Injections Without Infections: Basic Patient Safety

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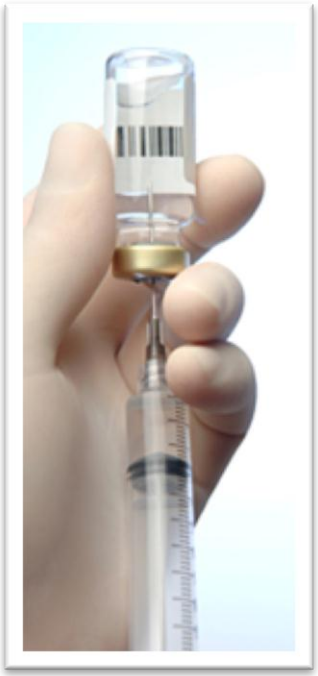
Centers for Disease Control and Prevention

Injections and Infusions are Central to Healthcare Delivery

- **Injections and infusions of parenteral medications likely represent the most common invasive procedure across all the healthcare continuum**
  - Chemotherapy
  - Intravenous antibiotics
  - Vaccination
  - Sedation/anesthesia for surgical procedures, endoscopy, and imaging/diagnostic studies
  - Joint injections
  - Cosmetic procedures
  - Alternative medicine



Injections Without Infections

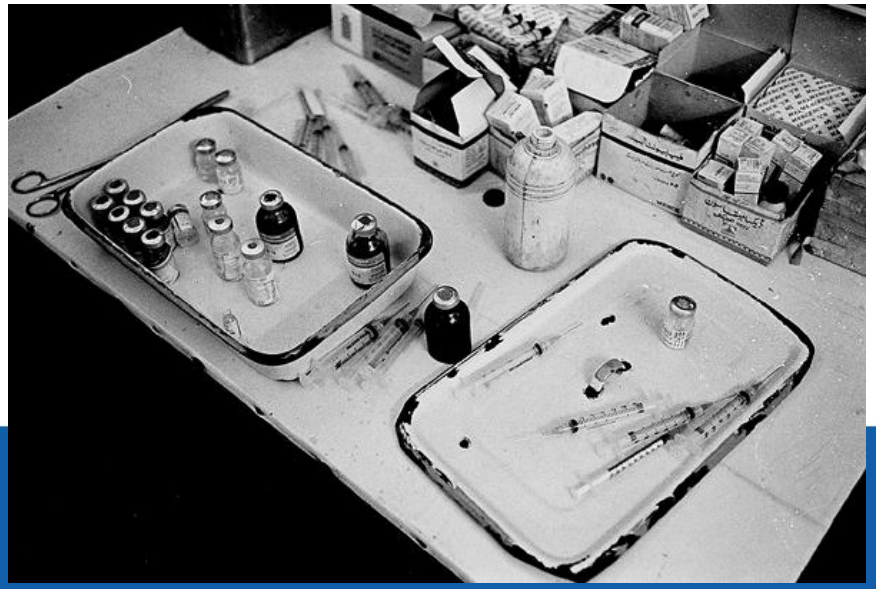
Safe Production	Sterile medication for injection/infusion
Safe Preparation	Right-sized dose in a ready-to-deliver format (typically a **syringe**)
Safe Administration	Adherence to Standard Precautions to **minimize risk of infection to patients** and healthcare personnel
Safe Disposal	Minimize risk of harm to patients and healthcare personnel

→ Focus of this Grand Rounds = **patient risks + clinical practices**

Global Burden of Disease Associated with Unsafe Injections

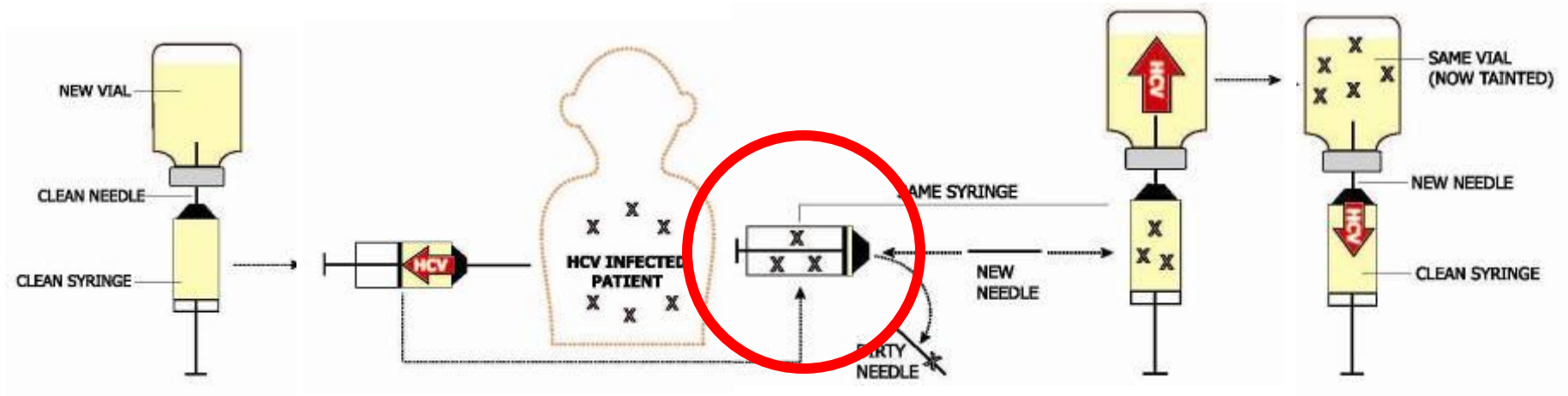
- **Traditionally recognized as an issue in low and middle-income countries**
- **Estimated annual incidence, 2000**
  - >20 million Hepatitis B virus infections
    - 30% of new infections
  - >2 million Hepatitis C virus infections
    - 40% of new infections
  - >250,000 HIV infections
    - 5% of new infections

SIGN
Safe Injection Global Network



Ezzati M et al. Lancet. 360(9343):1347-60, 2002
www.who.int/occupational_health/activities/1bestprac.pdf

Las Vegas, NV, Hepatitis C Outbreak, 2008



1. Clean needle and syringes are used to draw medication

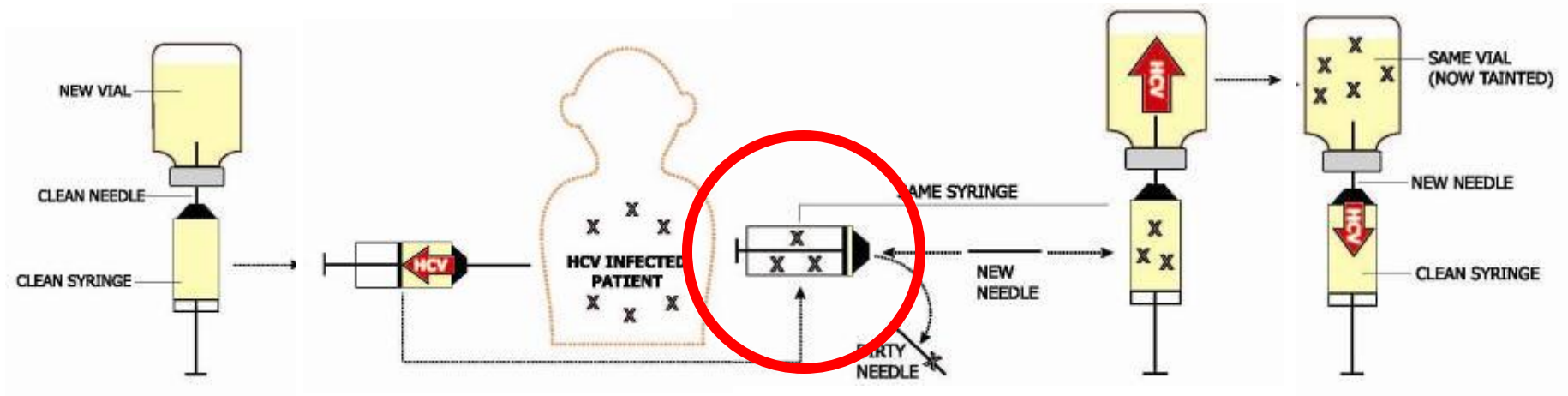
2. When used on an HCV-infected patient, backflow from the injection or removal of the needle contaminates the syringe

3. When used again to draw medication, contaminated syringe contaminates the medication vial

4. Contaminated vial that is reused exposes subsequent patients to risk of HCV infection

MMWR; May 16, 2008; 57:19
HCV: hepatitis C virus

Las Vegas, NV, Hepatitis C Outbreak, 2008



- This outbreak was identified by the local health department, which initially received 2 reports of acute hepatitis C
- Investigation uncovered the unsafe practices and confirmed 6 additional cases of transmission
- Over 50,000 patients were notified by public health authorities of potential exposure and advised to seek testing

Unsafe Injection Practices

- **Reuse of syringes**
  - **For multiple patients ("direct reuse")**
    - Examples include injecting through IV tubing, insulin pens and narcotics syringes that were subjected to tampering
  - **To access shared medications**
    - "Indirect reuse" a.k.a. "double dipping"
- **Mishandling and inappropriate sharing of medication vials and containers**
  - Administration of medication from a single-dose vial to multiple patients
  - Intravenous solution bags used as a common source of supply for multiple patients

Unsafe Injection Practices: U.S. Experience Since 2001

- **48 recognized outbreaks**
  - Viral hepatitis (n=21) or bacterial infections (n=27)
  - 90% (n=43) occurred in outpatient settings
    - 10 outbreaks in pain management clinics
    - 9 in outpatient oncology clinics
- **>150,000 patients have required notification to advise bloodborne pathogen testing following potential exposure to unsafe injections**
  - >40 notification events
    - Approximately one-third of notification events prompted by discovery of syringe reuse, absent evidence of disease transmission

Guh AY, Thompson ND, Schaefer MK et al. Med Care. 2012 Sep;50(9):785-91.

The Human Toll of Outbreaks and Patient Notifications

LIVING IN FEAR

Patients in hepatitis C case brace for fateful results

Left Image: http://www.denverpost.com/news/ci_12790134
Right Image: http://www.9news.com/rss/story.aspx?storyid=193134

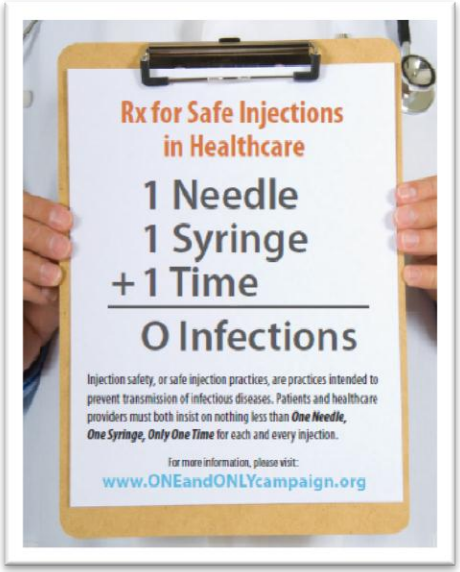
Injection Practices among Clinicians in U.S. Healthcare Settings

- Survey of 5,500 U.S. healthcare professionals
- 1% "sometimes or always" reuses a syringe on a second patient
- 1% "sometimes or always" reuses a multi-dose vial for additional patients after accessing it with a used syringe
- 6% use single-dose vials for more than one patient

Pugliese G, Gosnell C, Bartley J et al. American Journal of Infection Control, 38 (10), 789-798

The ONE & ONLY Campaign

- **Launched in response to outbreaks resulting from unsafe injection practices**
- **Led by CDC and the Safe Injection Practices Coalition**
- **Goals**
  - Increase understanding and implementation of safe injection practices among healthcare providers
  - Ensure patients are protected each and every time they receive a medical injection



CDC Standard Precautions, 2007: Safe Injection Practices

Key elements

- Use aseptic technique when preparing and administering medications
- Never administer medications from the same syringe to multiple patients
- Do not reuse a syringe to enter a medication vial or solution
- Do not administer medications from single-dose vials or intravenous solution bags to more than one patient
- Limit the use of multi-dose vials and dedicate them to a single patient whenever possible

www.cdc.gov/hicpac/pdf/isolation/isolation2007.pdf

Ensuring Safe Injections: Ways Forward

- Complex public health issue that requires a multi-dimensional approach, innovative solutions and partnerships
- **E**pidemiologic capacities and resources
  - Surveillance, reporting, and investigation
- **E**ducational initiatives to promote understanding of safe injection practices and basic infection control
- **E**nforcement and oversight
  - Implement policies and oversight mechanisms that support and ensure adherence
    to safe injection practices and basic infection control
  - Extend reach to all settings where injections are delivered

The Sharp End of the Needle: A Health Department's Experiences

Guthrie Birkhead, MD, MPH
Deputy Commissioner, Office of Public Health
New York State Department of Health

STATE OF NEW YORK DEPARTMENT OF HEALTH

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Overview of NYS DOH Experience

Year	Facility Type	Investigation Type	Mechanism	Number Notified
2002	Private urology practice	HIV Transmission	Possible reuse of single-use biopsy guide	40
2004	Private pain management clinic	Hepatitis C Transmission	Reuse of syringes in multi-dose vial	8532
2006	Dialysis center	Hepatitis C Transmission	Dialysis	170
2007	Private MD	Infection Control Breach	Reusing syringes	36
2008	Dialysis center	Hepatitis C Transmission	Dialysis	657
2009	Private MD	Infection Control Breach	Reusing syringes	25
2010	Psychiatric hospital	Hepatitis B Transmission	Shared glucometer	229
2011	Dialysis center	Hepatitis C Transmission	Dialysis	213
2011	Dialysis center	Hepatitis B Exposure	Dialysis	16
2011	Hosp apheresis unit	Hepatitis C Transmission	None identified	6
2012	Dialysis Center	Hepatitis C Transmission	Dialysis	153

Example: Pain Management Clinic Investigation

- **Routine case surveillance**
  - County Health Department identified 2 cases of acute HCV infection
  - Both reported epidural injections done by the same physician within the exposure period
- **Site visit**
  - Physician observed re-using syringe attached to spinal needle
  - Attached new needle to used syringe and drew up medications
  - Instructed to change practice immediately

HCV: hepatitis C virus

Pain Management Clinic Investigation

- **Active surveillance**
  - Patient list matched against hepatitis C registry
    - 1 additional patient identified
  - Letters initially sent to 98 patients who received injections the week before, week of, or week after each of the three known hepatitis C positive patients
  - 7 of 84 tested were HCV positive (8.3%)
- **Confirmation**
  - Transmission confirmed by phylogenetic molecular testing showing matching virus in two patients who had procedures on the same day

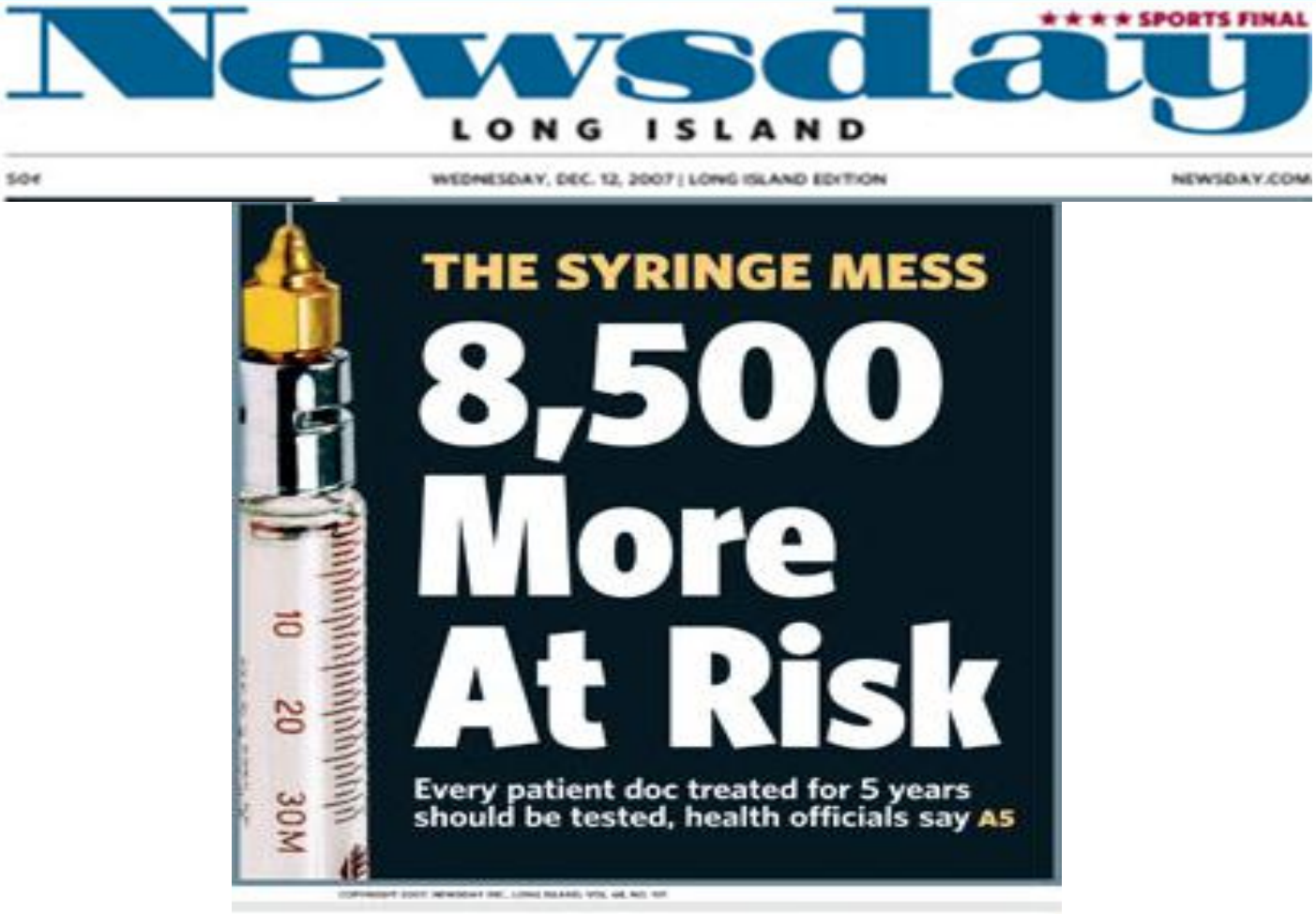
HCV: hepatitis C virus

Pain Management Clinic Investigation

- **Broad patient notification**
  - Physician in practice since late 1980s
  - First wave
    - List provided by provider initially included 627 patients
    - Discovered at-risk patients not on notification list
  - Second wave
    - Letter sent to all 8,532 patients in database, independent of exposure
- **Offer of free bloodborne pathogen testing by NYS Department of Health, in coordination with county health department**

NYS: New York State

Pain Management Clinic Investigation



Newsday

★★★★ SPORTS FINAL

LONG ISLAND

50¢ WEDNESDAY, DEC. 12, 2007 | LONG ISLAND EDITION NEWSDAY.COM

THE SYRINGE MESS

8,500 More At Risk

Every patient doc treated for 5 years should be tested, health officials say A5

Pain Management Clinic Investigation: Effect of Notification

- **Physician**
  - Media attention
  - Litigation
  - Medical Board – conditions placed on practice for 3 years
- **State/county health departments**
  - Media attention
  - Litigation
  - Freedom of Information Act requests

Potential Impact on Preventive Care

- **High-profile investigations could affect health-seeking behaviors by discouraging use of preventive care (e.g. immunizations, colonoscopies)**
  - No anecdotal reports of negative impact
  - Issue requires further study

NYS Policy Response to Pain Management Clinic Investigation

- **Changes to Public Health Law**
  - Strengthened rules for professional medical conduct
  - Enhanced mandatory infection control training with new emphasis on injection safety
- **Formation of Healthcare Disease Transmission (HDT) workgroup**
  - Multidisciplinary group under NYS Department of Health
- **Initiation of *One & Only* campaign**
- **Increase in regulation of ambulatory surgery**

NYS: New York State

New York Public Health Law 239

- **Established in 1994, requires health professionals to complete a course in infection control and barrier precautions every 4 years**
  - Physicians, physician assistants, specialist assistants, registered nurses, licensed practical nurses, dentists, dental hygienists, podiatrists, optometrists
  - Updated in 2008 to enhance training in safe injection practices and equipment cleaning, disinfection, and sterilization

Healthcare Disease Transmission Workgroup

- **State DOH Workgroup**
  - Members: epidemiology, laboratory, legal, public affairs, healthcare regulatory, and physician discipline offices and executive staff
  - Meets regularly to review active investigations to ensure consistent, coordinated, and timely response
  - Developed guidelines for investigating reports of healthcare associated bloodborne pathogen transmission

NYS Guidelines for Public Health Response to Healthcare Exposures

		One Apparent Healthcare Exposure		More than One Healthcare Exposure
	Case Status	No Non-Healthcare Risk Behaviors	One or More Non-Healthcare Risk Behaviors	___
Single Case	Clinically Consistent Acute Case	Initial Epi	Monitor	Monitor
	Other Case Documented Seroconversion	Initial Epi	Monitor	Monitor
	Other Case No Documented Seroconversion	Monitor	Monitor	Monitor
Multiple Cases	Documented seroconversions or more than one clinically consistent acute case	Full Epi	Initial Epi	Initial Epi
	Other Cases No Documented Seroconversion	Initial Epi	Initial Epi	Initial Epi

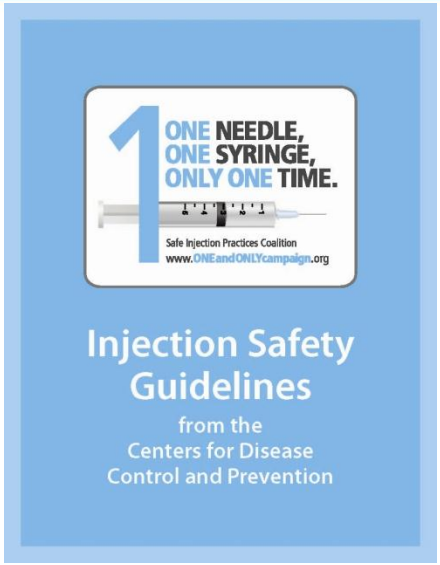
One & Only Campaign in NYS

- Name based on the principle that each needle and syringe should be used for one, and only one, injection
- New York is the oldest "charter" partner state in the campaign
- Campaign activities funded by CDC grant and directed by the Safe Injection Practices Coalition (SIPC)

One & Only Campaign Workgroup

- **External Stakeholder Workgroup includes 30 professional healthcare and patient advocacy groups**
- **Presentations to:**
  - Infection control practitioners
  - NYS Board of Medicine
  - Medical malpractice carriers and large insured practices
- **Jointly develop state and local health department toolkit**

One & Only Campaign Outreach



The Health Show on WAMC

Thursdays, 3pm - 3:30pm; Sundays, 6:30pm - 7pm

BOB BARRETT AND DR. NINA SAX

The Health Show is a nationally syndicated public radio program produced by the National Productions unit at Northeast Public Radio. The program covers all aspects of modern health: prevention, treatment, research, administration and more. Each week The Health Show breaks the issues down so you can be a better informed patient or care-provider.

www.oneandonlycampaign.org

Responding to Unsafe Injection Practices: Lessons Learned

- Healthcare associated bloodborne pathogens transmission occurs more often than realized
- Active surveillance and follow-up investigations will uncover previously undetected transmissions
- Standardized and collaborative investigations are necessary, but are resource intensive

Responding to Unsafe Injection Practices: Lessons Learned

- Providers need to be educated and their denial addressed to raise awareness and decrease risk
- Patients should be encouraged to ask their provider about injection safety as part of increased patient involvement in medical decision making

Progress Made and Actions Needed to Increase Injection Safety

Thomas E. Hamilton
Director, Survey and Certification Group
Center for Clinical Standards and Quality
Centers for Medicare and Medicaid Services

CMS Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

CMS: Who We Are and What We Do

- **The single largest purchaser of health care**
  - Value-based purchasing
  - Increasing collaboration with CDC and AHRQ
- **A force for innovation and technical assistance**
  - Quality Improvement Organizations (QIOs)
  - ESRD Networks
  - Healthcare Engagement Networks (HENS)

AHRQ: Agency for Healthcare Research and Quality
QIOs: Quality Improvement Organizations
ESRD: End Stage Renal Disease
HENS: Healthcare Engagement Networks

CMS: A Force for Quality and Safety

- **In partnership with states and accrediting organizations**
  - Quality Measurement and Reporting
  - Conditions for Participation (CoPs) – Providers
  - Conditions for Coverage (CfCs) – Suppliers such as ASCs, ESRDs
  - Survey and Certification

CoPs: Conditions of Participation
CfCs: Conditions for Coverage
ESRD: End Stage Renal Disease
ASCs: Ambulatory Surgical Centers

What is CMS Survey and Certification?

Entry and Recertification Point for Most Providers and Suppliers (for Medicare, Medicaid, and Clinical Laboratories)

- Ambulatory Surgical Centers
- Clinical Laboratories
- Dialysis (ESRD) Facilities
- Hospitals –Acute Care, Solid Organ Transplant, Rehabilitation, Long- Term Care, Psychiatric, Critical Access
- Nursing Homes
- Outpatient PT and SLP (Rehab Agency), Comprehensive Outpatient Rehabilitation Facilities (CORFs)
- Portable X-Ray Suppliers
- Rural Health Clinics
- Home Health Agencies
- Hospices

ESRD: End Stage Renal Disease
PT: Physical Therapy
SLP: Speech and Language Pathology
CORFs: Comprehensive Outpatient Rehabilitation Facilities

Some Survey and Certification Functions

Function	Who Does This	How
1. **Surveys:** Onsite surveys of most provider types *(100,000 surveys per year)*	• States • CMS • Accrediting • Organizations	**Onsite Observation:** • Care Processes • Interviews • Records and Policies
2. **Certification:** Approval for Medicare, CLIA, and/or Medicaid participation	• CMS *for* Medicare • CMS for Clinical Labs States *for* Medicaid	**Based on Results of:** • Survey *and* • Admin. Review
3. **Enforcement:** Potential termination from participation	• CMS-Medicare • Labs States *for* Medicaid	**Based on Results of:** • Survey

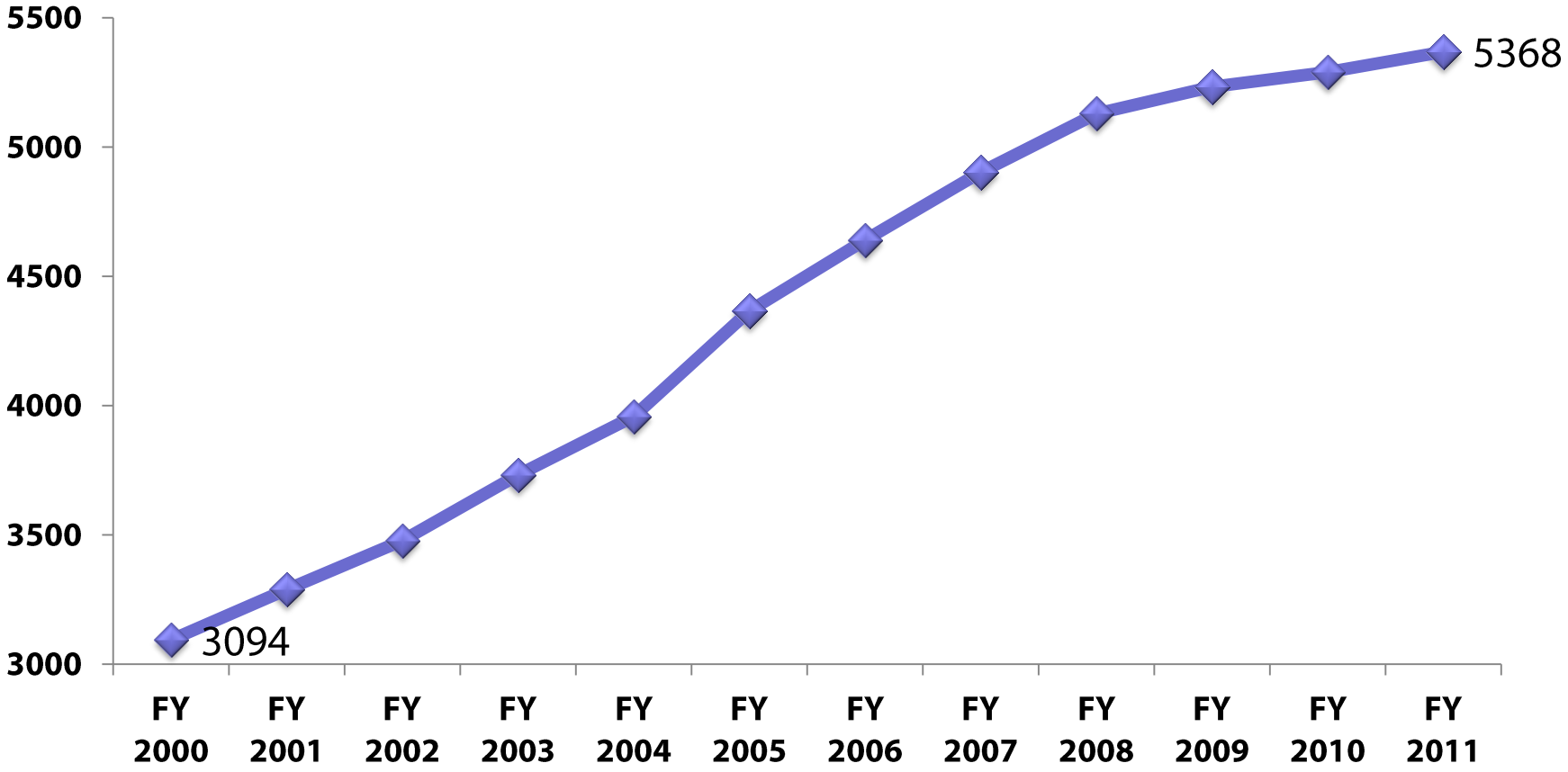
SSA: Social Security Act
PHSA: Public Health Service Act
CLIA: Clinical Laboratory Improvement Act

Infection Control Challenges in Ambulatory Surgical Centers

- **Large number of dispersed settings**
- **Large differences in size, scope, and complexity of practice**
- **High prevalence of for-profit business model**
  - 91% of ASCs are for-profit
- **Fastest growth in number of facilities of all types of Medicare-participating providers and suppliers**

ASCs: Ambulatory Surgical Centers
www.ascassociation.org/advocacy/AmbulatorySurgeryCentersPositiveTrendHealthCare.pdf

Number of Ambulatory Surgical Centers (ASCs) Participating in Medicare



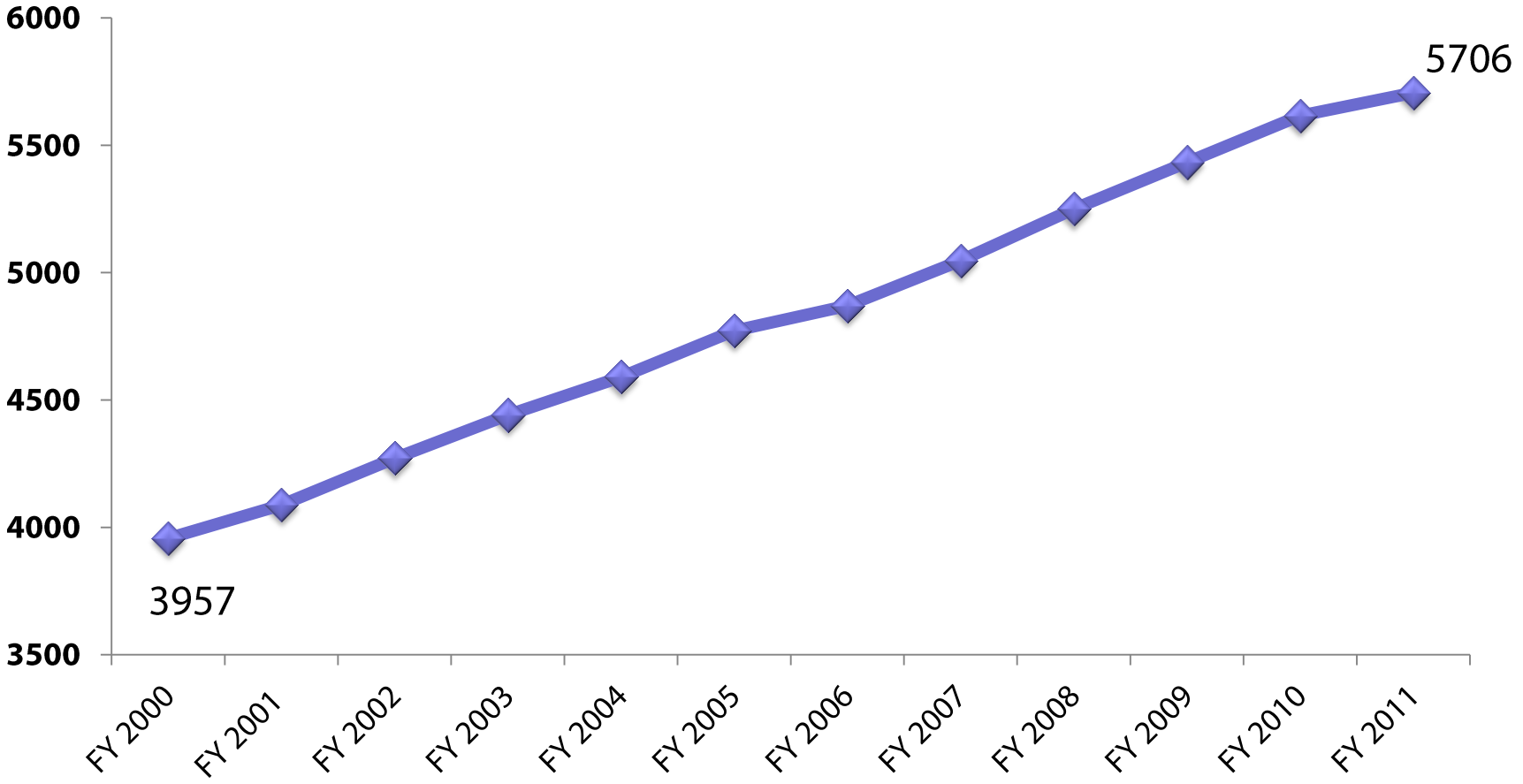
Survey and Certification Group, Center for Clinical Standards and Quality, Centers for Medicare and Medicaid Services, CASPER Database
FY: Fiscal Year

Conditions for Coverage (CfC) Strengthened for ASCs

Infection Control Nov.18, 2008	42 CFR 416.51	• Maintain ongoing infection control program • Adhere to professional standards (e.g., CDC) • Designated, qualified IC professional • Implement nationally recognized IC Guidelines • Integrated into ASC QAPI program
Quality Assessment and Performance Improvement (QAPI)	42 CFR 416.43	• Measure, analyze, track QIs, adverse events • Measure, analyze, track infection control • Implement preventive strategies • Conduct performance improvement projects

CFR: Code of Federal Regulations
ASCs: Ambulatory Surgical Centers
IC: Infection Control
QAPI: Quality Assurance Performance Improvement

Number of ESRD Facilities in Medicare



Survey and Certification Group, Center for Clinical Standards and Quality, CMS, CASPER Database
ESRD: End Stage Renal Disease
FY: Fiscal Year

Conditions for Coverage (CfC) Strengthened for ESRD

Infection Control April 15, 2008	42 CFR 494.30	• Maintain On-Going Infection Control Program • Specific Guidelines (i.e., CDC) • Staff Demonstrate Aseptic Technique • Reporting Infection Issues
Quality Assessment and Performance Improvement (QAPI)	42 CFR 494.110	• Measure, Analyze, Track QIs, Adverse Events, • Measure, Analyze, Track Infection Control • Implement Preventive Strategies • Conduct Performance Improvement Projects
ESRD Network	42 CFR 494.180	• Must Participate in ESRD Network Activities • Must Act on Network Recommendations

CFR: Code of Federal Regulations
ESRD: End-Stage Renal Disease
QAPI: Quality Assurance Performance Improvement

Systemic Action: Where are the Leverage Points?

- **Federal agencies**
  - Centers for Disease Control and Prevention (CDC)
  - Agency for Healthcare Research and Quality (AHRQ)
  - Centers for Medicare & Medicaid Services (CMS)
  - Food and Drug Administration (FDA)
- **State agencies**
  - State public health departments
  - State survey agencies
  - State Medicaid agencies
- **Professional societies**
- **Providers**
- **Patient advocacy and safety organizations**

Synergy *through* Syzygy

Best Prospect for Systemic Success

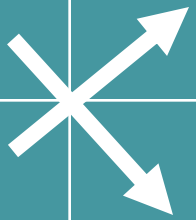
- **Synergy:**
  - Total is greater than the sum of the parts

through

- **Syzygy:**
  - Alignment of agencies
  - Authorities
  - Strategies

CDC and CMS Have Mutually Reinforcing Strengths

Agency	Strengths	Struggle
CDC	• Expertise • Communications • Credibility • Investigations	• Provider Adherence to Guidelines • Voluntary Action by Providers
CMS	• Onsite Presence • Investigations • Enforcement • Motivating Power	• Depth of Expertise • Keeping Up-to-Date • Communications



Case Example: CDC and CMS Collaboration to Improve Infection Control in ASCs

- **Infection Control Worksheet**
  - Random sample surveys in pilot states in 2008
  - All states in 2010 and 2011
  - Standard part of every survey now
- **Accrediting organizations required to have equivalency**
- **Better training of surveyors**
  - Classroom
  - Webinars
  - National Infection Control (IC) Specialist with CDC Assistance
- **Improved ability of surveyors to identify IC lapses**

ASCs: Ambulatory Surgical Centers
IC: Infection Control

Published Results of 2008 Pilot Survey Findings Randomly Selected ASCs

- **2008 Three-State Pilot (n=68)**
  - 67.6% had IC lapses
  - 57.4% cited for CMS deficiencies in infection control
  - 29.4% cited for CMS deficiencies in medication (e.g. multi-patient use of single-use medication vials)

Schaefer MK, Jhung M, Dahl M et al. JAMA. 2010 Jun 9;303(22):2273-9
ASC: Ambulatory Surgical Center
IC: Infection Control

Injection Safety as Part of Patient Safety and Hospital-Associated Infection Prevention

"…these problems may be pervasive. If the findings by Schaefer et al are generalizable, then among the estimated more than 6 million patients who undergo procedures in ASCs annually in the United States, it is possible that several million patients could be at potential risk for HAI each year. This risk is not acceptable and must be corrected immediately and definitively."

Phillip S. Barie: Infection Control Practices in Ambulatory Surgical Centers
***JAMA*. 2010;303(22):2295-2297**

PS Barie.JAMA. 2010;303(22):2295-2297
ASCs: Ambulatory Surgical Centers
HAI: Healthcare-associated infection

Follow-up Survey Findings from Randomly Selected ASCs

- **All states, percent of randomly selected ASCs with deficiency citations for infection control:**
  - 2010: 51.3%
  - 2011: 43.5%
  - 2012: 42.1%
- **Somewhat of a decline in IC lapses compared to 2008 pilot which had 57.4% deficiency rate**
- **Substantial portion of surveys still revealing correctable deficiencies**

Survey and Certification Group, Center for Clinical Standards and Quality, CMS, CASPER database
ASC: Ambulatory Surgical Center
IC: Infection Control

In a Partnership … One Thing Leads to Another

- **Hospital Risk Management Surveys-Three Dimensions**
  - Infection Control Risk Management Worksheet
  - QAPI Risk Management Worksheet
  - Discharge Planning Risk Management Worksheet
- **Pilot-tested in 2012**
  - All States do one 3-D full review in 2013
- **Risk Management Tool in 2013 and 2014**
  - Educational approach in 2013, possibly 2014
  - No deficiency citations or sanctions
  - Surveyors may use tool in 2015 for standard surveys or complaints

QAPI: Quality Assurance Performance Improvement

Closing Thoughts

- **Need more targeted technical assistance**
  - Are we increasingly pushing on a string?
- **Directed plans of correction might be explored further for ASC "repeat offenders"**
- **Mutually reinforcing collaboration yields results**
  - Syzygy is more than a good Scrabble Word
- **Special thanks from CMS to CDC**

ASC: Ambulatory Surgical Center

Injection Safety: Context and Concern

- Where should attention be focused next?
  - Nursing homes, skilled nursing facilities, oncology clinics, pain management clinics, physician offices
- Need for tailored implementation of education, practice assessment, and corrective actions
- As healthcare providers and recipients, we are all at risk, and we all have a stake in assuring safe injections

Unsafe Injection Practices in the U.S. Healthcare System

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