The Role of CMS in Assessing Infection Prevention and Control Compliance

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No disclosures

Objectives

• Describe the evolution of CMS infection control regulations in the last decade.

• List most common IPC citations.

• Review CMS survey strategies for Infection Prevention and Control programs.

• Not discussing payment systems!
Disclaimer

The views and opinions expressed in this lecture are those of this speaker and do not reflect the official policy or position of any agency of the U.S. government.
CMS covers 100 million people...

...through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace.

- 1 of every 3 Americans;
- 105 million beneficiaries;
- paying out $1.5 billion in benefits

Preceding Agency
Health Care Financing Administration (1977-2001)
www.CMS.gov

Website
Headquarters
Woodlawn, Baltimore County Maryland
CMS Survey and Certification Group (SCG) Structure

Federal
CMS Headquarters ------ AOss

10 Regional Offices
https://www.cms.gov/About-CMS/Agency-Information/RegionalOffices/RegionalMap.html

State Agencies

Organization of SCG

- Division of Acute Care Services (DACS)
  - Acute Care Hospitals, LTACs, CAHs, ASCs, Rehab, Psychiatric
- Division of Nursing Homes (DNH)
  - Nursing Homes
- Division of Continuing Care Providers (DCCP)
  - Home Health and Hospice, ESRD, Psychiatric Residential Treatment Facilities
- Clinical Laboratory Improvement Amendments (CLIA)
Where to Submit a Question or Inquiry?

Division of Acute Care Services (DACS)
• PFP.SC@cms.hhs.gov

Division of Nursing Homes (DNHs)
• DNH.TriageTeam@cms.hhs.gov

ESRD Survey & Certification Group
• ESRDSurvey@cms.hhs.gov
• Find resources for compliance with the ESRD Conditions for Coverage here:
• www.cms.gov/GuidanceforLawsAndRegulations/05_Dialysis.asp

SCG General Information
• http://www.cms.gov/SurveyCertificationGenInfo/

The Vision

High quality health care system that ensures better care, access to coverage, and improved health.
Operationalizing the Vision

• Enhanced surveyor training
• Partnerships with AOs, CDC, FDA and stakeholders
• New & improved survey tools for building compliance, consistency, and facility self assessment
• Updated/revised health & safety standards
CMS Conditions of Participation (CoPs) & Conditions for Coverage (CfCs)

CMS develops CoPs - (hospitals, CAHs, ASCs)
CfCs - (ESRD, LTC/NH, ASCs)

- Minimum health and safety **standards** that providers and suppliers must meet in order to be Medicare and Medicaid certified and receive reimbursement.
- The Interpretive Guidelines (IGs) provide instructions to the surveyors on how to survey the CoP. *Note: key are “should” versus “must” statements*

cms.gov

Teamwork: Collaboration & Alignment

- **CDC** - Interagency agreements (IA), surveyor and provider training, policy
- **FDA** - device reprocessing, sterilization, compounding, enzymatic cleaners
- **AAMI** - standards ESRD, issue papers, summits
- **APIC, SHEA, AORN, AMDA** (stakeholders) - input and feedback
- **State Agencies** (SAs) and **Regional Offices** (ROs)
- **Accrediting Organizations** (AOs) –(e.g. TJC, DNV) have a Memorandum of Agreement
CMS Deemed Status and national accreditation organizations (AOs)

- AOs (e.g. TJC,) are approved by CMS for enforcing standards that meet the CMS CoPs/CfCs.
- CMS grants AO "deeming" authority as meeting the CMS certification
- CMS conducts random validation surveys and complaint investigations of HCO with deemed status.
- AOs must provide CMS with a listing of documentation for HCO receiving conditional accreditation, preliminary, and non-accreditation.
- AOs provide CMS with accreditation decision reports for HCO involved in CMS validation surveys and any other survey report CMS requests.

CMS SCG IPC Training

- Surveyor training to keep current:
  - APIC Courses and Annual Conference
  - IPC Webinars Division specific (e.g. ASCs)
  - Universal IPC Course (eta. Fall 2016)
- Provider Training
  - Medical Learning Network (MLN) courses
    - Injection safety, Hand hygiene, Environmental cleaning
  - https://learner.mlnlms.com
State Agency’s Role in Patient/Resident Safety

- Ensuring better care, access to coverage, and improved health.
- Compliance with minimal health & safety standards safeguards the vision
- Surveyors = win for patient safety

Surveyor’s Role in Patient Safety

As integral parts of determining compliance with the CoPs/CfCs, the surveyor will:
- Verify an active and effective surveillance program
- Evaluate if the program is meeting the needs of patients and staff throughout the complex
- Verify a sanitary environment
- Verify comprehensive educational outreach
- Validate the program has been evaluated or revised if needed
Frequent Hospital Citations
Dirty Environments

- Unsanitary sterile processing areas
- Layers of dust, tape, mold
- Leaking washers & sinks
- Holes in walls, missing floor & ceiling tiles
- Rooms, bathrooms and common areas with debris, spider webs, blood stains
- Clean instruments & scopes touching the floor, placed in dirty bins

Frequent Hospital Citations
Untrained staff

- Reusing syringes
- Disregard for manufacturer instructions
- Staff not formally trained for their role
  - Housekeeping and cleaning products
  - Sterile processing techs cleaning instruments/scopes
  - Patient care staff not abiding by basic IPC practices
  - Cluster investigation process
Frequent Hospital Citations
Improper Reprocessing Instruments

- Immediate Use Steam Sterilization (IUSS) used for all cases...not as urgent need only!
- Not verifying efficacy of the HLD solution before use
- Not following manufacturer’s Instruction for use (IFUs)
  - Pre-cleaning of scopes
  - Exact step by step process
  - Improper tray loading
IUSS Sterilization S&C memo
(released 8/29/14)

Change in Terminology and Update of Survey and Certification (S&C) Memorandum 09-55 Regarding Immediate Use Steam Sterilization (IUSS) in Surgical Settings

Key memo points:
Based current recommendations from nationally recognized organizations (AORN, AAMI, CDC) with expertise in infection prevention and control and other professional organizations

Applies to all settings using IUSS: (e.g. hospitals, CAHs, ASCs)
• Abandons use of “flash” terminology and replaces it with IUSS.
• Clarifies that routine or exclusive use for one instrument type is out of compliance.
• Must follow manufacturer’s device IFU for IUSS.
• Must follow sterilizer IFU for IUSS
• Must use an FDA cleared rigid container or a tray with IUSS process.

S&C Alert: ERCP Outbreaks
Guidance to Surveyors

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2 22-1
Baltimore, Maryland 21244-4350

Center for Clinical Standards and Quality/Survey & Certification Group

DATE: April 3, 2015
TO: State Survey Agency Directors
FROM: Director, Survey and Certification Group
SUBJECT: Alert Related to Outbreaks of Carbapenem-Resistant Enterobacteriaceae (CRE) during gastrointestinal endoscopy, particularly Endoscopic Retrograde Cholangiopancreatography (ERCP)

Memorandum Summary
• Situation: Recent newspaper articles, medical publications, and adverse event reports associate multidrug-resistant bacterial infections caused by CRE with patients who have undergone ERCP. Duodenoscopes used to perform ERCP are difficult to clean and disinfect, even when manufacturers' reprocessing instructions are followed correctly, and have been implicated in these outbreaks. The U.S. Food and Drug Administration (FDA) has issued a Safety Communications warning, with related updates, that the design of duodenoscopes may impede effective cleaning.
• Expectations for Reprocessing Duodenoscopes: Hospitals, critical access hospitals (CAHs), and ambulatory surgical centers (ASCs) are expected to meticulously follow the manufacturer’s instructions for reprocessing duodenoscopes, as well as adhere to the nationally recognized Multisociety consensus guidelines developed by multiple expert organizations and issued in 2011.
Frequent Hospital Citations
Hand Hygiene and Glove Use

- Failure to clean hands after removing gloves
- Moving from patient to patient without cleaning hands and changing gloves
- Using ABHR on gloves rather than changing the gloves
- Thinking double gloving protects against puncture injury.
- Not having gloves accessible in locations where they are needed/used.

Dialysis Hand Hygiene and Glove Use Citations

<table>
<thead>
<tr>
<th>#</th>
<th>V-Tag</th>
<th>Tag Description</th>
<th># Citations</th>
<th>% Surveys Cited</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>V113</td>
<td>IC-Wear Gloves/Hand Hygiene</td>
<td>648</td>
<td>33.6%</td>
</tr>
<tr>
<td>2</td>
<td>V122</td>
<td>IC-Clean, disinfect surfaces &amp; equipment/written protocols</td>
<td>581</td>
<td>30.1%</td>
</tr>
<tr>
<td>3</td>
<td>V543</td>
<td>POC-Manage volume status</td>
<td>323</td>
<td>16.8%</td>
</tr>
<tr>
<td>4</td>
<td>V403</td>
<td>PE-Equipment maintenance- manufacturer’s DFU</td>
<td>307</td>
<td>15.9%</td>
</tr>
<tr>
<td>5</td>
<td>V147</td>
<td>IC-Staff education re catheters/catheter care</td>
<td>269</td>
<td>14.0%</td>
</tr>
</tbody>
</table>
CDC and SCG Collaborate

Collaborative efforts to refine and expand IPC efforts and surveyor tools (and analyze findings)

- Ambulatory Surgical Centers (ASCs) – piloted in 2008 - final in 2009
- Hospitals -piloted 2011- final in 2014
- ESRD – Agency for Healthcare Research and Quality (AHRQ) pilot 2011- 2012 final 2013
- New Division of Nursing Homes– Pilot 2016 – 2018
- New draft Home Health IPC CoPs
- S&C Memos, Department of Health and Human Services (DHHS) activities – Reportable Breaches

Draft Updated Infection Control Breaches Memo

DATE: May 30, 2014

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Infection Control Breaches Which Warrant Referral to Public Health Authorities

Memorandum Summary

- Infection Control Breaches Warranting Referral to Public Health Authorities: If State Survey Agencies (SAs) or Accrediting Organizations (AOs) identify any of the breaches of generally accepted infection control standards listed in this memorandum, they should refer them to appropriate State authorities for public health assessment and management.

- Identification of Public Health Contact: SAs should consult with their State’s Healthcare Associated Infections (HAI) Prevention Coordinator or State Epidemiologist on the preferred referral process. Since AOs operate in multiple States, they do not have to confer
What’s coming soon from CMS...

- Updated Hospital IPC CoPs (closed September 15th) will revise interpretative guidelines (IGs), and ICW.

- Revised Nursing Home IPC CoPs, IGs and availability of ICW.


- New Home Health IPC regulation and interpretive guidance.

Survey Tools for Assessing Infection Control Compliance


- ASCs: FY16 worksheet collection from 450 randomly selected facilities – new electronic submission process

- ESRD: In use since 2013 on all surveys

- NHs: IC worksheet draft in pilot testing – hospitals & NH pilot.
CMS Hospital Infection Control Worksheets (ICWs)

- Are being used for validation, certification, compliant surveys done at by CMS at hospitals.
- Not currently being used for CAH surveys
- However, highly suggested that CAHs use ICW as a self-assessment tool
- Questions or concerns should be addressed to: PFP.SCG@cms.hhs.gov

Hospital and Nursing Home CMS IPC Pilot

CMS has begun a 3 year pilot project to improve assessment of IPC regulations in nursing homes, and hospitals including during transitions of care.
CMS IPC Pilot Project

- CMS Survey and Certification Group (SCG) and (CDC) Division of Healthcare Quality Promotion History
- Ebola funding
- New Regulations
- Combating Antibiotic Resistant Bacteria (CARB)

CMS IPC Pilot Goals

- Improve assessment of infection control and prevention regulations in nursing homes, hospitals, and during transitions of care.
- Develop and test new surveyor tools
- Promote transparency of regulations
- Prevent infections in nursing home residents
CMS IPC Pilot Surveys

- Unannounced surveys
- Educational surveys – no citations (except IJ)
- Facility selection
- 2016: (beta test) 10 pilot nursing home surveys
- 2017: 40 hospital and 40 nursing home surveys
  - Review findings
  - Technical assistance
  - 2018: Revisit surveys

CMS IPC Surveyor Tools and Processes

- New and Proposed Regulations (Antibiotic stewardship)
- Develop Pilot Nursing Home Infection Control Worksheet (ICWS)
- Revise Hospital ICWS
- Assess for Infection Control and Prevention During Transitions of Care
New CMS Processes

- Analyze hospital and nursing home survey results
- Develop action plans for improvement
- Provide technical assistance
- Perform revisit surveys
- Observe National Health Safety Network (NHSN) data as metric for outcome

Outcomes of CMS Pilot

- Developing new tools (consistency, transparency)
- Test new processes to assess infection prevention during transitions of care
- Optimize surveyor assessment of infection control regulations in hospitals and nursing homes
- Prepare for the future
Hospitals have until November to prepare for new CMS NFPA rule

• CMS will begin surveying health care facilities on its new Conditions of Participation (CoPs) on Nov. 7.
• CoPs now include the National Fire Protection Association’s 101: Life Safety Code and 99: Health Care Facilities Code.

Notice of Proposed Rule Making (NPRM) for Hospitals

• June 13, CMS proposed new standards to improve the quality of care including IPC.
• CMS estimates new requirements could save hospitals up to $284 million annually, while also improving care and potentially saving lives.
• Proposed rule includes: Reducing readmissions; Reducing the incidence of hospital-acquired conditions (including HAIs); and follow nationally recognized guidelines.

Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care (CMS-3295-P)
CMS Hospital and CAH Changes to Promote Innovation, Flexibility, and Improvement in Patient Care

- Hospital-wide IPC and antibiotic stewardship programs (ASP) for the surveillance, prevention, and control of HAIs and other infectious diseases, and for appropriate use of antibiotics;
- Designate leaders of the IPCP and the ASP respectively, who are qualified through education, training, experience, or certification.
- Quality Assessment and Performance Improvement (QAPI) program incorporate quality indicator data related to hospital readmissions and hospital-acquired conditions;

Katrina 2005 to Ebola Threat 2014
**New CMS Emergency Preparedness Rule**

1) Emergency plan based on a risk assessment of the emergency preparedness program...utilizes an all-hazards approach,

2) Policies and procedures based on the plan and the risk assessment,

3) Communication plan to maintain continuity of patient care and coordination with state and local Public Health Departments (PHD); and Emergency management (EM) systems;

4) Personnel training and annual testing of the emergency preparedness program.


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**Summary of CMS Survey Process**

- Moving away from significant surveyor time spent on document review
- Assessing basic IPC in all areas of ASC, hospital, nursing homes, and dialysis facilities
- Observing patients and procedures where there is high risk of infection transmission
- Focusing on prevention efforts for HAIs in HHS HAI Action Plan and Patient Safety Initiatives.
Thank You!..Questions

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