Injections Without Infections: Basic Patient Safety

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Centers for Disease Control and Prevention

Accessible version: https://youtu.be/RON5u27OGPM
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

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

- **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

The Human Toll of Outbreaks and Patient Notifications

LIVING IN FEAR
Patients in hepatitis C case brace for fateful results

Dear Parents,

The physicians at the Med Pe very seriously. 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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

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

Ensuring Safe Injections: Ways Forward

- Complex public health issue that requires a multi-dimensional approach, innovative solutions and partnerships
- Epidemiologic capacities and resources
  - Surveillance, reporting, and investigation
- Educational initiatives to promote understanding of safe injection practices and basic infection control
- Enforcement 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
# Overview of NYS DOH Experience

<table>
<thead>
<tr>
<th>Year</th>
<th>Facility Type</th>
<th>Investigation Type</th>
<th>Mechanism</th>
<th>Number Notified</th>
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<tr>
<td>2002</td>
<td>Private urology practice</td>
<td>HIV Transmission</td>
<td>Possible reuse of single-use biopsy guide</td>
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<td>Hepatitis C Transmission</td>
<td>Reuse of syringes in multi-dose vial</td>
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<td>2006</td>
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<td>Hepatitis C Transmission</td>
<td>Dialysis</td>
<td>170</td>
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<td>2007</td>
<td>Private MD</td>
<td>Infection Control Breach</td>
<td>Reusing syringes</td>
<td>36</td>
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<td>2008</td>
<td>Dialysis center</td>
<td>Hepatitis C Transmission</td>
<td>Dialysis</td>
<td>657</td>
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<tr>
<td>2009</td>
<td>Private MD</td>
<td>Infection Control Breach</td>
<td>Reusing syringes</td>
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<td>2010</td>
<td>Psychiatric hospital</td>
<td>Hepatitis B Transmission</td>
<td>Shared glucometer</td>
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<td>2011</td>
<td>Dialysis center</td>
<td>Hepatitis C Transmission</td>
<td>Dialysis</td>
<td>213</td>
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<tr>
<td>2011</td>
<td>Dialysis center</td>
<td>Hepatitis B Exposure</td>
<td>Dialysis</td>
<td>16</td>
</tr>
<tr>
<td>2011</td>
<td>Hosp apheresis unit</td>
<td>Hepatitis C Transmission</td>
<td>None identified</td>
<td>6</td>
</tr>
<tr>
<td>2012</td>
<td>Dialysis Center</td>
<td>Hepatitis C Transmission</td>
<td>Dialysis</td>
<td>153</td>
</tr>
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</table>
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**
Pain Management Clinic Investigation

Newsday
LONG ISLAND

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
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**
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

<table>
<thead>
<tr>
<th>Case Status</th>
<th>One Apparent Healthcare Exposure</th>
<th>More than One Healthcare Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No Non-Healthcare Risk Behaviors</td>
<td>One or More Non-Healthcare Risk Behaviors</td>
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<tr>
<td>Single Case</td>
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<tr>
<td>Clinically Consistent Acute Case</td>
<td>Initial Epi</td>
<td>Monitor</td>
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<tr>
<td>Other Case Documented Seroconversion</td>
<td>Initial Epi</td>
<td>Monitor</td>
</tr>
<tr>
<td>Other Case No Documented Seroconversion</td>
<td>Monitor</td>
<td>Monitor</td>
</tr>
<tr>
<td>Multiple Cases</td>
<td>Documented seroconversions or more than one clinically consistent acute case</td>
<td>Full Epi</td>
</tr>
<tr>
<td>Other Cases No Documented Seroconversion</td>
<td>Initial Epi</td>
<td>Initial Epi</td>
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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)
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: 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)
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
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

<table>
<thead>
<tr>
<th>Function</th>
<th>Who Does This</th>
<th>How</th>
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</table>
| 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
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
<table>
<thead>
<tr>
<th>Conditions for Coverage (CfC)</th>
<th>Strengthened for ASCs</th>
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<tr>
<td><strong>Infection Control</strong></td>
<td></td>
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<tr>
<td>Nov. 18, 2008</td>
<td></td>
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<tr>
<td>42 CFR 416.51</td>
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<tr>
<td>• Maintain ongoing infection control program</td>
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<td>• Adhere to professional standards (e.g., CDC)</td>
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<td>• Designated, qualified IC professional</td>
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<tr>
<td>• Implement nationally recognized IC Guidelines</td>
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<tr>
<td>• Integrated into ASC QAPI program</td>
<td></td>
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<tr>
<td><strong>Quality Assessment and Performance Improvement (QAPI)</strong></td>
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<tr>
<td>42 CFR 416.43</td>
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<tr>
<td>• Measure, analyze, track QIs, adverse events</td>
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</tr>
<tr>
<td>• Measure, analyze, track infection control</td>
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<tr>
<td>• Implement preventive strategies</td>
<td></td>
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<tr>
<td>• Conduct performance improvement projects</td>
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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  | 42 CFR 494.30 | Maintain On-Going Infection Control Program  
| April 15, 2008    |              | 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

- **Syzygy:**
  - Alignment of agencies
  - Authorities
  - Strategies
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<tr>
<th>Agency</th>
<th>Strengths</th>
<th>Struggle</th>
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</thead>
<tbody>
<tr>
<td>CDC</td>
<td>• Expertise&lt;br&gt;• Communications&lt;br&gt;• Credibility&lt;br&gt;• Investigations</td>
<td>• Provider Adherence to Guidelines&lt;br&gt;• Voluntary Action by Providers</td>
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<tr>
<td>CMS</td>
<td>• Onsite Presence&lt;br&gt;• Investigations&lt;br&gt;• Enforcement&lt;br&gt;• Motivating Power</td>
<td>• Depth of Expertise&lt;br&gt;• Keeping Up-to-Date&lt;br&gt;• Communications</td>
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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**
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)
“...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
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
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
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

- **Injections Without Infections: Basic Patient Safety**
  Joseph Perz, DrPH, Team Leader, Ambulatory and Long Term Care Prevention and Response Branch, Division of Healthcare Quality Promotion Centers for Disease Control and Prevention

- **The Sharp End of the Needle: A Health Department’s Experience**
  Guthrie Birkhead, MD, MPH, Deputy Commissioner Office of Public Health New York State Department of Health

- **Progress Made and Actions Needed to Increase Injection Safety**
  Thomas E. Hamilton, MD, Director, Survey and Certification Group Center for Clinical Standards and Quality Centers for Medicare and Medicaid Services