Accreditation/Standards Hospital (Sterile Compounding)

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Disclosure Statement

Norman Pillsbury, Pharm.D, BCPS has disclosed that he has no relevant financial disclosures. No one else in a position to control content has any financial relationships to disclose.

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Objectives

At the completion of this activity, the participant will be able to:

- Discuss The Joint Commission, Det Norske Veritas, ISMP, ASHP and their role in maintaining standards of practice
- Understand the standards of practice and best practices for hospital accreditation (Medication Management standards)
- Understand the hospital accreditation process and Joint Commission survey process
- Discuss the process of Continuous Survey Readiness
- Discuss the standards of sterile product compounding and regulations (USP 797, USP 800, FDA, FL Regulations/SOP, TJC, CMS)

Discuss The Joint Commission, Det Norske Veritas, ISMP, ASHP and their role in maintaining standards of practice

Joint Commission

- The Joint Commission is an independent, not-for-profit organization that accredits and certifies over 22,000 health care organizations and programs in the United States.
- Their stated mission: "To continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value."

Source: The Joint Commission

Det Norske Veritas

- Hospital accreditation
- Management system certification
- Specialized program certification and training

Source: DNV GL Healthcare Accreditation and Certification

ISMP

- The **Institute for Safe Medication Practices (ISMP)** is the only 501c (3) nonprofit organization devoted entirely to preventing medication errors.
- ISMP is known and respected as the gold standard for medication safety information.

Source: ISMP

ISMP

- ISMP collects reports on medication errors and converts thousands of reports into change in both medical practice and pharmaceutical products through a four-step process.
  - Report
  - Investigate
  - Inform
  - Prevent

Source: ISMP

ISMP

- Prevention includes:
  - Interaction with the US Food and Drug Administration to influence regulatory change
  - Working with manufacturers, packagers, distributors, etc. to effect change at the source of the product-related problem
  - Working with standards organizations
  - Working with the healthcare community on specific medical practices
  - Work with professional/trade organizations
  - Provide proactive risk assessments and educational services to healthcare facilities

Source: ISMP

American Society of Health System Pharmacists (ASHP)

- Guidelines: Minimum Standard for Pharmacies in Hospitals
  - Leadership and Practice Management
  - Drug Information and Education
  - Optimizing Medication Therapy
  - Medication Distribution and Control
  - Facilities, Equipment, and Information Resources

American Society of Health-System Pharmacists. ASHP guidelines: minimum standard for pharmacies in hospitals. Am J Health-Syst Pharm. 1995; 52:2711–7

Which of the following is the only 501c (3) nonprofit organization devoted entirely to preventing medication errors?

A. The Joint Commission
B. Det Norske Veritas
C. The Institute for Safe Medication Practices
D. American Society of Health-System Pharmacists

Which organization is the only 501c (3) nonprofit organization devoted entirely to preventing medication errors?

- The **Institute for Safe Medication Practices (ISMP)** is the only 501c (3) nonprofit organization devoted entirely to preventing medication errors.

Understand the standards of practice and best practices for hospital accreditation (Medication Management standards)

Medication Management Standards

- This chapter in the Joint Commission's Comprehensive Accreditation Manual for Hospitals addresses a well-planned and implemented medication management system. It includes:
  - Selection
  - Procurement
  - Storage
  - Ordering
  - Transcribing of Orders
  - Preparation
  - Dispensing
  - Administration
  - Monitoring[1]

Medication Management Standards[2]

- **MM.01.01.01** The hospital plans its medication management processes.
- **MM.01.01.03** The hospital safely manages high-alert and hazardous medications.
- **MM.01.02.01** The hospital addresses the safe use of look-alike/sound-alike medications.
- **MM.02.01.01** The hospital selects and procures medications.

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Medication Management Standards[2]

- **MM.03.01.01** The hospital safety stores medications.
- **MM.03.01.03** The hospital safely manages emergency medications.
- **MM.03.01.05** The hospital safely controls medications brought into the hospital by patients, their families, or licensed independent practitioners.
- **MM.04.01.01** Medication orders are clear and accurate.
- **MM.05.01.01** A pharmacist reviews the appropriateness of all medication orders for medications to be dispensed in the hospital.
- **MM.05.01.07** The hospital safely prepares mediations.
- **MM.05.01.09** Medications are labeled.

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Medication Management Standards[2]

- **MM.05.01.11** The hospital safely dispenses medications.
- **MM.05.01.13** The hospital safely obtains medications when the pharmacy is closed.
- **MM.05.01.17** The hospital follows a process to retrieve a recalled or discontinued medication.
- **MM05.01.19** The hospital safely manages returned medications.
- **MM.06.01.01** The hospital safely administers medication.
- **MM.06.01.03** Self-administered medications are administered safely and accurately.
- **MM.06.01.05** The hospital safely manages investigation medications.
- **MM.07.01.03** The hospital responds to actual or potential adverse drug events, significant adverse drug reactions, and medications errors.

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Medication Management Standards[2]

- **MM.08.01.01** The hospital evaluates the effectiveness of its medication management system.
- **MM.09.01.01** The hospital has an antimicrobial stewardship program based on current scientific literature.

Understand the hospital accreditation process and Joint Commission survey process

Hospital Accreditation Process

- This is a process that assesses a hospital's performance against a set of standards.
- Recognition as accredited by such a process is a demonstration that the hospital is committed to the highest level of safety and quality.

Hospital Accreditation Process – Survey Process

Joint Commission surveys are unannounced, with some exceptions, such as non-deemed initial surveys. A survey is designed to be individualized to each organization, to be consistent, and to support the organization's efforts to improve performance. During the on-site survey, Joint Commission surveyors evaluate an organization's performance of functions and processes aimed at continuously improving patient outcomes.

Source: ISMP, Fact Sheets

Hospital Accreditation Process – Survey Process

They do this by:

- Tracing the care delivered to patients, residents or individuals served.
- Reviewing information and documentation provided by the organization.
- Observing and interviewing staff and, if appropriate, patients.

Source: ISMP, Fact Sheets

Hospital Accreditation Process

- **Accreditation decisions**
  The scoring and decision process is based on an evaluation of compliance with Joint Commission standards and other requirements. Compliance with the standards is scored according to specific performance expectations called elements of performance. While a preliminary Summary of Survey Findings Report is provided at the conclusion of the on-site survey, the final accreditation decision is made at a later date.

Source: ISMP, Fact Sheets

Hospital Accreditation Process

- **Accreditation decisions**
- The accreditation decisions that can be awarded are:
  - Preliminary Accreditation
  - Accreditation
  - Accreditation with Follow-up Survey
  - Preliminary Denial of Accreditation
  - Denial of Accreditation

Source: ISMP, Fact Sheets

Hospital Accreditation Process

- **Expectations of accreditation**
  An organization's accreditation cycle is continuous, as long as the organization has a full, unannounced survey within 36 months of its last survey, and continues to meet all accreditation-related requirements.

Source: ISMP, Fact Sheets

Case Study

- Joint Commission reports that 42.3% of surveys were scored for Competency Assessment pertaining to Sterile Compounding under HR.01.06.01.[3]
- You have examined your Sterile Compounding Policy to ascertain that it meets all of the requirements of USP <797>. You want to be able to provide evidence of compliance, and to have this evidence readily available.

Case Study

- Current conditions include:
  - Your initial training and annual training is uploaded to an electronic file in a Human Resources database.
  - Your annual media fill testing is documented on a manual log that is provided by the manufacturer of the media fill product. This is kept in a filing cabinet in your IV stockroom.
  - Your annual fingertip testing is reported by your lab in your hospital information system.
  - Your IV Pharmacists perform annual visual observation of sterile compounding and have USP <797> Appendix III and Appendix IV records in a filing cabinet in that office.

Case Study

- What strategies can you suggest to ascertain that all of these records are readily available?

Case Study

- Our strategy will be to store all of these records in one, easily accessible location, and to make sure that all appropriate personnel know where that is. Can they all be stored in one file on the intranet? Can they all be printed out and stored in one physical location?
- Do something so that you do not find yourself among those 42.3% of hospitals that were scored for Competency Assessment pertaining to Sterile Compounding under HR.01.06.01.[3]

Discuss the process of Continuous Survey Readiness

Continuous Survey Readiness

The Joint Commission tells you what they are going to look for and then they come and look for it.

Continuous Survey Readiness

Keep policies up to date.

Continuous Survey Readiness

Keep documentation organized, available, and current.

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Continuous Survey Readiness

Inspect areas often.

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Continuous Survey Readiness

Keep the pharmacy area clean and neat.

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Continuous Survey Readiness

Prepare staff monthly.

Continuous Survey Readiness

Perform mock surveys.

Continuous Survey Readiness

Concentrate on problematic areas:

- What Requirements for Improvement (RFIs) were received during last survey?
- What has been noted by other agencies?
- What was discovered by mock surveys?

Which of the following are methods to maintain continuous survey readiness?

A. Keep policies up to date.
B. Keep documentation organized, available, and current.
C. Keep the pharmacy area clean and neat.
D. Prepare staff monthly.
E. Perform mock surveys.
F. All of the above

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Which of the following are methods to maintain continuous survey readiness?

A. Keep policies up to date.
B. Keep documentation organized, available, and current.
C. Keep the pharmacy area clean and neat.
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F. All of the above

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Discuss the standards of sterile product compounding and regulations (USP 797, USP 800, FDA, FL Regulations/SOP, TJC, CMS)

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Sterile Compounding

- United States Pharmacopeial Convention (USP) published a Notice of Intent To Revise (NITR) to postpone the official date for revised <795> Pharmaceutical Compounding – Nonsterile Preparations, <797> Pharmaceutical Compounding – Sterile Preparations and new chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging, which were published on June 1, 2019.

Updates on appeals to USP Compounding Standards: Latest Updates: https://www.usp.org/compounding/compounding-appeals

Sterile Compounding

- In the interim, the currently official chapters of <795> (last revised in 2014) and <797> (last revised in 2008) including the section Radiopharmaceuticals as CSPs will remain official. The decisions on the appeals to <795>, <797>, and <825> do not foreclose the possibility of future revisions to these chapters.

Updates on appeals to USP Compounding Standards: Latest Updates: https://www.usp.org/compounding/compounding-appeals

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Sterile Compounding

- General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings is not subject to any pending appeals and became official on December 1, 2019. During the postponement and pending resolution of the appeals of <795> and <797>, <800> is informational and not compendially applicable. USP encourages utilization of <800> in the interest of advancing public health.

Updates on appeals to USP Compounding Standards: Latest Updates: https://www.usp.org/compounding/compounding-appeals

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Sterile Compounding

- The U.S. Food and Drug Administration (FDA) enforces the standards set by USP by means of the sections of the FD&C Act that cover adulteration and misbranding.

Sterile Compounding

- Florida Board of Pharmacy issues a separate permit called "Sterile Compounding Permit." The Standards of Practice for Compounding Sterile Products are listed in Florida Administrative Code Rule: 64B16-27.797. This was most recently published 08/19/2019 and is provided in your material for this course. This is the required reading for this session.

Source: Florida Board of Pharmacy, Sterile Compounding Permit

Sterile Compounding

- Some recent Joint Commission surveys included findings related to competency assessment in Sterile Compounding under Standard HR.01.06.01.
- Some recent surveys included findings related to infection control practices in Sterile Compounding under Standard IC.02.01.01.

Sterile Compounding

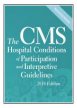
- Some recent surveys included findings related to appropriate and safe environment in Sterile Compounding under Standard EC.02.06.01.
- Some recent surveys included findings related to maintaining air pressure in Sterile Compounding under Standard EC.02.05.01.
- And some recent surveys included findings related to taking action for testing certification reports in Sterile Compounding under Standard LD.01.02.01.

Sterile Compounding

- Some specific areas where RFIs are found include:
  - Bacteria or fungi were not identified
  - Those reviewing the results of the testing and certification reports did not understand what was tested and what reference material was used to determine compliance
  - There were actionable findings with no response
  - Smoke testing was not done
  - HEPA filter was not appropriately tested
  - All required competencies for each compounder were not available
  - Testing and certification of engineering controls were not incorporated into the organization's quality improvement program

Sterile Compounding

- The Centers for Medicare and Medicaid Services (CMS) has standards governing Sterile Compounding in the Acute Care Hospital manual. Standard 25.01.02 identifies extensive and specific requirements for compounded preparations.



Source: Healthcare Facilities Accreditation Program. Accreditation Requirements for Acute Care Hospitals

Sterile Compounding

- These requirements include:
  - Details concerning Physical Layout and Structure
  - Processes, precautions, and quality assurance practices to be implemented during the preparation, transport, and storage of Compounded Sterile Products (CSPs)
  - Prevention and/or minimizing the risk of microbial contamination of CSPs
  - Suggested standard operating procedures to protect the quality of the environment in which CSPs are prepared

Source: Healthcare Facilities Accreditation Program. Accreditation Requirements for Acute Care Hospitals

Sterile Compounding

- Quality control related to ingredients, devices, and equipment used in relation to CSPs
- Quality checks to be performed before CSPs are dispensed or administered
- Issues related to beyond-use dating and packaging, storage, and transportation conditions
- Protecting dispensed and distributed CSPs
- Patient education issues
- Monitoring for and reporting adverse patient events related to CSPs
- Requirements for a formal quality assurance program to be maintained by providers of CSPs

Sterile Compounding

- Proper packaging and labeling to reduce the risk of error
- Dispensing of the CSP in a manner that is safe and meets the needs of the patient

References

1. Useltom, J.P., Lienle, P.C., Murdaugh, L.B., (2010). *Assuring Continuous Compliance with Joint Commission Standards: A Pharmacy Guide*. Bethesda, Maryland: American Society of Health-System Pharmacists, Inc.
2. The Joint Commission Comprehensive Accreditation and Certification Manual for Hospitals, E-dition published January 1, 2020
3. https://store.jcrinc.com/2019-medication-management-webinar-series/?_ga=2.94352285.1872230514.1576340587-1261606185.1575831034