PATIENT SAFETY 101: PREVENTING INFECTIOUS DISEASE TRANSMISSION DURING BLOOD GLUCOSE MONITORING

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The findings and conclusions in this presentation are those of the author and do not necessarily represent the official position of the Centers for Disease Control and Prevention

Objectives

- List key factors that contribute to infection transmission during blood glucose monitoring and use of associated point of care devices
- Discuss best practices and current prevention recommendations for ensuring patient safety
- Evaluate the use of point of care devices, identify opportunities for infection transmission, and determine appropriate corrective action

Outline

- Background, bloodborne pathogen transmission during blood glucose monitoring
- HBV infection outbreaks during blood glucose monitoring
  - Recent outbreaks, patient notifications
- Prevention recommendations
- Recent federal prevention initatives
  - CDC: Education, outreach
  - CMS: Inspection, enforcement
  - FDA: Device regulation

Features of bloodborne viruses relevant to healthcare transmission

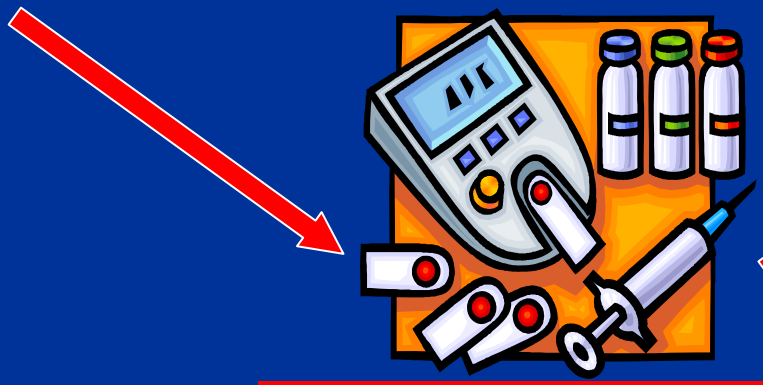
Characteristic	HBV	HCV	HIV
# with chronic infection (U.S.) Millions	1.25	3.8	1.1
Titer (per ml)*	10^{8-9}	10^{6}	10^{3-6}
Environmental stability	>week	days	hours
Infectivity (needlestick)	30%	~3%	~0.2%

* Blood, acute infection

Beltrami et al. Clin Micro Reviews, 2000.
Bond et al. Lancet 1981; 8219:550-1.
Shikata et al. J Infect Dis 1977;136:571µ76.
MMWR 2001;50(No. RR-11).
Kamilli et al. ICHE 2007; 28:519-524

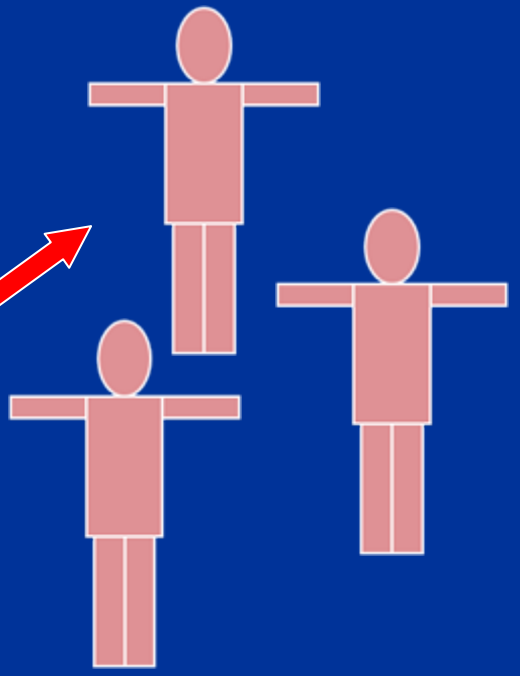
Person-to-person transmission of bloodborne viruses during blood glucose monitoring

Infected with agent

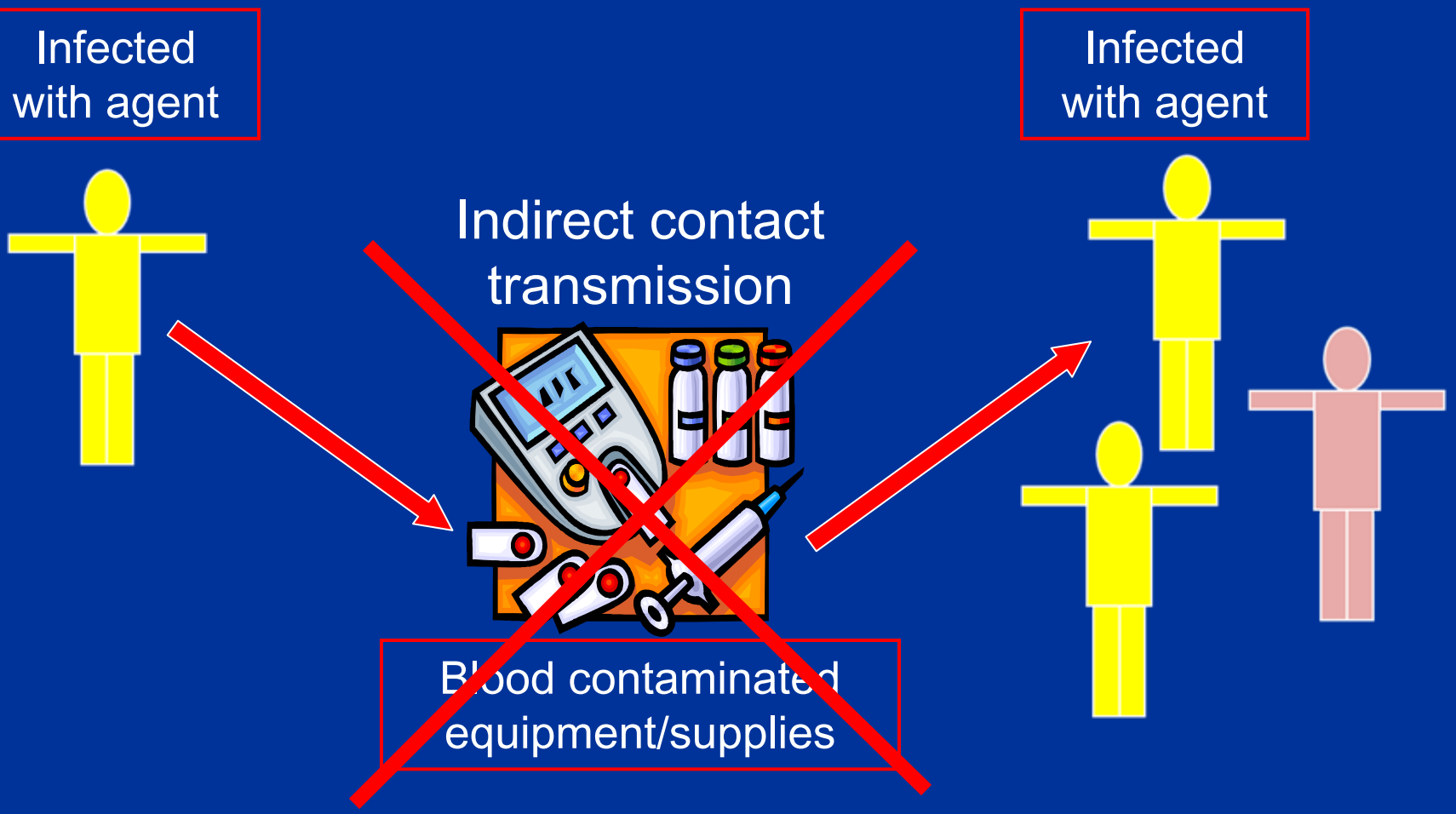


Blood contaminated equipment/supplies

Susceptible hosts



Person-to-person transmission of bloodborne viruses during blood glucose monitoring

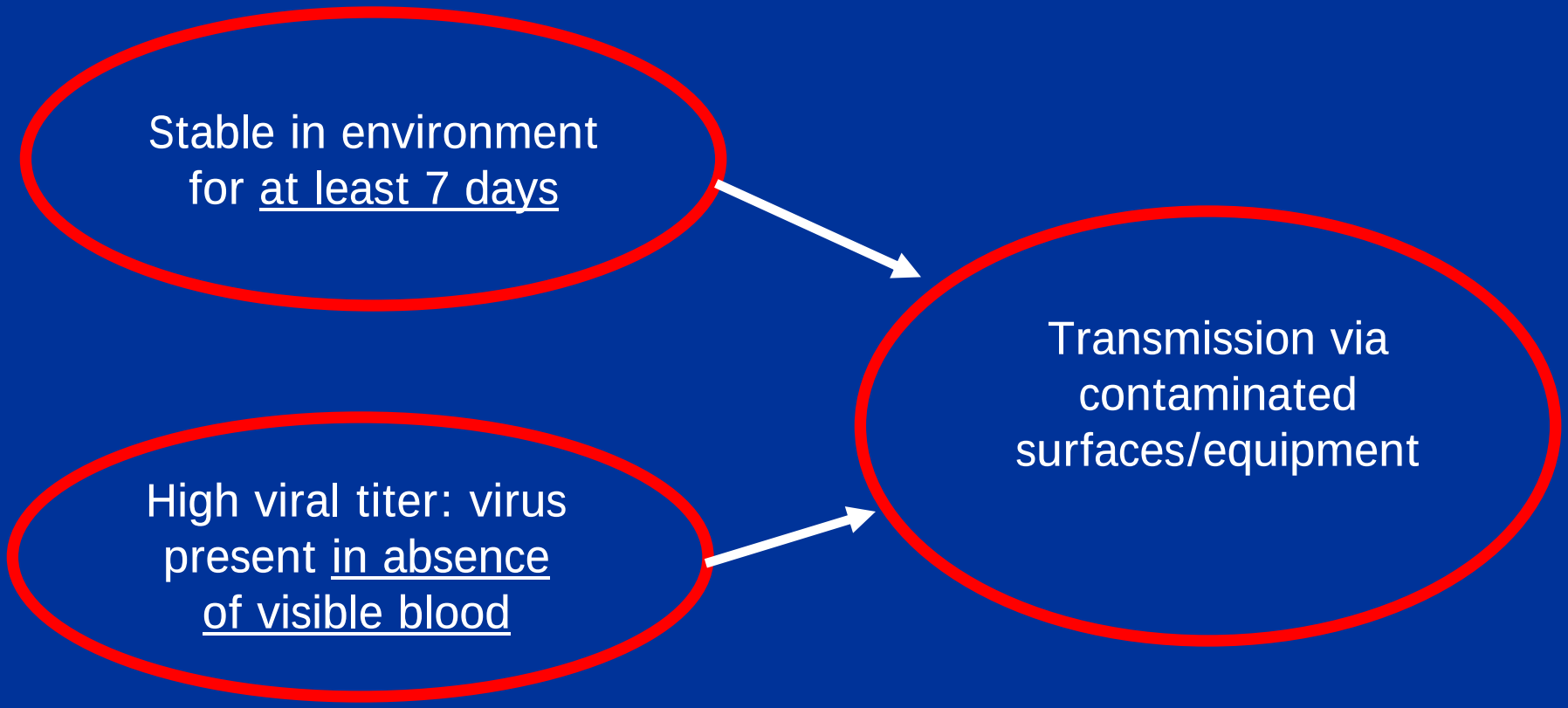


Indirect contact transmission

- 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

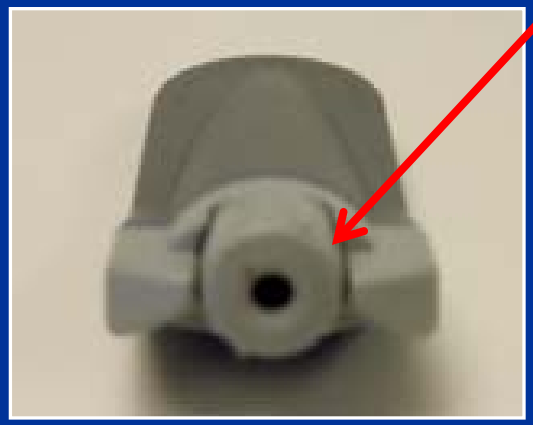
CDC : Preventing transmission of infectious agents in healthcare settings, 2007
www.cdc.gov/hicpac/2007IP/2007isolationPrecautions.html

Indirect transmission of HBV during diabetes care



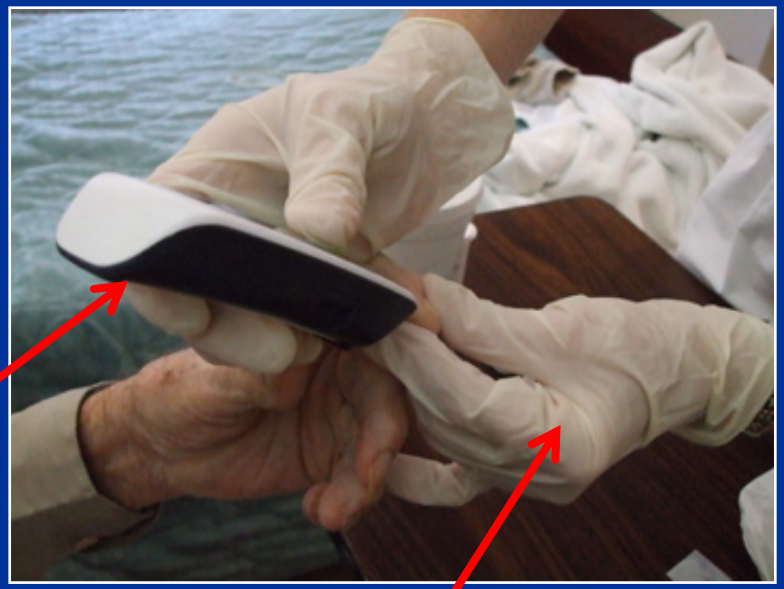
Bond et al. Lancet 1981; 8219:550-1.
Shikata et al. J Infect Dis 1977;136:571μ76.

Practices associated with HBV transmission during blood glucose monitoring



1. Use of fingerstick devices on multiple persons

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

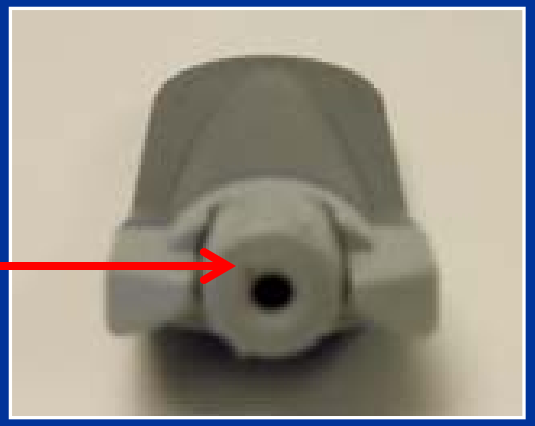


3. Failure to change or use gloves, or perform hand hygiene between procedures

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

1. Sharing reusable fingerstick lancing devices

Non-disposable end cap, blood stained



2. Blood contamination of glucose meters

Photo courtesy of the Statewide Program for Infection Control and Epidemiology (SPICE) at the University of North Carolina

High prevalence of blood contamination on blood glucose meters

- Survey of 12 hospitals,
  - 609 blood glucose meters tested for presence of hemoglobin
- 30.2% (range 0 - 60.6%) meters had blood contamination
  - 48% in ICUs vs. 29% in non-ICUs
  - 31.4% for on-meter vs. 26.6% for off-meter test strip dosing
- Only 1 hospital cleaned meters between each patient use
  - 50% (6/12) no schedule for cleaning
- Hospital location, increased number of meter operators significantly associated with blood contamination

Louis et al. Point of Care 2005;4:158-163

High frequency of blood glucose meter use

- Assessment of glucose meter usage data in 214 bed acute care hospital

	October, 2008
Total number tests performed	11,665
Number of blood glucose meters	37 (315 tests/meter)
Number of patients	803 (12.5 tests/patient)
% tests performed sequentially on different patients	79.8% (9310)
-Within 24 hours	99.9% (9302)
-Within 1 hour	60.9% (5664)
Time needed to clean/disinfect meter following manufacturers instructions	310 hours (1.93 FTE)

Hellinger et al. Am J Infect Control 2011; In press

3. Hand hygiene, glove use

- Healthcare personnel hands can become contaminated with blood while performing blood glucose monitoring
  - Pricking the patientÑs finger
  - Handling the test strip
- Blood can be transferred back to the meter when handled to obtain reading
- If the meter is not cleaned and disinfected after use, blood remaining on the meter can be transferred to subsequent patients via healthcare personnel hands
- Numerous outbreaks have implicated this mechanism in the spread of HBV infections[1,2]

1:CDC. *MMWR* 2005;54:220-223.
2: Thompson & Perz. *J Diabetes Sci Technol* 2009;3(2):283-288.

Surveys of routine practices when providing blood glucose monitoring

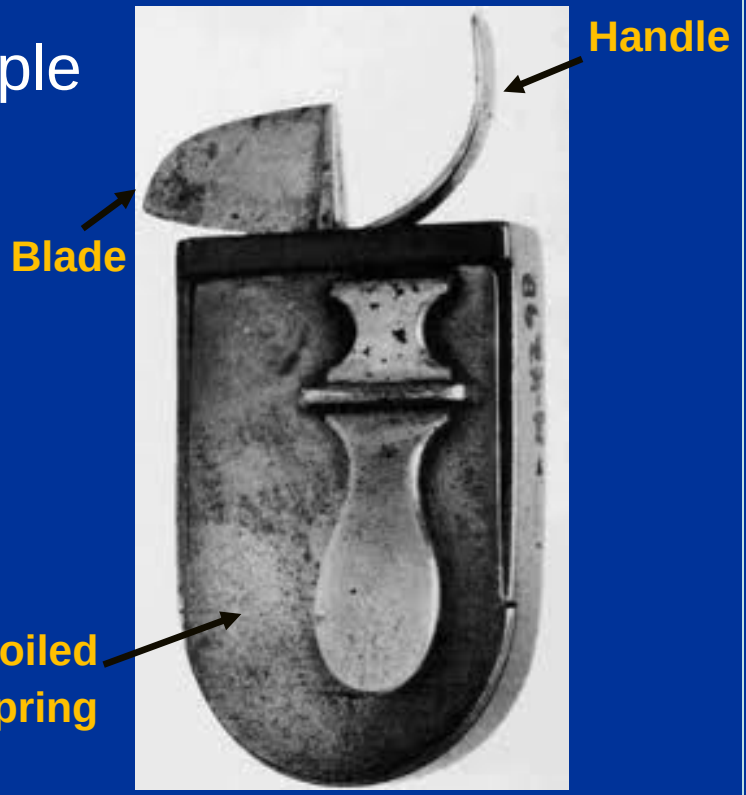
Setting, no. facilities	Virginia, 2006[1]	Florida, 2007[2]		3 States, 2008[3]
	Assisted Living Facilities, 50	Assisted Living Facilities, 33	Nursing Homes, 15	Ambulatory Surgery Centers, 68
% using personal use fingerstick devices for >1 person	16%, (7/45)	17%, (3/17)	7%, (1/15)	21%, (11/53)
% did not clean/ disinfect shared blood glucose meters between each use	50%, (4/8)	71%, (5/7)	73%, (11/15)	32%, (17/53)

1.Patel et al. ICHE 2009;30:209-14. 2. Thompson et al. J Am Geriatrics Soc 2010;58:914-18.
3. Schaefer et al. JAMA 2010; 303:2273-79.

HBV infection outbreaks during blood glucose monitoring

Blood glucose monitoring and hepatitis transmission: A long history

- Insulin introduced in 1922
- Spring lancet “Schnepper” to sample blood from earlobe of patients
- 1923 unexplained jaundice in 26 patients[1,2]
  - Schnepper used for multiple patients
  - Cleaned inconsistently between uses



1: Flaum et al. 1926. Actas Medica Scandinavica.
2: Schmid. Journal Gastero & Hepatology, 2001.

Two more historical examples

- 1938: Epidemic of jaundice in a diabetes clinic[1]
  - 28 cases noted over 2 ½ years
  - Multiple patients attending for blood draws
  - Overcrowding of clinic considered important contributing factor to transmission
- 1945: Hepatitis outbreak among persons with diabetes in a hospital[2]
  - 63 cases noted over 2 years
  - Transmission via sharing of contaminated syringes used to draw blood for glucose monitoring

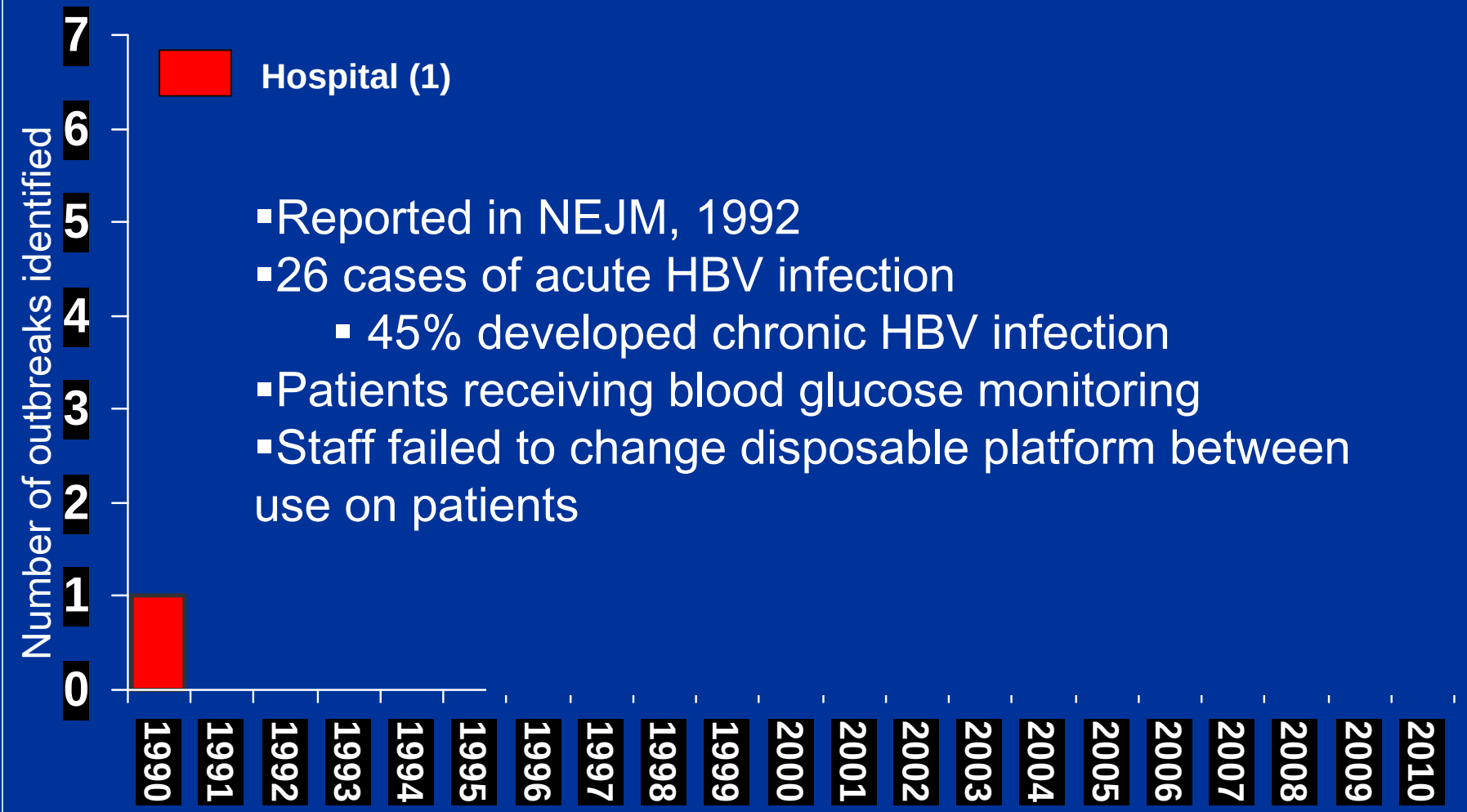
1:Graham. Lancet 1938;2, 1.
2: Droller. BMJ 1945;623-5.

Single case reports: HBV infection and blood glucose monitoring

- 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, fatal[2]
  - All contacts tested negative for HBV
  - Only risk identified repeated fingersticks for blood glucose monitoring at outpatient facility

1: Stapleton, Lemon. JAMA 1985:22;3250.
2: Mendez et al. Am J Gastero 1991:86;895-7.

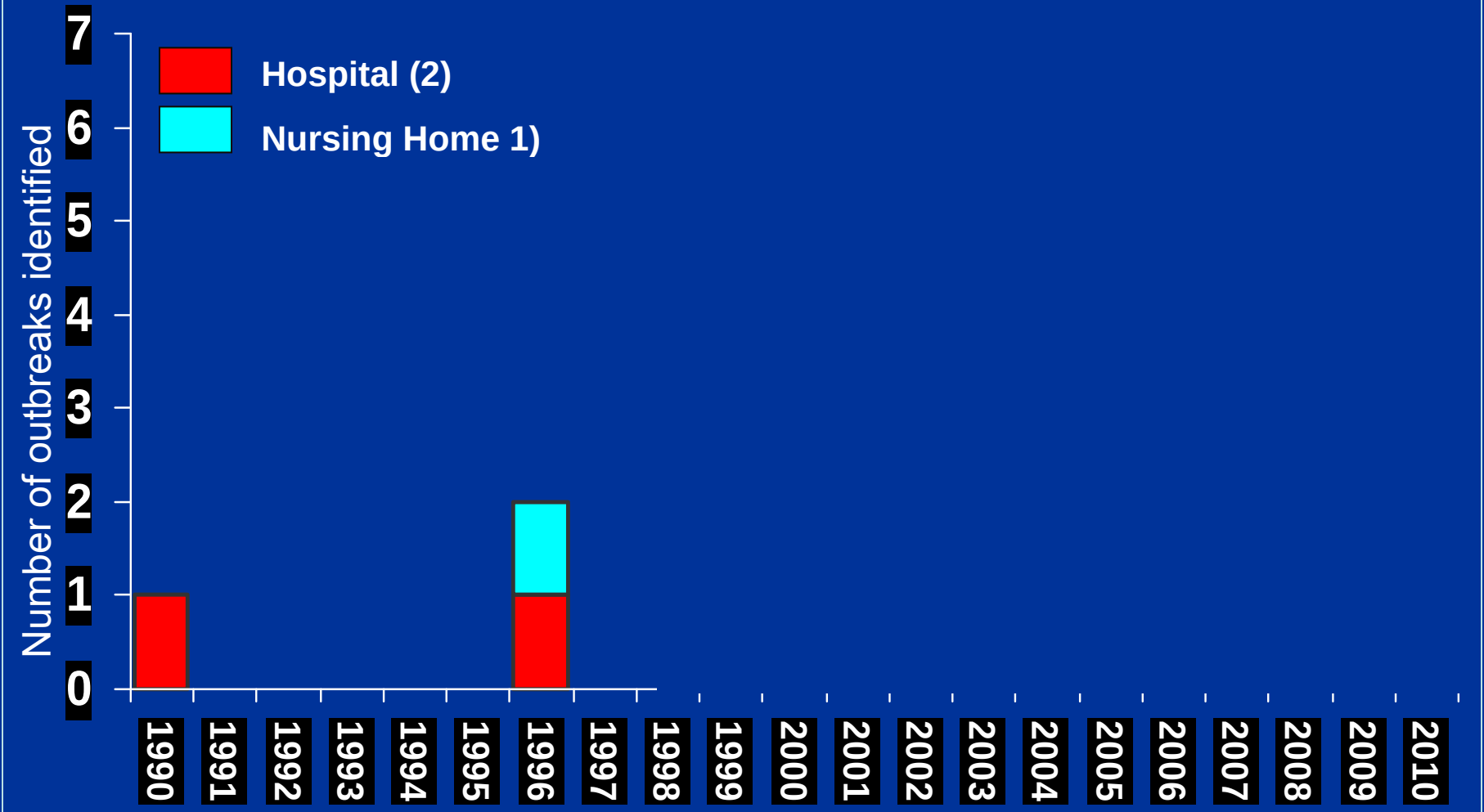
Outbreaks of HBV infection associated with blood glucose monitoring - 1990 to 2010, US



- Reported in NEJM, 1992
- 26 cases of acute HBV infection
  - 45% developed chronic HBV infection
- Patients receiving blood glucose monitoring
- Staff failed to change disposable platform between use on patients

Thompson, Perz. *J Diabetes Sci Technol* 2009; 3:283-88. CDC unpublished data (2009-10).

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



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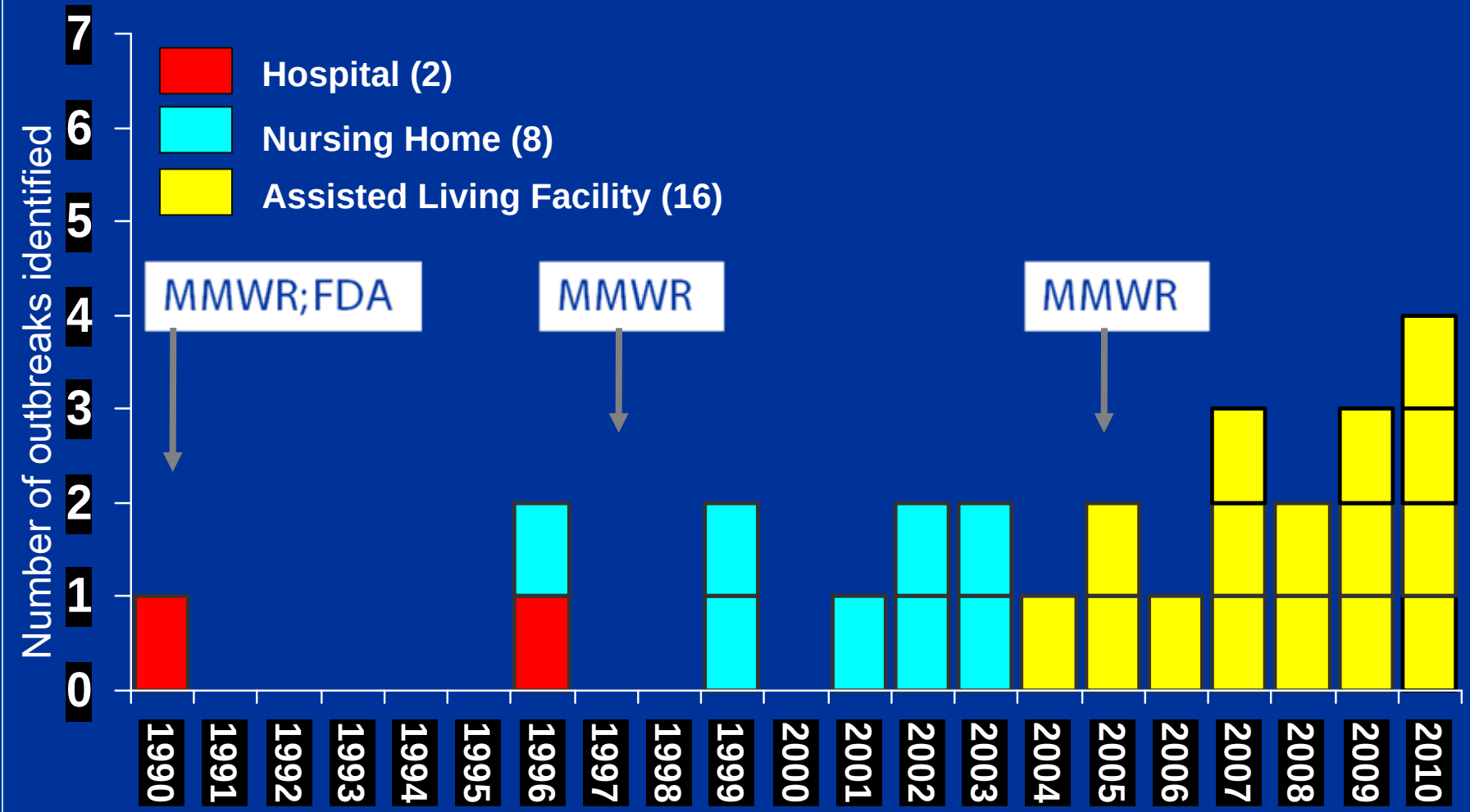
Outbreaks of HBV infection associated with blood glucose monitoring - 1990 to 2010, US



Thompson, Perz. *J Diabetes Sci Technol* 2009; 3:283-88. CDC unpublished data (2009-10).

International HBV infection outbreaks due to blood glucose monitoring

- France
- Canada
- United Kingdom – 2004-07, 5 outbreaks reported[1]
- Germany
- Poland
- Netherlands
- Belgium
- Japan

1: Duffel et al. Epi & Infection 2011; 139, 327μ335

Overview of recent outbreaks

- 7 HBV infection outbreaks identified 2009-10
  - All in residents of Assisted Living Facilities (ALFs) receiving blood glucose monitoring
  - 62 with new HBV infection
    - range 3 – 20/outbreak
- North Carolina outbreak[1]
  - 8 acute HBV infections; 6 died
- 2 outbreaks occurred across multiple ALFs
  - BGM services provided by same Home Health Nursing Agency
    - Includes 1 person receiving AMBG at home

1: MMWR. 2011 / 60(06);182

Data from four epidemiologic studies conducted during HBV infection outbreak investigations due to blood glucose monitoring - US, 2009-2010

	Receiving BGM		Not receiving BGM		
State	Tested	Acute HBV infection (%)	Tested	Acute HBV infection (%)	Relative Risk (95% CI)
NC	15	8 (53.3%); 6 died	25	0 (0%)	27.6 (3.4- 275.1)
VA	5	3 (60%)	26	1 (3.8%)	15.6 (2.7 – 97.1)
VA	13	12 (92%)	75	2 (2.8%)	35 (8.7– 137)
FL	10	6 (60%)	38	1 (2.6%)	22.8 (3.0– 168.3)

Reported outbreaks: the 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
- 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
  - Time consuming, expensive (patient notification, screening)

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

Assisted Monitoring of Blood Glucose (AMBG) and insulin administration

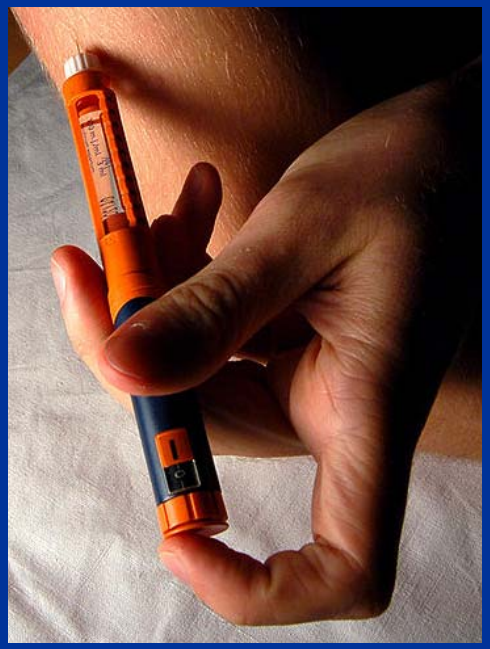
- Term introduced in response to safety concerns related to HBV infection outbreaks during blood glucose monitoring
- Where another person assists with or performs testing and insulin administration for multiple persons
- Settings where AMBG may occur:
  - Nursing homes
  - Assisted living facilities
  - Hospitals, clinics, physicians offices
  - Senior centers
  - Health fairs
  - Correctional facilities
  - Schools, camps, shelters

Klonoff, Perz. *J Diabetes Sci Technol* 2010;4:1207-31

An emerging problem: New generation of devices

Multi-lancet fingerstick device

Sharing of multi-lancet fingerstick devices reported as cause of HBV infection outbreak in Nursing Home[1]



Multidose Insulin Pens

Sharing of multidose insulin pens reported[2,3]

1: Gotz et al. Eurosurveillance 2008;13:1-4
2: www.newsinferno.com/archives/3066
3. www.lcsun-news.com/ci_11670031

Recent adverse events

- 4 patient notification events due to receipt of blood glucose monitoring or insulin administration
  - Recommendation for bloodborne pathogen testing (HBV, HCV and HIV) to groups of individuals potentially exposed to another personñs blood

Year, setting	Equipment misused	Length of misuse	Persons at risk
2008, Hospital	Insulin pen	7 months	908
2009, Hospital	Insulin pen	7 months	2114
2009, Community Health Center	Multi-lancet fingerstick device	6 months	283
2010, Health fair	Multi-lancet fingerstick device	1 day	64
Total at risk			3369

Texas Military Hospital 2009 – Insulin Pen Reuse

- Individual use insulin pens used on multiple patients
  - Needle changed, but insulin reservoir reused between patients
- Risk of blood backflow into insulin reservior[1,2]
- Error in use identified only after several months
- Failure to follow manufacturers recommendations for single patient use
  - Despite nurses receiving training when pens first introduce
  - No single patient use warning on pens

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Army Hospital May Have Spread Disease With Shared Insulin Pens

By Tom Randall - March 19, 2009 15:03 EDT

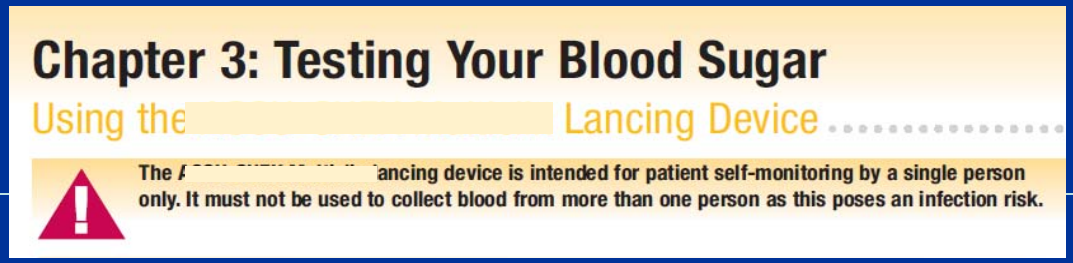
March 19 (Bloomberg) -- More than 2,000 people may have been put at risk of AIDS and hepatitis by sharing insulin pens and cartridges in two Army hospitals, the U.S. Food and Drug Administration said.

The FDA posted a warning today against sharing the disposable insulin shots after the William Beaumont Army Medical Center in El Paso, Texas, last month said 2,114 diabetic patients may be at risk "as a result of incorrect procedures." The sharing occurred from 2007-2009, the FDA said in a statement issued today.

1.Floch et al . *Diabetes Care 1998; 21:* 1502–04
2. Sonoki et a;. Diabetes Care 2001;24:303-4

North Carolina Community Healthcare Center 2009 – Fingerstick lancing device

- Individual use fingerstick lancing devices used for multiple patients for 6 months
  - Multi-lancet device; rotating barrel containing 6 lancets
- Error in use identified only after nurses found lancets were not rotating
  - Device malfunction
  - Misuse in device: should never have been used for multiple patients
- No individual patient use warning directly on the device
  - Warning on page 24 of 92 of blood glucose monitor owners manual

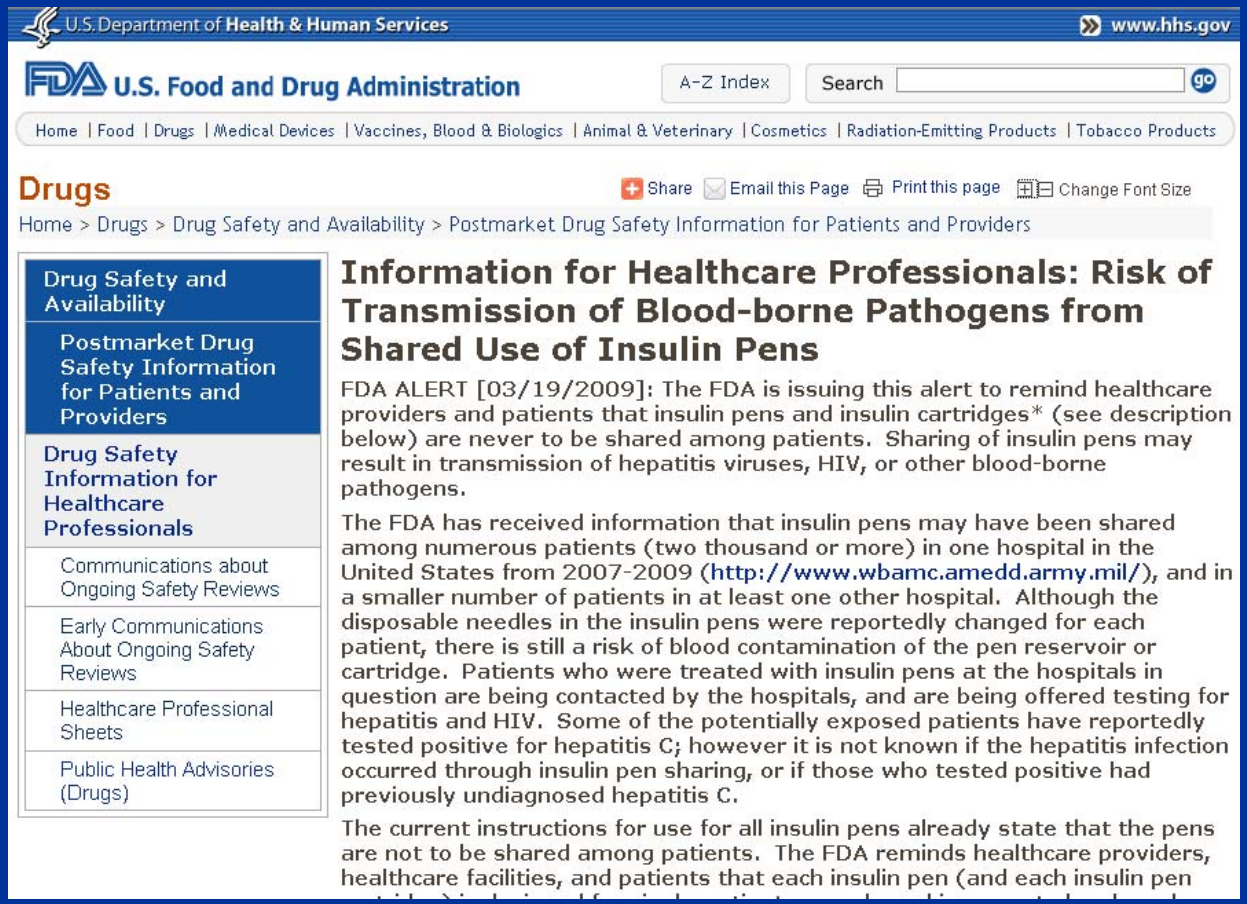


Chapter 3: Testing Your Blood Sugar

Using the [redacted] Lancing Device

The [redacted]ancing 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.

FDA Alert: Risk of BBP from shared use of insulin pens



U.S. Department of Health & Human Services www.hhs.gov

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Information for Healthcare Professionals: Risk of Transmission of Blood-borne Pathogens from Shared Use of Insulin Pens

FDA ALERT [03/19/2009]: The FDA is issuing this alert to remind healthcare providers and patients that insulin pens and insulin cartridges* (see description below) are never to be shared among patients. Sharing of insulin pens may result in transmission of hepatitis viruses, HIV, or other blood-borne pathogens.

The FDA has received information that insulin pens may have been shared among numerous patients (two thousand or more) in one hospital in the United States from 2007-2009 (http://www.wbamc.amedd.army.mil/), and in a smaller number of patients in at least one other hospital. Although the disposable needles in the insulin pens were reportedly changed for each patient, there is still a risk of blood contamination of the pen reservoir or cartridge. Patients who were treated with insulin pens at the hospitals in question are being contacted by the hospitals, and are being offered testing for hepatitis and HIV. Some of the potentially exposed patients have reportedly tested positive for hepatitis C; however it is not known if the hepatitis infection occurred through insulin pen sharing, or if those who tested positive had previously undiagnosed hepatitis C.

The current instructions for use for all insulin pens already state that the pens are not to be shared among patients. The FDA reminds healthcare providers, healthcare facilities, and patients that each insulin pen (and each insulin pen

www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm133352.htm

Prevention recommendations

CDC Recommended practices for preventing patient-to-patient transmission

- Diabetes care procedures and techniques
  - Single use, disposable lancets
  - Avoid shared equipment including glucose meters
- Hand hygiene
- Medical management (fingerstick frequency)
- Training and oversight

CDC. MMWR 2005; 54:220-3

Best practices: Fingerstick devices

- Reusable Devices: Lancet can be remove and replace after each use, device can be used more than once
- Some previously approved, marketed for multi-patient use
  - Failures to change the disposable component
  - Difficulties with cleaning and disinfection after use
  - 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 assisted monitoring of blood glucose performed, these devices should be used
- Safest for patients and provider; reduce needlestick injuries

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

Best practices: 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 manufacturerÑs instructions.
  - If the manufacturer does not specify how the device should be cleaned and disinfected then it should not be shared.

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

Best practices: Blood glucose meters

- FDA recently released guidance for manufacturers regarding appropriate products and procedures for cleaning and disinfection of blood glucose meters
  - *The disinfection solvent you choose should be effective against HIV, Hepatitis C, and Hepatitis B virus. Outbreak episodes have been largely due to transmission of Hepatitis B and C viruses. However, of the two, Hepatitis B virus is the most difficult to kill. Please note that 70% ethanol solutions are not effective against viral bloodborne pathogens and the use of 10% bleach solutions may lead to physical degradation of your device.*

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

One hospitalÑs experience with dedicating meters to individual patients

- Augmented glucose meter inventory from 38 to 115 throughout the hospital and assigned meter to individual patients on 3 high-use units

- Because of dedicated meters, time required for cleaning and disinfection of meters between patients reduced by 176 hours or 1.0 full-time equivalent
  - Offset cost for augmentation of the glucose meter inventory

Hellinger et al. Am J Infect Control 2011; In press

Best practices: Insulin administration

- Insulin Pens: Safe for single person use multiple times, new needle for each injection
  - Should be assigned to individual persons, labeled
  - Should never be used for more than one person
- Insulin Vials: Multi-dose vials should be dedicated to single person whenever possible
- If used for >1 person, store and prepared in a dedicated area away from potentially contaminated equipment
- Vials always entered with new needle and new syringe
- Needles and syringes should never be used to administer insulin to >1 person
  - Disposed of immediately after use in approved sharps container

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

Best practices: Hand hygiene and glove use

- Hand Hygiene: Hand washing with soap and water or use of an alcohol-based hand rub
- Gloves: Wear gloves during blood glucose monitoring and during any other procedure that involves potential exposure to blood or body fluids
- Change gloves between patient contacts or that have touched potentially blood-contaminated objects or fingerstick wounds before touching clean surfaces
- Discard gloves in appropriate receptacles
- Perform hand hygiene immediately after removal of gloves and before touching other medical supplies intended for use on other persons

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

Best practices: Training and oversight

- Provide hepatitis B vaccination series to previously unvaccinated staff with activities involving blood or body fluids
- Establish responsibility for oversight of infection control activities
  - Provide staff members with infection control training
  - Periodically observe staff to assess adherence to infection control recommendations
- Report to public health authorities any suspected instances of a newly acquired bloodborne infection, such as hepatitis B, in a patient, facility resident, or staff member

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

Recent federal prevention initiatives

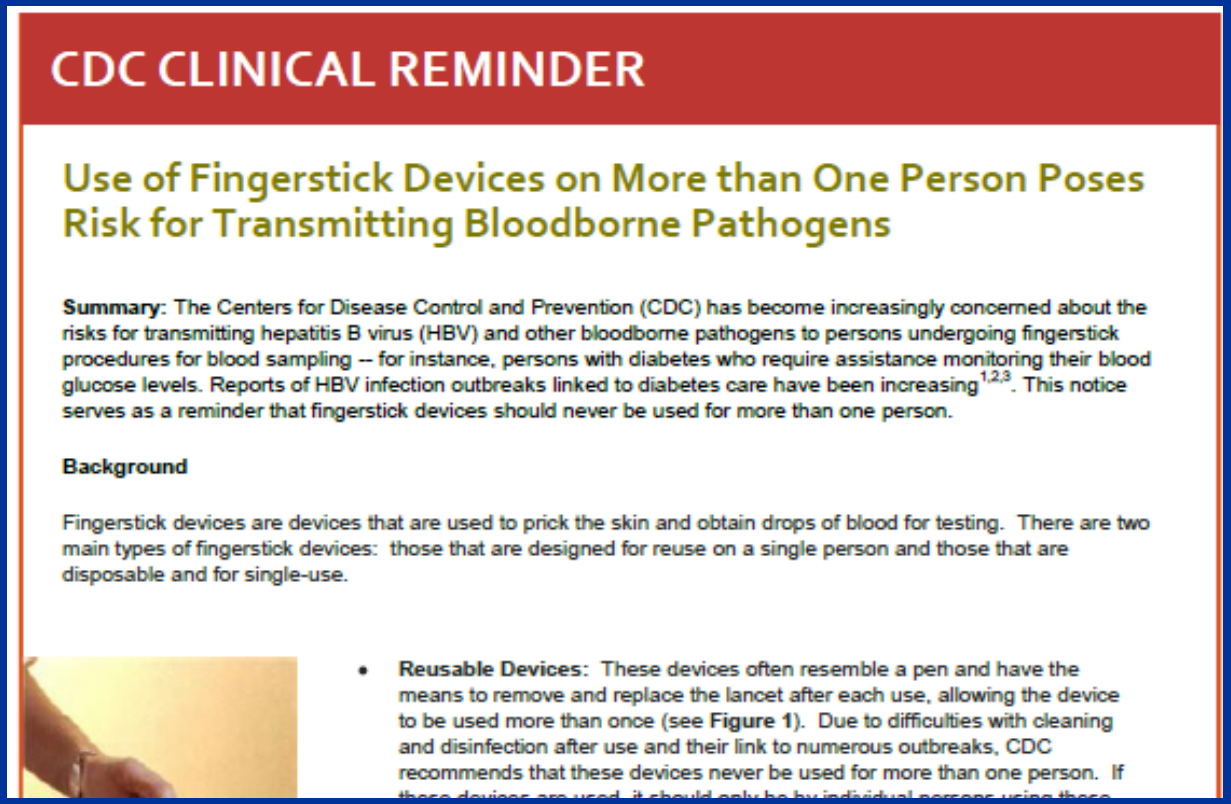
CDC: Communication, prevention activities - I

- Since Jan 2009, 7 CDC-authored publications
- Highlight 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 organized/hosted meetings (9/2009, 5/2010) to raise awareness of the needs for improved infection control oversight and device regulation[1]
  - Key federal partners (CMS and FDA)
  - Other stakeholders including device manufacturers, diabetes educators, health departments

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

CDC: Communication, prevention activities - II

- Issued clinical reminder



CDC CLINICAL REMINDER

Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens

Summary: 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.

Background

Fingerstick devices are devices that are used to prick the skin and obtain drops of blood for testing. There are two main types of fingerstick devices: those that are designed for reuse on a single person and those that are disposable and for single-use.

- **Reusable Devices:** These devices often resemble a pen and have the means to remove and replace the lancet after each use, allowing the device to be used more than once (see **Figure 1**). Due to difficulties with cleaning and disinfection after use and their link to numerous outbreaks, CDC recommends that these devices never be used for more than one person. If

www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

CDC: Communication, prevention activities - III

- Updated infection control guidance[1]
  - Fingerstick devices should never be used for more than one person
    - In settings where *assisted* monitoring of blood glucose is performed, single-use, auto-disabling fingerstick devices should be used
  - Whenever possible, blood glucose meters should be assigned to an individual person and not be shared
    - If blood glucose meters must be shared, the device should be cleaned and disinfected after every use

Best Practices for Assisted Blood Glucose Monitoring and Insulin Administration

The following are infection control recommendations that anyone who performs or assists with blood glucose monitoring and /or insulin administration should review to assure they are not placing themselves or persons in their care at risk.

These recommendations apply not only to licensed healthcare facilities but also to any setting where fingerstick procedures are performed and/or insulin is administered, including assisted living or residential care facilities, clinics, health fairs, shelters, detention facilities, schools, and camps. Protection from bloodborne viruses and other infections is a basic requirement and expectation anywhere healthcare is provided.

Top of page

Fingerstick Devices

Fingerstick devices, also called lancing devices, are devices that are used to prick the skin and obtain drops of blood for testing. There are two main types of fingerstick devices: those that are designed for reuse on a single person and those that are disposable and for single-use.

- **Reusable Devices:** These devices often resemble a pen and have the means to remove and replace the lancet after each use, allowing the device to be used more than once. Some of these devices have been previously approved and marketed for multi-patient use, and require the lancet and disposable components (platforms or endcaps) to be changed between each patient. However, due to failures to change the disposable components, difficulties with cleaning and disinfection after use, and their link to multiple HBV infection outbreaks, CDC recommends that these devices **never** be used for more than one person. If these devices are used, it should only be by individual persons using these devices for self-monitoring of blood glucose.

Reusable fingerstick device*

- **Single-use, auto-disabling fingerstick devices:** These are devices that are disposable and prevent reuse through an auto-disabling feature. In settings where assisted monitoring of blood glucose is performed, single-use, auto-disabling fingerstick devices should be used.

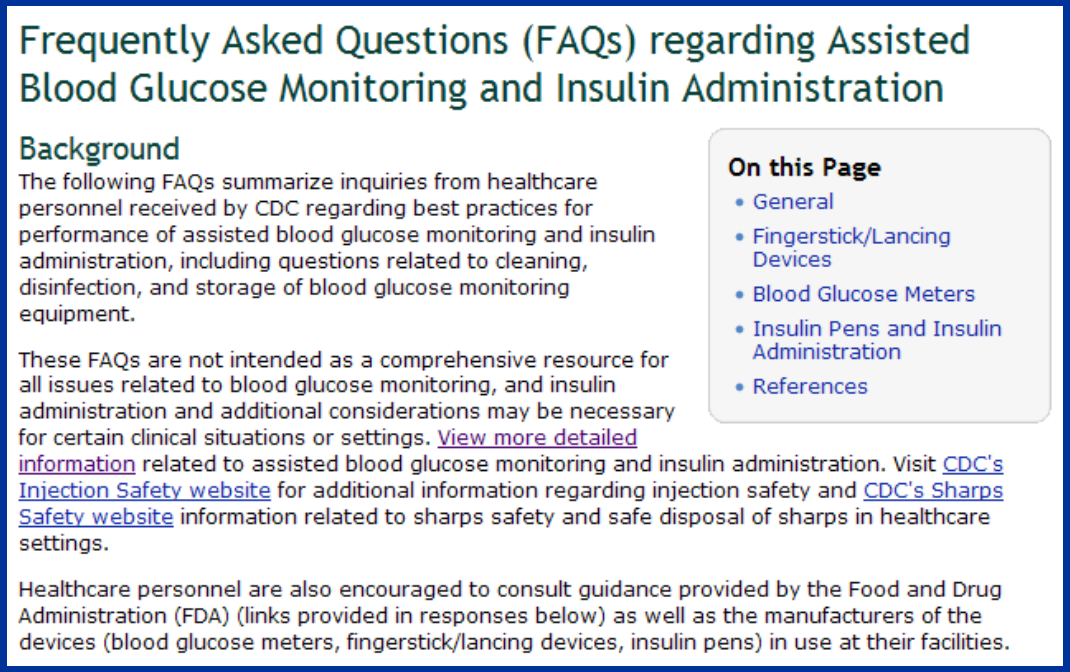
Single-use, disposable fingerstick devices*

A simple rule for safe care:
Fingerstick devices should **never** be used for more than one person.

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

CDC: Communication, prevention activities - III

- Frequently asked questions regarding AMBG[1]
  - General
  - Fingerstick devices
  - Blood glucose meters
  - Insulin pens



Frequently Asked Questions (FAQs) regarding Assisted Blood Glucose Monitoring and Insulin Administration

Background

The following FAQs summarize inquiries from healthcare personnel received by CDC regarding best practices for performance of assisted blood glucose monitoring and insulin administration, including questions related to cleaning, disinfection, and storage of blood glucose monitoring equipment.

On this Page

- General
- Fingerstick/Lancing Devices
- Blood Glucose Meters
- Insulin Pens and Insulin Administration
- References

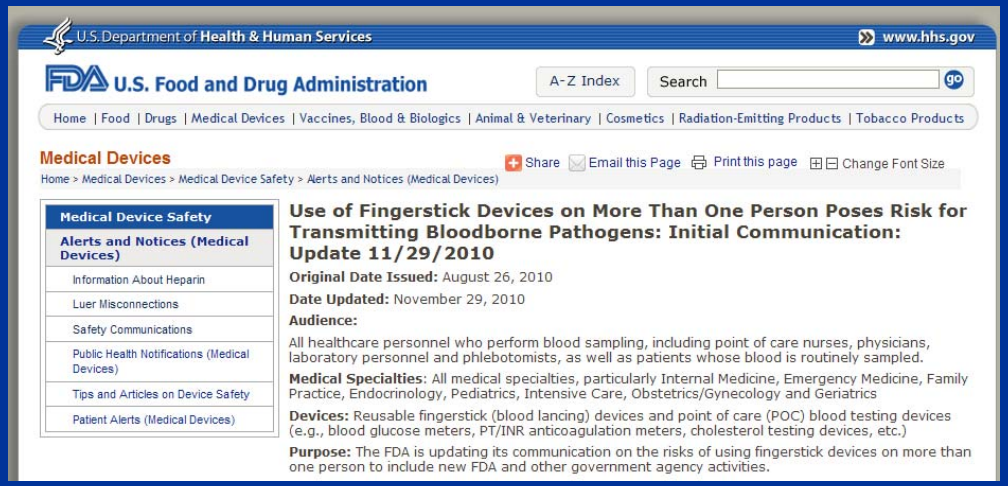
These FAQs are not intended as a comprehensive resource for all issues related to blood glucose monitoring, and insulin administration and additional considerations may be necessary for certain clinical situations or settings. View more detailed information related to assisted blood glucose monitoring and insulin administration. Visit CDC's Injection Safety website for additional information regarding injection safety and CDC's Sharps Safety website information related to sharps safety and safe disposal of sharps in healthcare settings.

Healthcare personnel are also encouraged to consult guidance provided by the Food and Drug Administration (FDA) (links provided in responses below) as well as the manufacturers of the devices (blood glucose meters, fingerstick/lancing devices, insulin pens) in use at their facilities.

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

FDA: Communication, device evaluation

- FDA issued Medical Device Alert for point of care blood testing devices[1]



- FDA notice to manufacturers of revised process for evaluating, approving blood glucose monitoring devices, and increased focus on addressing infection prevention[2]
  - To include clear labeling of single patient use, validated instructions for cleaning/disinfecting meters

1: www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm
2: www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm227935.htm

CMS: Regulatory activities

- CMS issued new infection control guidance to surveyors who conduct facility inspections
  - Includes review of blood glucose monitoring practices at Nursing Homes and Ambulatory Surgery Centers
- For nursing homes, directive specifies that sharing of fingerstick devices must be cited as Ìmmediate Jeopardyš
  - Requires immediate steps to remove the jeopardy from the Nursing Home or risk termination from Medicare/Medicaid programs
- Guidance is carrying over to other licensed settings
  - Acute care hospitals, home health agencies

Summary - I

- Shared use of blood contaminated equipment increases risk of exposure to bloodborne pathogens
- Increasing frequency of HBV infection outbreaks associated with Assisted Monitoring of Blood Glucose
- Routine misuse of equipment, failure to follow infection control recommendations identified in a variety of settings
  - Acute care hospitals, ambulatory surgery centers, health fairs

Summary - II

- Continued efforts needed to
  - Increase adherence to recommended infection control practices
  - Improve device labeling, instructions for use, cleaning and disinfection guidance
- Recent changes made by CMS and FDA are expected to aid adoption of recommendations
- Prevention in settings such as assisted living facilities remains challenging
  - Standardized training and education, oversight needed

Prevention in assisted living facilities

- Remains challenging
  - Operate under a social model of care
  - Care primarily provided by non-professional staff, limited professional oversight
  - Resources, expertise in infection control is poor
  - Staff turn-over very high, limits impact of education/training efforts
- ALFs not federally regulated
  - Licensing, inspection at state level highly variable
  - Outside the scope of CMS; however, home health agencies are regulated by CMS

Assisted Living

- Group living arrangement, in home-like environment
- Developed partially in response to consumer dissatisfaction with nursing homes as a place to live
- Provide residents help with activities of daily living , medication administration includes Assisted Monitoring of Blood Glucose
- Currently, ~1 million residents
- Estimated , ~2 million residents by 2030

Assisted Living State Regulatory Review 2010: www.ahcancal.org