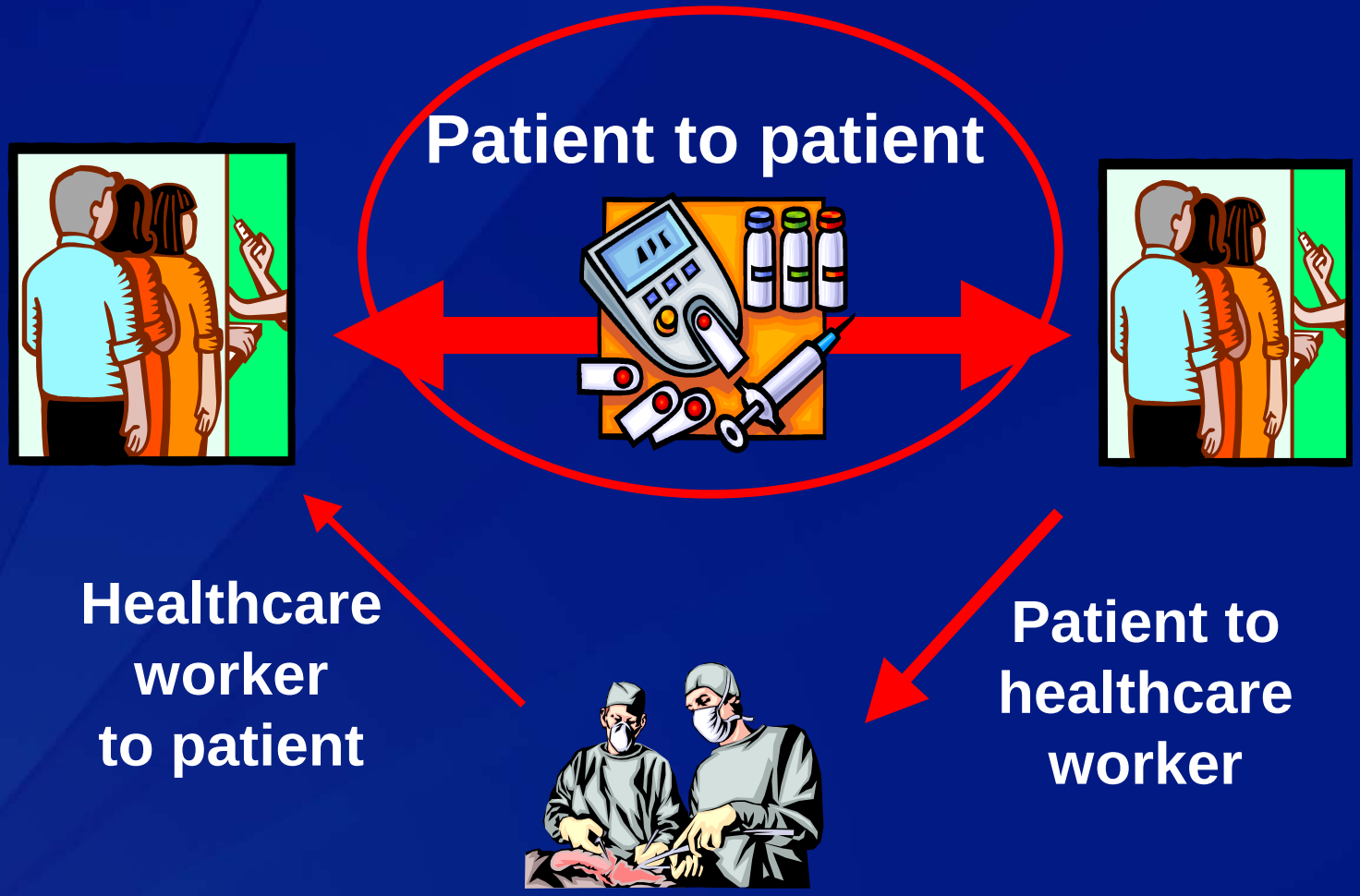
# Characteristics of HBV, HCV and HIV relevant to healthcare transmission

| Characteristic | HBV | HCV | HIV |
|---|---|---|---|
| # chronic infection (U.S.) | 1.25 M | 3.2 M | 1.1 M |
| Titer (per ml)* | $10^{8-9}$ | $10^{6}$ | $10^{3-6}$ |
| Environmental stability | >week | days | hours |
| Infectivity (needlestick) | 30% | ~3% | ~0.2% |

* Blood, acute infection


Beltrami et al, Clin Microbio Reviews, 2000.
MMWR 2001;50(No. RR-11).
Bond et al. Lancet 1981; 8219:550-1.
Shikata et al.. J Infect Dis 1977;136:571–76. 1977;136:571–76.
Kamilli et al. ICHE 2007;28:519-24.

# Modes of BBP transmission in healthcare settings



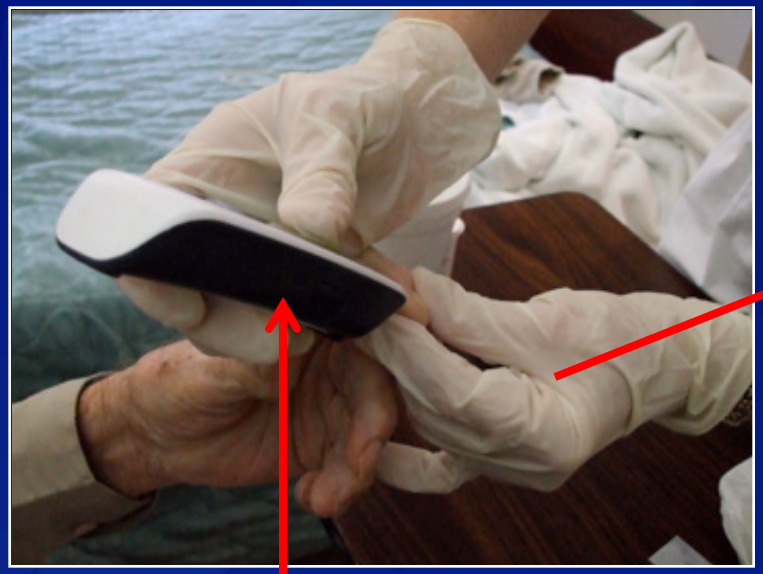

Williams et al. Clinical Infectious Diseases 2004; 38:1592–8

# Indirect contact transmission

- The transfer of an infectious agent from one patient to another through a *contaminated intermediate object or person*
  - Healthcare personnel hands
  - Blood glucose meter
  - Blood lancets (fingerstick devices)

**CDC : Preventing transmission of infectious agents in healthcare settings, 2007**
**www.cdc.gov/hicpac/2007IP/2007isolationPrecautions.html**

# Indirect contact transmission during blood glucose monitoring



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

Blood contamination of glucose meters

CDC. MMWR 2005;54:220-23. www.cdc.gov/injectionsafety/blood-glucose-monitoring.html

# Indirect contact transmission during reuse and common storage of blood lancet devices


Common storage of fingerstick devices

Blood contamination of fingerstick device used on multiple persons

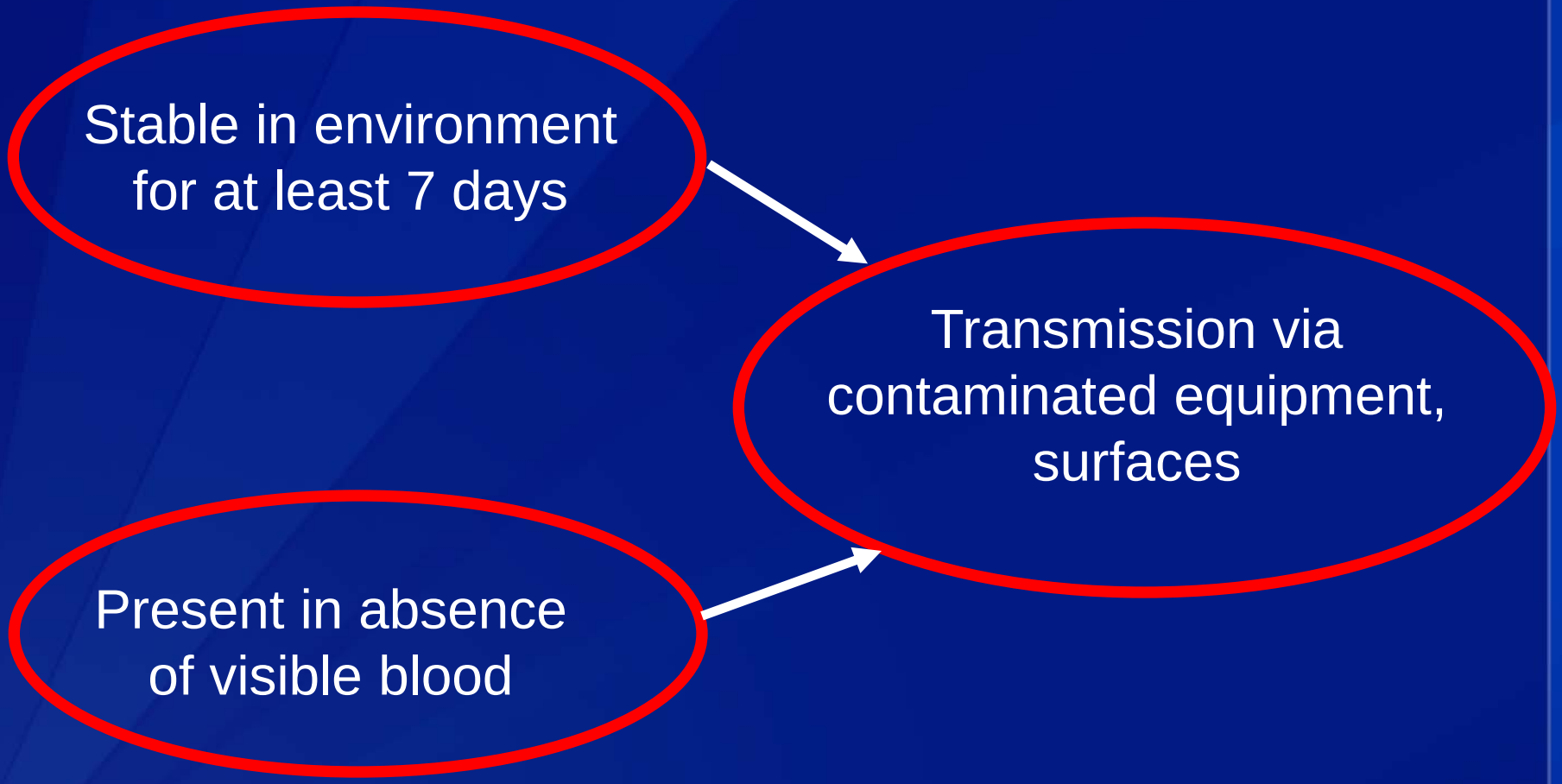
CDC. MMWR 2005;54:220-23. www.cdc.gov/injectionsafety/blood-glucose-monitoring.html

# Example - Indirect contact transmission of HBV infection in hemodialysis settings

- HBV is transmitted by percutaneous (puncture through the skin) or permucosal (direct contact with mucous membranes) exposure to infectious blood or to body fluids that contain blood
- HBV at titers of $10^{2-3}$ virions/mL can be present on environmental surfaces in the absence of any visible blood and still result in transmission
- HBV is relatively stable in the environment and remains viable for at least 7 days on environmental surfaces at room temperature. HBsAg has been detected in dialysis centers on clamps, scissors, dialysis machine control knobs, and doorknobs
- Blood-contaminated surfaces that are not routinely cleaned and disinfected represent a reservoir for HBV transmission

CDC. Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients. MMWR 2001 / 50(RR05);1-43.

# Why transmission of HBV during reuse of blood lancets?



# Impact of HBV infection

- Acute HBV infection[1]
  - **Many (50-70%) persons asymptomatic**
  - **Illness in 30-50% persons: fever, fatigue, nausea, jaundice,**
  - **Case fatality ratio ~1%**
  - **Outcomes more severe in persons >60 years**
- Chronic HBV infection → cirrhosis, liver cancer[1]
  - **Serve as reservoir of infection for others**
- Older, immune suppressed persons at high risk for developing chronic infection
  - **Older persons[1] (mean age 74 years) - 59%**
  - **Persons receiving hemodialysis[2] - 40-45%%**
  - **HIV-infected persons[2,3] - 6-22%**

**1: www.cdc.gov/hepatitis/HBV/HBVfaq.htm 1: Kondo at al. Hepatology 1993;18:768-74.**
**3: Hyams CID 1995;20:992-1000. 4: Alter et al. J Hepatol 2006; 44:S6–9.**

# HISTORY, REVIEW OF OUTBREAKS RELATED TO USE OF BLOOD LANCETS

# History: Blood lancets and viral hepatitis

- 1922, insulin introduced
- Spring activated lancet "Schnepper" used to obtain blood sample from earlobe for blood sugar monitoring
- 1923, unexplained jaundice in 26 patients at a diabetes clinic in Sweden[1,2]
  - Schnepper used for multiple patients
  - Cleaned perfunctorily between each use
- 1926, outbreak of "Schnepper Ikterus" reported by Flaum[1]
  - Believed to be serum hepatitis (HBV infection)[2]
- Similar reports in literature from 1938 and 1945[3,4]

1:Flaum et al. 1926. Actas Medica Scandinavica.
2:Schmid. Journal Gastero & Hepatology, 2001.
3: Graham. Lancet 1938;2,1.
4: Droller. BMJ 1945;623-5

# Single case reports HBV infection due to blood lancets

- Female with diabetes, diagnosed with acute HBV infection[1]
  - Only risk identified sharing her capillary blood sampler with co-worker who had hypoglycemic episode
  - Co-worker found to have chronic HBV infection
- 75 y/o female with diabetes, diagnosed with HBV/HDV co-infection, subsequently died[2]
  - All contacts tested negative for HBV
  - Only risk identified repeated fingersticks for blood glucose monitoring at outpatient facility
- 28 y/o female with diabetes, diagnosed with HBV infection[3]
  - Father later treated for deterioration of glycemic control, and found to have HBV infection
  - Only risk factor for transmission was father's use of daughters blood lancet and meter at home

1: Stapleton, Lemon. JAMA 1985:22;3250.
2: Mendez et al. Am J Gastero 1991:86;895-7.
3: Farkas. Diabetic Medicine; 1997:14: 263

# Frequency of blood lancet contamination

- Outbreak in a French hospital[1]
  - 18 patients with HBV infection identified
  - Disposable platform was not removed each time
  - *Prospective assessment: Lancing device platforms visibly contaminated with blood after 20 (24%) of 85 fingersticks*

- Prospective assessment performed by laboratory[2]
  - *Lancing device end caps visibly contaminated with blood after 30 (29%) of 104 fingersticks*
  - Procedure lab implemented between end cap uses
    - Scrub with detergent to remove excess blood, rinse in tap water
    - Chemical disinfectant, soak for 60 minutes in Cidex solution

**1: Douvin et al. NEJM 1990;322:57-58.**
**2: Shier et al, NEJM 1993; 328:969-970.**

# HBV Infection Outbreak, California Hospital -1990

- 265-bed acute care VA hospital, California
- Increase in patients with acute HBV infection noted by hospital staff
  - All patients with acute HBV infection confirmed via serologically testing
  - All admitted to single medical ward during 6-months before HBV infection diagnosis

Polish et al. NEJM 1992;326:721-725

# Outbreak and case description

- Serum collected from 61% patients on ward
  - 27 (7%) found to have acute HBV infection
    - Only 7 (26%) had hepatitis symptoms, most asymptomatic
  - 71 (17%) evidence of resolved HBV infection
  - 1 with chronic HBV infection (HBsAg+)
- Mean age of cases: 65 years (range 42-79 years)
- 23 of 27 (85%) persons with acute HBV infection had diabetes, as did the chronic carrier
  - Of 4 person without diabetes, 3 received fingersticks while in hospital

Polish et al. NEJM 1992;326:721-725

# Study to assess risk factors for acute HBV infection

- Cohort study included 60 person with diabetes
- Receipt of fingersticks the only significant risk factor for acute HBV infection
  - 23/55 with finger-sticks (42%)
  - 0/5 without finger-sticks (0%), P=0.008
- Dose-response relationship identified

| # fingersticks | # Patients | Relative Risk |
|---|---|---|
| 0-6 | 14 | Referent group |
| 7-14 | 16 | 4.4 |
| 15-20 | 13 | 4.6 |
| >20 | 15 | 8.4 |

Polish et al. NEJM 1992;326:721-725

# Survey of staff practices

- Spring loaded Autolet (Owen Mumford, Oxford, England) used for sampling blood
- Blood lancet devices were not restricted to individual patient use
- Survey of 41 nurses who performed fingersticks
  - All reported that lancets were always changed
  - However, 13 (31%) reported they did not change fingerstick platform between each use

Polish et al. NEJM 1992;326:721-725

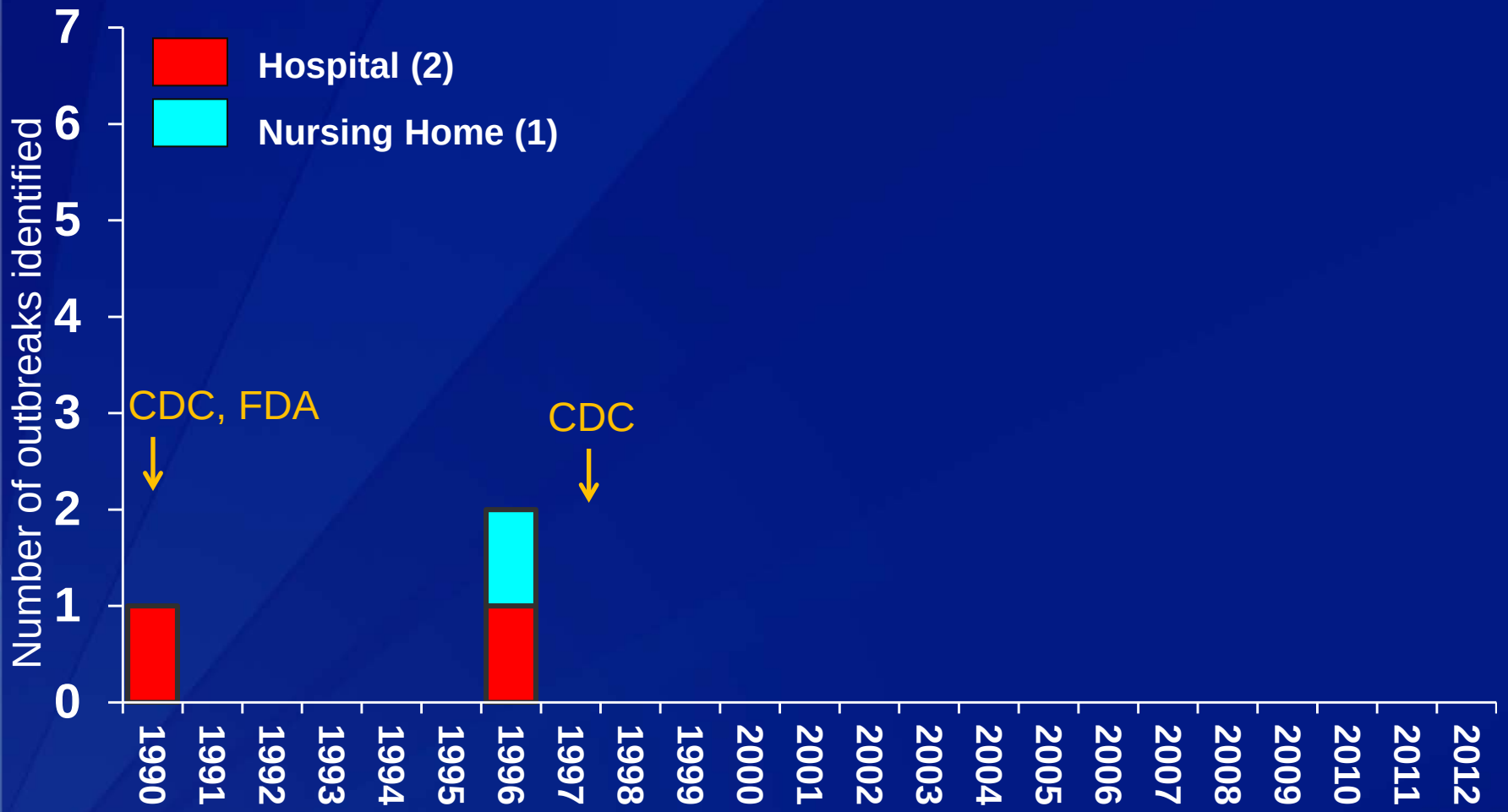
# CDC & FDA recommendations issued, 1990[1,2]

- Because platforms may not be routinely changed after each use, *fingerstick devices with disposable platforms optimally should be used only on individual patients*. …if used on multiple patients, after disposal of the lancet and platform, the device should be cleaned and disinfected[1]
- *Some spring-loaded fingerstick devices do not employ disposable platforms. Use of these devices also optimally should be restricted to one patient*, but if used on multiple patients, the lancet should be discarded and the device disinfected between patients[1]
- *Devices without a removable platform should only be used with one patient in the hospital or outpatient setting*. After the patient is discharged, the device may be reused **only** if it is disinfected according to the manufacturer's instructions. *If there are no instructions for disinfection, the device should be discarded*[2]


1: CDC. MMWR 1990:39(35);610-613

2: www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm241809.htm

# Outbreaks of HBV infection associated with reuse of blood lancets - 1990 to 2012, US

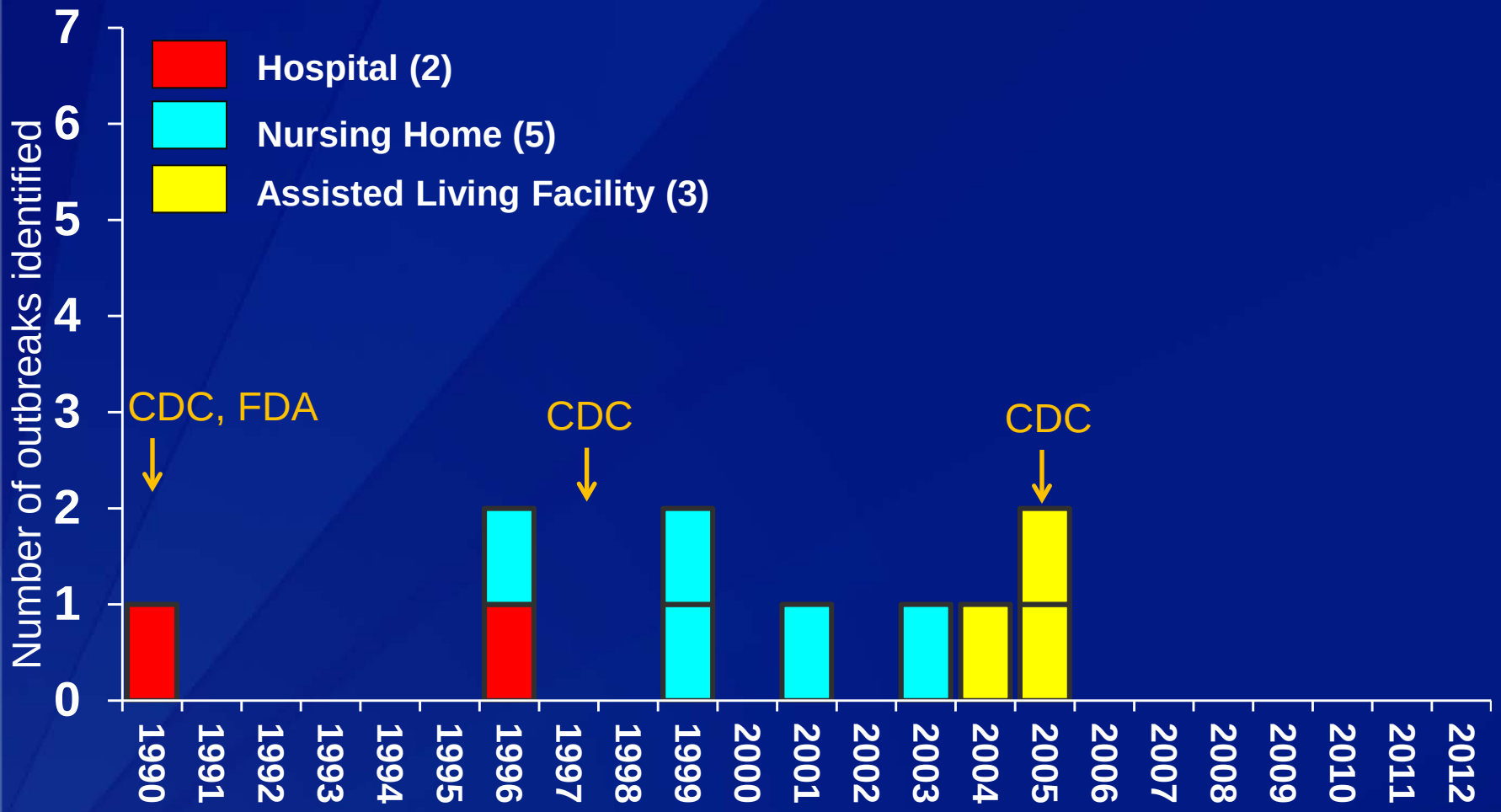




Thompson, Perz. J Diabetes Sci Technol 2009; 3:283-88.

Thompson, Schaefer J Diabetes Sci Technol 2011;5:1396-1402

# Outbreaks of HBV infection associated with reuse of blood lancets - 1990 to 2012, US




Thompson, Perz. J Diabetes Sci Technol 2009; 3:283-88.

Thompson, Schaefer J Diabetes Sci Technol 2011;5:1396-1402

**Transmission of Hepatitis B Virus Among Persons Undergoing Blood Glucose Monitoring in Long-Term–Care Facilities — Mississippi, North Carolina, and Los Angeles County, California, 2003–2004**

BOX 1. Recommended practices for preventing patient-to-patient transmission of hepatitis viruses from diabetes-care procedures in long-term–care settings

Diabetes-care procedures and techniques

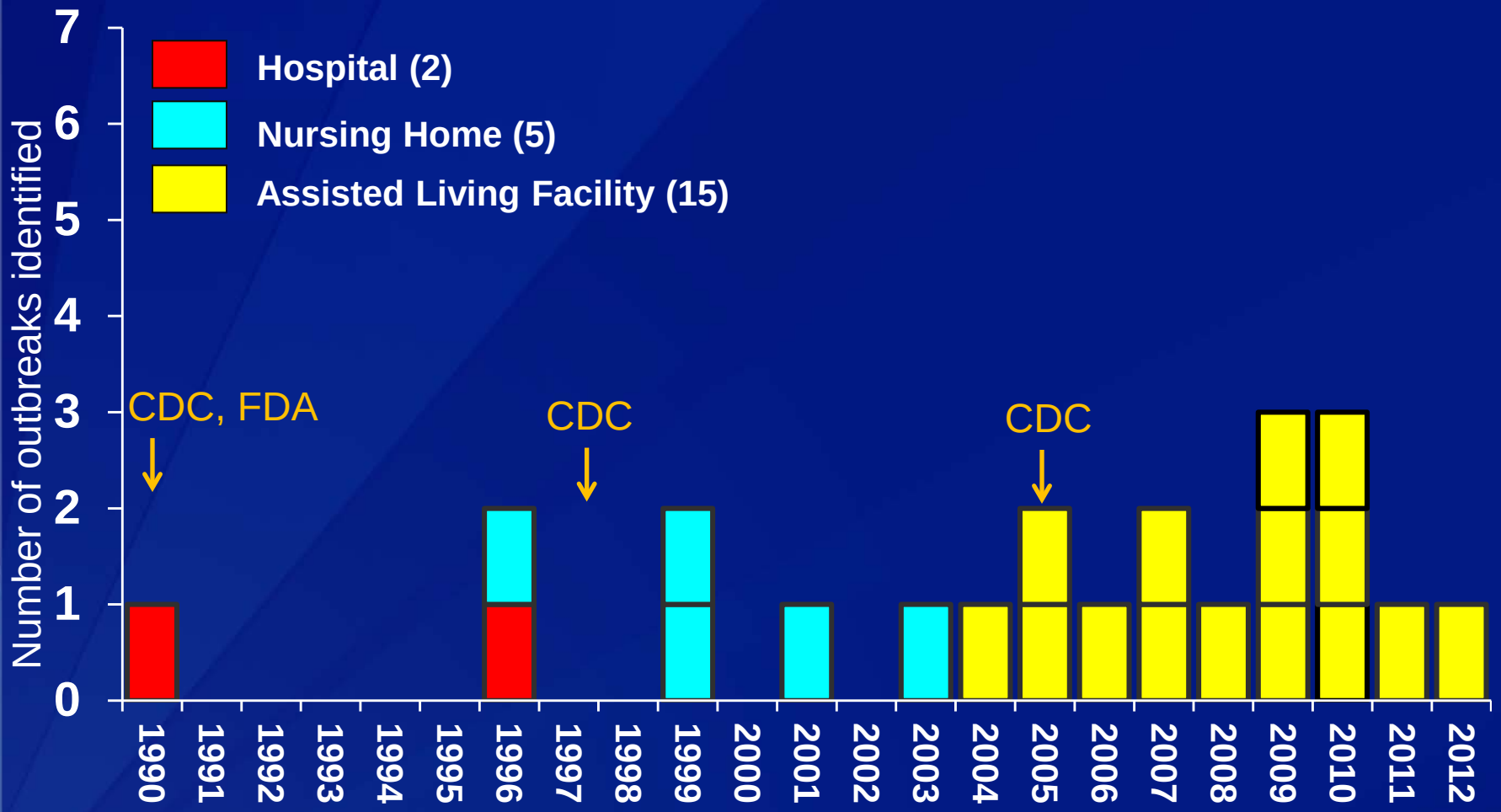
- Prepare medications such as insulin in a centralized medication area; multidose insulin vials should be assigned to individual patients and labeled appropriately.
- Never reuse needles, syringes, or lancets.

## 2005 CDC Recommendations

- Never reuse needles, syringes, or lancets
- Restrict use of fingerstick capillary blood sampling devices to individual patients
  - Consider using single-use lancets that permanently retract upon puncture
- Additional guidance related to glucose meter use, hand hygiene, medical management (fingerstick frequency), training and oversight

CDC. MMWR 2005; 54:220-3

# Outbreaks of HBV infection associated with reuse of blood lancets - 1990 to 2012, US




Thompson, Perz. J Diabetes Sci Technol 2009; 3:283-88.

Thompson, Schaefer J Diabetes Sci Technol 2011;5:1396-1402

# Summary: Recent outbreaks

- **Assisted Living Facility – Virginia, 2010[1]**
  - 126 (91%) residents tested during the investigation
    - 14 found to have acute HBV infection
  - Acute HBV infection developed in 12/13 who received fingerticks (92%) vs. 2/75 who did not (3%), RR = 35; 95% CI, 8.7 to 137
  - Identified infection control breaches included shared use of fingerstick devices for multiple residents
- **Assisted Living Facility – North Carolina, 2010[2]**
  - 8 residents found to have outbreak associated acute HBV infection, all were hospitalized - 6 died
  - Identified infection control breaches included shared use of fingerstick devices for multiple residents

1: Bender et al. PLoS ONE 2013; 7(12): e50012
2: CDC. MMWR 2011;60(06);182.

# Prevention challenges in assisted living facilities

- Operate under a social model of care
- Care primarily provided by non-professional staff, limited professional oversight
- Infection control resources, expertise is poor
- High staff turn-over, limits impact of education/training
- ALFs not federally regulated
  - Licensing, inspection at state level highly variable
  - Outside the scope of the Centers for Medicare & Medicaid Services (CMS)

# Reported outbreaks: the tip of an iceberg?

- Under-reporting of cases
  - Long incubation period, up to 6 months for HBV infection
  - Most (50-70%) infections are asymptomatic
  - Many persons go undiagnosed
- Under-recognition of healthcare as mode of BBP transmission
  - Traditionally, thought to be rare events in the US
- Many persons have multiple healthcare exposures
  - Identification of a single healthcare encounter as the venue of transmission can be difficult
- Difficult to detect and investigate
  - Time and resource intense
  - Cooperation of facility ownership, staff needed

**Thompson et al. Ann Intern Med 2009;150:33-39**.

# International outbreaks due to use of blood lancets

- Belgium - 5 persons with acute HBV infection, 2 died[1]
- France - reports of HBV[2] and HCV[3] infection outbreaks
- Germany - 19 persons with acute or recent HBV infection[4]
- Netherlands - HBV infection outbreak, re-use of multi-lancet device[5]
- United Kingdom - 5 HBV infection outbreaks during 2004-07[6]


1: De Schrijver et al. Acta Clinica Belgica 2005;60;63-69
2: Douvin et al. N Engl J Med 1990;322:57-58.
3: Desenclos et al. ICHE 2001;22:701-707.
4: Dreesman et al. Epidemiol. Infect 2006;134:1102–1113
5: Gotz et al. EuroSurveillance 2009;13(l).
6: Duffel et al. Epi & Infection 2011; 139, 327–335

# HCV infection outbreak due to reuse of fingerstick device – Acute care hospital, France

- Group 1: 22 of 38 (58%) cystic fibrosis patients (children, teenagers) tested were HCV antibody positive
  - 18/18 (100%) patients had ever undergone self-monitoring of blood glucose in the unit were HCV positive, compared to 4 of 20 (20%) who had not (RR, 5.0; 95% CI, 2.1-12.0)
    - Only 2 patients with diagnosis of HCV infection prior to the outbreak
  - Disposable platform of devices not changed between patient use
- Group 2: 12 of 70 (19%) patients with diabetes tested were HCV antibody positive
  - Patients with diabetes had routine capillary blood glucose monitoring while hospitalized
  - Shared with cystic fibrosis patients the same devices for blood sampling

**Desenclos et al. ICHE 2001;22:701-707.**

# Key findings from investigation of HBV infection outbreaks in the United Kingdom

- United Kingdom - 5 outbreaks between 2004-07 reported
- *"This highlights the potential for confusion regarding the correct use of blood glucose monitoring equipment, as the models for self-use and professional use appear very similar*
- *Informal surveys conducted in London indicated that incorrect use of the devices was widespread in a range of healthcare settings*
- *The outbreak teams concluded that the manufacturer's information that accompanies these devices is not always clear"*

**Duffel et al. Epi & Infection 2011; 139, 327–335**

# Common features of these outbreaks

- **Only those with definitive evidence of blood lancet device reuse on multiple persons included**
  - Investigator direct observation or staff self-report of reuse of blood lancet on multiple persons
- **In most, blood glucose monitoring performed by facility staff**
  - However, outbreaks and case reports of BBP transmission when persons performing self-monitoring of blood glucose (SMBG) share blood lancet devices[1,2,3]
- **Outbreaks reports frequently include**
  - Epidemiologic evidence that identifies receipt of fingerstick using blood lancets as the primary risk factored for infection[4]
  - Sequencing of viral genome demonstrating infected person have indistinguishable virus[4]

1: Stapleton, Lemon. JAMA 1985:22;3250.
2: Farkas. Diabetic Medicine; 1997:14: 263
3: Desenclos et al. ICHE 2001;22:701-707
4: Example - Bender et al. PLoS ONE 2013; 7(12): e50012.

# MISUSE OF BLOOD LANCETS

# Surveys on use of blood lancets

(during routine practices, not during outbreak investigations)

| | Virginia, 2006[1] | Florida, 2007[2] | | 3 States, 2008[3] |
|---|---|---|---|---|
| *Setting, # facilities* | *Assisted Living, 50* | *Assisted Living, 33* | *Nursing Home, 15* | *Ambulatory Surgery, 68* |
| % facilities using blood lancet fingerstick devices for >1 person | 16%, (7/45) | 17%, (3/17) | 7%, (1/15) | 21%, (11/53) |


1. Patel et al. ICHE 2009;30:209-14.
2. Thompson et al. JAGS 2010;58:914-18.
3. Schaeffer et al. JAMA 2010; 303:2273-79.

# Recent patient notifications due to systematic misuse of blood lancets

- Patient notification events due to multi-patient use of blood lancets
  - Patient notification: Recommendation for bloodborne pathogen testing (HBV, HCV and HIV) to groups of individuals potentially exposed to another person's blood during receipt of healthcare

| Year, setting | Equipment | Length of misuse | Persons at risk |
|---|---|---|---|
| 2009, Community Health Center | Multi-lancet fingerstick device | 6 months | 283 |
| 2010, Health fair | Multi-lancet fingerstick device | 1 day | 64 |

**Thompson, Schaefer J Diabetes Sci Technol 2011;5:1396-1402**

# North Carolina Community Healthcare Center
## 2009 – Fingerstick lancing device

- Staff used fingerstick lancing devices on multiple patients for ~ 6 months
  - Multi-lancet device; rotating barrel containing 6 lancets
- Error in use identified only after nurses suspected lancets were not rotating
  - Misuse of device: should never have been used for multiple patients
- Warning on page 24 of 92 page owners manual

**Chapter 3: Testing Your Blood Sugar**

Using the ACCU-CHEK Multiclix Lancing Device

**The ACCU-CHEK Multiclix lancing device is intended for patient self-monitoring by a single person only. It must not be used to collect blood from more than one person as this poses an infection risk.**

# INFECTION CONTROL RECOMMENDATIONS AND GUIDANCE REGARDING USE OF BLOOD LANCETS

# Additional issuance of recommendations, guidance regarding use of blood lancets for multiple persons

- 1997: American Association of Diabetes Educators
  - Position statement on risk of BBP transmission during diabetes care
- 2005: CMS Texas - Survey and Certification
  - Multiple patient use of fingerstick and glucose monitoring devices in healthcare facilities
- 2007: Healthcare Infection Control Practices Advisory Committee
  - Preventing Transmission of Infectious Agents in Healthcare Settings
- 2009: New York State Department of Health
  - Health Advisory: Preventing exposure to BBP during diabetes care procedures
- 2009: UK Health Protection Agency
  - Infection prevention and control guidelines for performing blood glucose monitoring in care homes

# Recent issuance of recommendations, guidance regarding use of blood lancets for multiple persons

- 2010: North Carolina Department of Health and Human Services
  - Warning on spread of hepatitis B through unsafe diabetes care
- 2010: CDC
  - Update guidance on Infection Prevention during Blood Glucose Monitoring and Insulin Administration
- 2010: CMS Survey & Certification
  - Infection Control Standards for Nursing Homes and Ambulatory Survey Centers regarding reuse of fingerstick devices
- 2010: FDA Medical Devices
  - Safety Communication: Use of Fingerstick Devices on More Than One Person Poses Risk for Transmitting Bloodborne Pathogens
- 2011: Advisory Committee for Immunization Practices
  - Due to going concerns regarding HBV transmission related to use of blood lancets and glucose monitoring recommendation for hepatitis B vaccination of persons with diabetes

# Updated (2010) CDC Infection Control Guidance:
## Best practices for use of fingerstick devices

Reusable Devices: Lancet can be remove and replace after each use, device can be used more than once

- Some previously approved and marketed for multi-patient use
  - Failures to change the disposable components
  - Difficulties with cleaning and disinfection equipment after use
  - Reusable devices linked to multiple HBV infection outbreaks
- Never to be used for more than one person

Single-use, disposable fingerstick devices: disposable, prevent reuse through an auto-disabling feature

- When performing fingerstick procedures for blood glucose monitoring on others, these devices should be used
- Safest for patients and providers

www.cdc.gov/injectionsafety/blood-glucose-monitoring.html

# Additional prevention activities

- Many CDC-authored publications, highlight the need for improved
  - Awareness of risks
  - Adherence to infection control recommendations
  - Enforcement of infection control recommendations
  - Improvements in device design/labeling, use of engineering controls
- CDC hosted meetings (9/2009, 5/2010) to raise awareness of needs for improved infection control oversight and device regulation[1]
  - Federal partners CMS and FDA
  - Stakeholders including healthcare facilities, device manufacturers, diabetes educators, public health departments

1: www.cdc.gov/injectionsafety/meetings/stickingWsafety52010.html

# Summary

- Shared use of blood lancets increases risk of exposure to bloodborne pathogens (HBV, HCV, HIV)
- Increasing frequency of HBV infection outbreaks associated with reuse of blood lancets in the US
- Routine misuse of blood lancets identified in a wide variety of settings
  - Nursing Homes, Assisted Living Facilities, Ambulatory Surgery Centers, Health Centers, Health Fairs
- Continued efforts needed to prevent misuse of blood lancets

# Thank you

E-mail dvq0@cdc.gov

**For more information please contact Centers for Disease Control and Prevention**
1600 Clifton Road NE, Atlanta, GA 30333
Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov Web: www.cdc.gov

# *Assisted* Monitoring of Blood Glucose (AMBG)

- Term introduced in 2010 by CDC in response to safety concerns related to HBV infection outbreaks related to receipt of fingersticks for blood glucose monitoring
- Where another person assists with or performs fingerticks for the purpose of blood glucose monitoring on multiple persons
- Settings where AMBG may occur:
  - Hospitals, clinics, physicians offices, health fairs
  - Nursing homes, Assisted living facilities, Senior centers
  - Schools, camps, shelters, correctional facilities

**Klonoff, Perz. Journal of Diabetes Science and Technology 2010;4:1207-31**
**www.cdc.gov/injectionsafety/blood-glucose-monitoring.html**