Quality Assurance Practices

THE United States Pharmacopoeia (USP) is the official public standards setting authority for all prescription medication manufactured and sold in the United States. The USP sets standards for the quality of these products and works with healthcare providers to help them reach the standards. Chapter 797 is the section that outlines standards for pharmaceutical compounding of sterile preparations.

Objective:

Summarize ICD 10 and USP 797 quality assurance practices.

Key Terms:

- acute
- aseptic technique
- compounded
- endotoxins
- hood
- ICD 10
- idiopathic
- International Organization for Standardization (ISO)
- intravenous
- media fill test
- necrosis
- parenteral
- personal protective equipment (PPE)
- sequela
- United States Pharmacopeia (USP)
- World Health Organization (WHO)

ICD 10 and USP Quality Assurance Programs

SUMMARY OF ICD 10 QUALITY ASSURANCE PRACTICES

ICD 10 stands for International Statistical Classification of Diseases and Related Health Problems 10th Revision. This is often shortened to International Classification of Diseases.

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The **World Health Organization (WHO)**, a specialized agency of the United Nations that is concerned with international public health, publishes and regularly updates ICD 10 codes.

ICD 10 codes are alphanumeric codes used by doctors, health insurance companies, and public health agencies across the world to represent diagnoses. Every disease, disorder, injury, infection, and symptom has its own ICD 10 code. Healthcare professionals use ICD codes to record and identify health conditions, public health workers can use ICD codes to see trends in health, and insurers use IDC codes to classify conditions and determine insurance reimbursement.

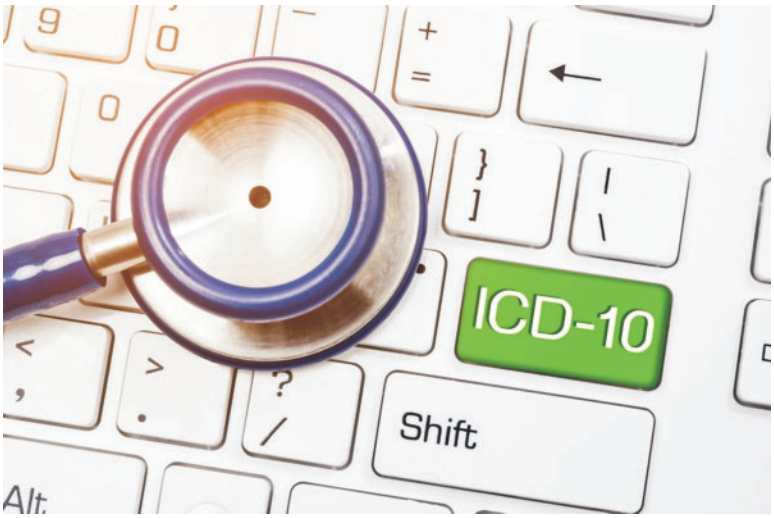

FIGURE 1. ICD 10 codes can help organizations to identify patients in need of disease management and to develop more effective disease management programs.

ICD codes are found on patient paperwork, including hospital records, physician records, and death certificates. There are over 70,000 codes. ICD 10 codes are alphanumeric and contain 3–7 characters. Each code describes a particular diagnosis in detail.

Characters are added to the code as the diagnosis gets more specific. Each code begins with a letter, and that letter is followed by two numbers. All ICD 10 codes will begin with a letter of the alphabet each of which describes a specific condition, organ system, or characteristic of a condition. For example, M is used for the musculoskeletal system, J for the respiratory system, and K for the digestive system.

Characters 1, 2, 3

The first 3 characters define the category of the disease, disorder, infection, or symptom. For example, codes starting with M00-M99 are for diseases of the musculoskeletal system, codes starting with J00-J99 are for diseases of the respiratory system, and codes starting with K00-K95 are for diseases of the digestive system. The code K85 stands for **acute**, sudden onset, pancreatitis.

Characters 4, 5, 6

The next 3 characters, 4, 5, and 6, define the body site, the severity of the problem, and the cause of the injury or disease. The ICD 10 code K85.0 stands for **idiopathic**, cause unknown, acute pancreatitis. The code K85.00 stands for acute pancreatitis without **necrosis**, death of living tissue, or infection. K85.02 stands for acute pancreatitis with infected necrosis.

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Character 7

Character 7 is an extension character used to define whether the condition is the initial encounter for the problem, a subsequent encounter, or **sequela**, an aftereffect of a disease, arising as a result of another condition. If it is the first time a healthcare provider has seen the patient for this condition, it's listed as the initial encounter. Every encounter after the first is listed as a subsequent encounter. Patient visits related to the effects of a previous injury or disease is listed with the term sequela.

To review: the first digit of an ICD 10 code is always an alpha, the second digit is always numeric, and digits three through seven may be alpha or numeric. Here is a simplified look at ICD 10 code format:

Example 1:

A01 (Disease)
A01.0… disease of the lungs
A01.01 …simple
A01.02…complex
A01.020…affecting the trachea
A01.021…affecting the cardiopulmonary system
A01.021A…initial encounter
A01.021D…subsequent encounter
A01.021S…sequela

Example 2:

S72 (Fracture of the femur)
S72.00… fracture of the neck of the femur
S72.001… fracture of the neck of the right femur
S72.002… fracture of the neck of the left femur
S72.002A…initial encounter

Medical coders read medical records and translate the diagnoses into ICD 10 codes. Most coders have computer software programs to help them. The process can be done by hand using the alphabetical index of diagnostic terms and the tabular list of ICD 10 codes to look up codes.

Healthcare providers using ICD 10 codes have a better understanding of their patient populations and the conditions that affect them. Healthcare providers make better informed treatment decisions and have better information for patient health management. ICD 10 codes advance healthcare by:

- Improving the overall efficiency of the healthcare industry.
- Offering updated medical terminology and disease classifications.

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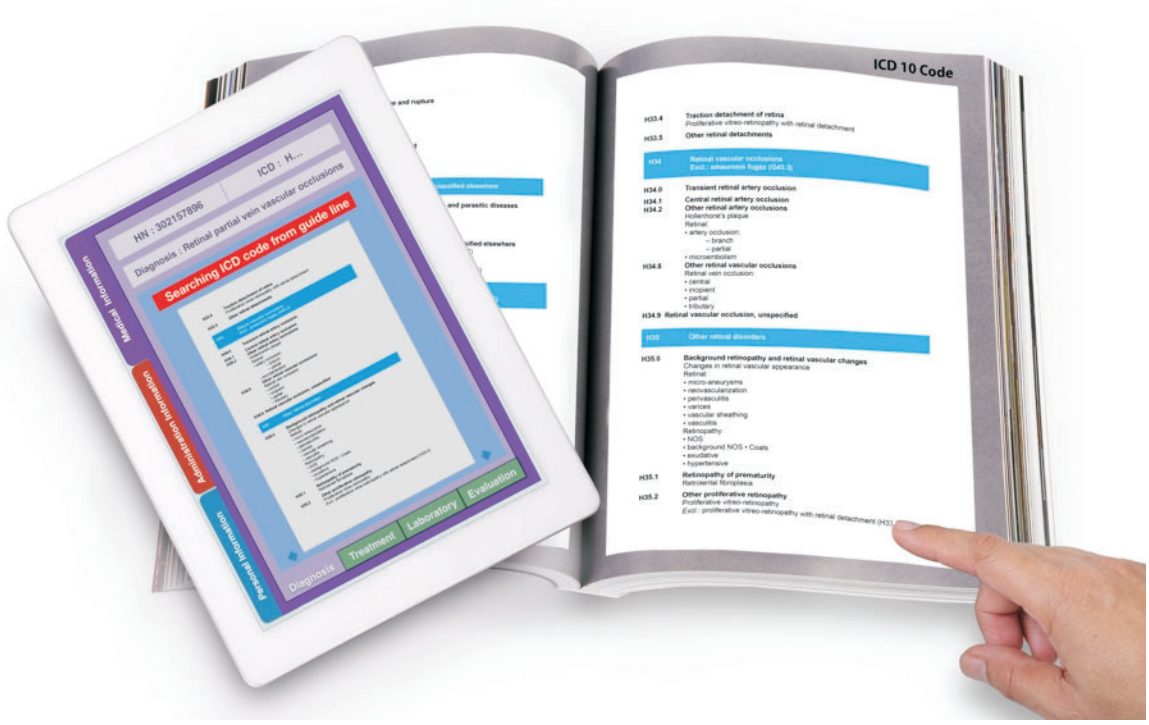

FIGURE 2. ICD 10 codes can be accessed electronically or by using medical guide books. ICD 10 codes are to be used and reported at their highest number of characters available.

- Improving the accuracy of diagnosis codes.
- Supporting reimbursement models that pay doctors more for complex medical issues.
- Improving payment efficiency and preventing errors.
- Providing better data for the study of disease and their patients.

SUMMARY OF USP 797 QUALITY ASSURANCE REGULATIONS

The **United States Pharmacopeia (USP)** is the organization responsible for providing safety guidelines for the preparation of **parenteral**, administered by injection, and other sterile medications. The USP 797 regulations were written to describe conditions and practices to prevent harm to patients resulting from contaminated or improperly **compounded**, prepared personalized medications for patients, sterile preparations. USP 797 provides minimum practice and quality standards for compounded sterile preparation of drugs and nutrients based on best sterile compounding practices. Pharmacies must document their standard operating procedures for meeting USP 797 regulations.

USP 797 has three major sections:

- Responsibilities of personnel: The risk levels of classification of compounded sterile preparations.
- Verification: Accuracy and sterility of compounded sterile preparations.

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- Training: Individual training and continued evaluation of personnel with respect to compounded products, including both quality and control of the preparation environment.

Responsibilities of Personnel

USP 797 has identified three risk levels based on the likelihood of contaminating a compounded sterile preparation with microorganisms, spores, **endotoxins**, a poison that is present inside a bacterial cell, or other foreign material. Knowing the level of risk corresponding to each compounded preparation is important because different rules apply to the compounding process depending on the risk level.

Low Risk: Level 1: Compounding involves the transfer, measuring, and mixing of not more than three packages of sterile products. There cannot be more than two ingredients entered into one sterile container. Sterile needles and syringes must be used to open disinfected vials. The time from compounding and administering the sterile preparation cannot exceed 48 hours. This is the most common type of **intravenous**, administered into a vein, preparation performed. The technique requires only minimal manipulations within the **hood**, cabinet used to prepare sterile medications.

Medium Risk: Level 2: Compounding involves multiple individual or small doses of sterile products combined to prepare a sterile preparation that will be administered to multiple patients or to one patient on multiple occasions. The compounding process takes a long time to complete. Many manipulations must be performed under the hood. The time period from the completion of the compounding and administration cannot exceed 30 hours.

High Risk: Level 3: Uses non-sterile ingredients not intended for sterile routes of administration. This involves compounding from non sterile bulk powders or measuring or mixing sterile ingredients in a non-sterile device. The time period from the completion of the compounding and administration cannot exceed 24 hours.

FIGURE 3. Remember the words that germs fear "soap and water." Just 30 seconds of simple hand washing with soap and water reduces the bacterial count on a health care workers hand by 58%.

Verification

A significant portion of USP 797 is dedicated to establishing and maintaining sterile conditions in the preparation area. Facilities should be designed to minimize contamination of sur-

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FURTHER EXPLORATION...

ONLINE CONNECTION: F.D.A. Details Contamination at Pharmacy

In 2012, the New England Compounding Center in Framingham Massachusetts was investigated due to a multistate outbreak of fungal meningitis. The Centers for Disease Control (CDC) and the Food and Drug Administration (FDA) investigation began after a patient was diagnosed with fungal meningitis after receiving a steroid injection prepared at the compounding center. Visit the web site https://www.nytimes.com/2012/10/27/health/fda-finds-unsanitary-conditions-at-new-england-compounding-center.html and read the article F.D.A. Details Contamination at Pharmacy. The owner and several employees were charged with crimes for their roles in the outbreak. Read the article "Owner and Four Former Employees of New England Compounding Center Convicted Following Trial," at the web site https://www.justice.gov/usao-ma/pr/owner-and-four-former-employees-new-england-compounding-center-convicted-following-trial. Do you agree with the jury and do you feel their sentences were adequate for their part in the outbreak?

faces, to promote effective cleaning, to limit unnecessary personnel and materials traffic, and to include any furniture and equipment that is necessary for compounding.

- Measuring, mixing, sterilizing and purifying devices are clean, accurate, and effective for their uses.
- Before dispensing, the clearness of the solution is visually confirmed.
- Single dose containers must be used within 1 hour of being opened.
- Multiple dose containers must be used within 28 days of being opened.
- Labels must list the names and amounts of active ingredients.
- Individuals entering the area must wear **personal protective equipment (PPE)**, clothing or equipment designed to protect from the risk of injury or illness.
- Hands and forearms must be properly washed before putting on sterile gloves.
- 70% isopropyl alcohol is used to clean hoods and surfaces.
- Compounding facilities are designed to minimize airborne contamination. USP 797 uses the **International Organization for Standardization (ISO)**, a classification system for defining the amount of potential airborne contamination allowed in the room where sterile preparations are compounded. The lower the ISO number is, the less particle matter is present in the air. USP 797 requires an ISO class 5 for a direct compounding area.
- **Aseptic technique**, using practices and procedures to prevent contamination from microbes or unwanted debris, must be used.

Training

Training and monitoring of compounding personnel are critical components for safe and effective sterile compounding. Both pharmacists and technicians must be able to show compe-

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tency in compounding. Before compounding is permitted, the pharmacist and technician must complete video and written instructions. Each must complete a media fill test. A **media fill test** demonstrates that the compounder can aseptically mix a compounded sterile preparation using sterile fluid bacterial culture media. The pharmacist and technician must also pass a written test. Training and testing must be repeated annually for low and medium risk levels and semiannually for the high risk level.

FIGURE 4. In healthcare safeguards are put in place to protect patients and health care workers from the spread of disease. Practicing aseptic technique is critical to maintaining a proper environment for compounding sterile preparations.

Summary:

A quality based program is vital in every compounding pharmacy to ensure that each preparation is compounded properly and is stable for its expected duration of use. Pharmacy compounding requires the development and maintenance of standard operating procedures to ensure quality and minimize compounding errors. The pharmacy must have compounding procedures that meet and or exceed United States Pharmacopeia 797 standards. When healthcare providers use ICD 10 codes more detailed information for measuring healthcare quality is accessible. ICD 10 codes provide more detail about the patient's condition leading to improved patient outcomes.

Checking Your Knowledge:

1. Explain the purpose of ICD 10 codes.
2. Explain what each of the characters in an ICD 10 code stands for.
3. Explain how ICD 10 codes advance healthcare.
4. Describe the three main sections of USP 797.
5. Differentiate between the three risk levels when compounding sterile preparations.
6. Describe 10 standards required by USP 797 when compounding sterile preparations.

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Expanding Your Knowledge:

Visit your local pharmacy. Ask the pharmacy technician to explain their sterile compounding policies and procedures to you. Report your findings to your classmates.

Web Links:

ASHP Guidelines on Compounding Sterile Preparations
https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/compounding-sterile-preparations.ashx

The Web's Free 2019 ICD 10 CM/PCS Medical Coding Reference
https://www.icd10data.com

USP General Chapter 797: A Guide to Sterile Compounding for Pharmacy Personnel
https://www.powerpak.com/course/content/114849

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