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Review Article

Insights into Pharmaceutical Medical Coding in Clinical Trial Processes

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ABSTRACT

The increasing complexity of medical terminology in clinical trials necessitates the use of standardized medical coding systems to ensure uniformity in data interpretation. This article provides an overview of the processes involved in medical coding within clinical data management, specifically highlighting the role of established medical dictionaries like the Medical Dictionary for Regulatory Activities (MedDRA) and the World Health Organisation Drug Dictionary Enhanced (WHO-DDE). These dictionaries aid in categorizing medical terms from reports generated throughout the lifecycle of clinical trials, addressing challenges such as variations in data presentation due to diverse investigator backgrounds. Medical coding typically involves a precoding process, followed by auto coding where terms matching those in the dictionary are automatically assigned codes. However, discrepancies may arise, necessitating manual coding to address unclear or ambiguous terms. The medical coding team plays a critical role in ensuring accurate coding by collaborating with investigators to clarify ambiguous terms and rectify errors in data recorded on Case Report Forms (CRFs). The MedDRA structure includes multiple hierarchical levels from Low Level Terms (LLTs) to System Organ Classes (SOCs), providing a comprehensive framework for handling diverse medical terms. Common issues faced by coders, including illegible terms, abbreviations, and improper categorization, are also discussed. By understanding these processes and challenges, medical coders can enhance the reliability of clinical trial data, ultimately contributing to safer and more effective therapeutic outcomes.

INTRODUCTION

In the context of clinical trials, the meticulous collection and management of data are fundamental to the success and reliability of the research outcomes [1,2]. This data collection process is primarily conducted through Case

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Record Forms (CRFs) for paper-based studies and electronic Case Record Forms (eCRFs) for digital or web-based trials [3]. These data collection instruments are meticulously designed to capture a wide range of relevant information that is crucial for evaluating the safety and efficacy of clinical interventions. Key elements documented in these forms include Adverse Events (AEs), Medical History (MH), and Concomitant Medications (CM) that participants may be taking concurrently with the study medication. When conducting multicentric clinical trials—studies that involve multiple research sites often located in different countries—there is a heightened complexity due to the involvement of diverse investigators and clinical research teams [4]. Each of these professionals may come from varied cultural and educational backgrounds, which can lead to discrepancies in how medical and scientific data are recorded [5,6]. Factors such as local medical practices, terminology variations, and even language differences can significantly influence the uniformity of data collected across different sites [7,8]. This variability can pose challenges when analyzing the aggregated data, potentially leading to misunderstandings or misinterpretations of the trial results [9]. To mitigate these challenges and ensure that all collected data is interpreted consistently, medical coding is an essential process [10]. Medical coding involves the systematic application of standardized medical dictionaries—such as MedDRA (Medical Dictionary for Regulatory Activities) and WHO-DDE (World Health Organization Drug Dictionary Enhanced)—to categorize and encode the information collected in the CRFs and eCRFs[11,12]. This coding process not only enhances clarity and facilitates the identification of medical terms but also plays a critical role in ensuring that the data can be uniformly analyzed across different sites and populations[11,13]. The coding of AEs, Serious Adverse Events (SAEs), Medical History (MH), and Concomitant Medications (CM) is particularly noteworthy. AEs refer to any undesirable experiences associated with the use of a medical product, while SAEs are instances of more severe adverse events that may require more immediate attention. Furthermore, documenting the medical history of trial participants provides essential context for understanding the overall safety profile of the intervention being studied [14]. Concurrently recorded medications are also crucial, as they may interact with the study medication or confound the results. Importantly, the process of medical coding is not merely a recommendation but is considered a mandatory requirement under regulatory guidelines for clinical trials[15].Ensuring that AEs, SAEs, and CM are meticulously coded helps to align with regulatory expectations and enhances the quality of data reporting. By establishing a framework for consistent data interpretation, researchers can improve the overall reliability and validity of their findings. The benefits of leveraging standardized medical coding extend beyond mere compliance. This structured approach fosters consistency in analysis, enabling researchers to draw more accurate conclusions regarding the safety and efficacy of the medical interventions being tested. It also facilitates the integration of data across multicentric trials, allowing for meaningful comparisons and insights to be generated from diverse populations.

This article aims to:

- Explain the process of medical coding in clinical trials using standardized coding dictionaries.
- Provide a brief overview of two of the most widely utilized dictionaries by regulatory agencies and professionals in the pharmaceutical and contract research organization (CRO) industries.

- Outline the medical coding procedures and highlight some common challenges faced by coders during the coding process.

While there are multiple standardized medical coding dictionaries available, the following five are commonly employed for coding purposes:

COSTART - Coding Symbols for the Thesaurus of Adverse Reaction Terms

COSTART is a medical coding system designed to help researchers document and classify adverse reactions to drugs in a consistent manner. This terminology serves as a valuable reference for reporting adverse events in clinical studies, ensuring that when an adverse reaction occurs, everyone understands exactly what it refers to. By providing standardized terminology, COSTART helps streamline communication among healthcare professionals, regulatory bodies, and researchers, ultimately enhancing the clarity of safety reporting.

ICD9CM - International Classification of Diseases, 9th Revision, Clinical Modification

ICD9CM is a coding system that gives healthcare providers a systematic way to categorize a wide variety of diagnoses and health conditions. Although it has been largely overshadowed by the newer ICD-10 classification, ICD9CM played a critical role in managing health data and statistics for many years. By allowing healthcare professionals to uniformly code and report health issues, it aids in understanding health trends and outcomes over time, providing important insights into patient care and epidemiology.

MedDRA - Medical Dictionary for Regulatory Activities

MedDRA is an essential tool in the pharmaceutical industry, created specifically for regulatory purposes. This comprehensive dictionary includes a vast array of medical terms related to adverse events, diseases, and medical histories. Its hierarchical structure allows coders to classify and analyze terms at various levels—from broad categories to specific medical conditions. MedDRA is widely utilized by regulatory agencies and pharmaceutical companies alike as it promotes standardized language for reporting clinical trial data, making it easier to assess the safety and effectiveness of medications.

WHO-ART - World Health Organization Adverse Reactions Terminology

Developed by the World Health Organization, WHO-ART is a standardized vocabulary that focuses specifically on adverse drug reactions. It provides clear definitions and classifications, making it a vital resource for pharmacovigilance—monitoring the effects of medications after they have been approved for use. By using WHO-ART, researchers and healthcare professionals can communicate effectively about drug safety, ensuring that data on adverse reactions is collected and analyzed uniformly across different regions and organizations.

WHO-DDE - World Health Organization Drug Dictionary Enhanced

The WHO-DDE is an expanded version of the WHO Drug Dictionary that serves as a comprehensive database for medicinal products. It includes detailed information about both brand-name and generic drugs, along with their classifications and therapeutic uses. This dictionary is particularly important for researchers as it helps accurately record and categorize drug information during clinical trials. By using the WHO-DDE, clinical trial teams can ensure that they are capturing all relevant details about the medications being studied, which enhances the reliability of their findings related to safety and effectiveness. These five dictionaries play a significant role in the world of clinical research. They provide a framework for ensuring that all medical terms are consistently defined and understood across different studies and regions. By implementing these standardized coding systems, researchers can improve the quality of

their data, enhance collaboration among stakeholders, and ultimately contribute to more reliable insights into medical treatments and therapies. This consistency is key to advancing patient safety and therapeutic efficacy in the healthcare landscape.

Precoding Process:

In the medical coding workflow, the precoding process involves a series of important steps to ensure that the relevant medical coding dictionaries are correctly integrated into the coding tool used for clinical trials. For instance, in the context of Oracle Clinical (OC), the coding tool is called Thesaurus Management System (TMS). Initially, the database programming team is responsible for importing or loading the chosen dictionary—and any future updates—into TMS. Once this loading process is completed, the programming team conducts a thorough check to verify that all tables and records are correctly set up in the system. This step is only performed once for each version of the dictionary. After confirming that everything is in order, the operational team steps in to conduct a User Acceptance Test (UAT). During this testing phase, team members review the system to ensure that the loaded dictionary functions as expected and produces the required outputs. Once the operational team successfully clears the UAT, the dictionary is approved and officially released for use in a specific project or study. However, if the same dictionary version is needed for a different project or study in the future, the operational team will need to go through the UAT process again to ensure everything is still functioning properly. This repeat testing ensures consistency and accuracy across different projects.

Before assigning a medical coding dictionary to a project or study, it's crucial to verify the following points as prerequisites:

- Confirm that the latest validated version of the dictionary is available in the coding tool at the beginning of the project.
- Review the policy or requirements regarding the use of the same dictionary version throughout the entire project, even if newer versions become available.
- Assess the availability of upgraded versions to be implemented prospectively as they are released during the project's duration.
- Consider the implications of incorporating upgraded versions retrospectively if they become available during the project lifecycle.

Live Project coding

In the context of clinical trials and research studies, coding serves as a bridge that connects raw data gathered from investigations to actionable insights and conclusions. Each data point—be it a diagnosis, a symptom, or an adverse event—needs to be systematically categorized using standardized terminologies to ensure uniformity and accuracy throughout the study.

Roles Involved in the Coding Process

1. Data Managers:

Data managers play a pivotal role in the initial stages of the coding process. They oversee data validation and ensure that the information collected is not only accurate but also cleaned of any discrepancies. Their work lays the foundation for reliable coding by ensuring that data is formatted according to predetermined standards and is ready for processing.

2. Medical Coders:

Medical coders are specialized professionals responsible for the accurate assignment of codes to both auto-coded and manually coded terms. Their expertise in medical terminology, coding standards, and the specific dictionaries being used is invaluable. Medical coders must maintain a thorough understanding of the hierarchical structures within medical dictionaries, as well as

the medical context surrounding the terms they are coding.

Detailed Overview of Coding Processes

Auto Coding

Auto Coding:- uses algorithms and predefined criteria to facilitate the rapid assignment of codes. Here's how it typically functions:

Automated Matching: The system scans the terms entered by investigators against the medical dictionary in real time. Technologies like Natural Language Processing (NLP) may be employed to enhance the matching process, allowing for better recognition of variations in phrasing or terminology.

Efficiency: By automating coding for terms that are accurately represented in the dictionary, researchers can process high volumes of data quickly. This rapid processing is especially beneficial in large clinical trials where speed is crucial for maintaining study timelines.

Error Reduction: Auto coding helps minimize human error by relying on established criteria and logic. When a term is coded automatically, it reduces the risk of misinterpretation that may come from manual entry.

Manual Coding

When terms do not match established codes through auto coding, manual coding becomes essential. This process involves several key steps:

Reviewing Uncoded Terms:

The medical coder reviews each term that has not been auto-coded to determine why the system did not recognize it. This could be due to differences in terminology, nuances in clinical language, or specific phrasing used by investigators.

Contextual Analysis:

Coders must analyze the context of the term, understanding the clinical scenario in which it was recorded. This requires a solid grasp of medical concepts and terminologies to ensure that the correct code is selected.

Hierarchical Navigation:

Medical dictionaries often use a hierarchical structure, with terms organized from broad categories to specific instances. Coders must navigate this structure to find the most appropriate match for the term they are coding. For example, a general term like "respiratory distress" must be linked accurately to the corresponding more specific diagnosis in the hierarchy.

Documentation and Record Keeping:

After coding, it is crucial for coders to keep detailed records of their decisions. This is essential for compliance and future reference, especially during audits or when the data is reviewed by regulatory agencies.

Importance of Accurate Coding

Accurate coding is not merely a technical requirement; it has far-reaching implications for the entire clinical research process:

Regulatory Compliance: Regulatory bodies, such as the FDA or EMA, require precise coding for adverse events and medical conditions to ensure patient safety. Any discrepancies in coding can lead to serious compliance issues and may even impact the approval process of new drugs or therapies.

Data Analysis and Interpretation: The integrity of data analysis hinges on the accuracy of the coded data. Statistical analyses, outcomes reporting, and future research conclusions all rely on consistent and accurate coding. Inconsistent codes can skew results and lead to erroneous conclusions about a treatment's safety and efficacy.

Patient Safety and Monitoring: In clinical trials, ensuring that all adverse events are correctly coded is critical for ongoing patient safety monitoring. Misclassified data could delay the identification of potential safety signals. Accurate coding allows for timely responses to unforeseen complications or adverse reactions.

Facilitating Communication: Standardized coding promotes better communication among various stakeholders, including clinical researchers, regulatory authorities, and healthcare providers. When everyone uses the same terminology, it reduces confusion and enhances collaboration across different phases of a study.

The same process is depicted in a flow chart below

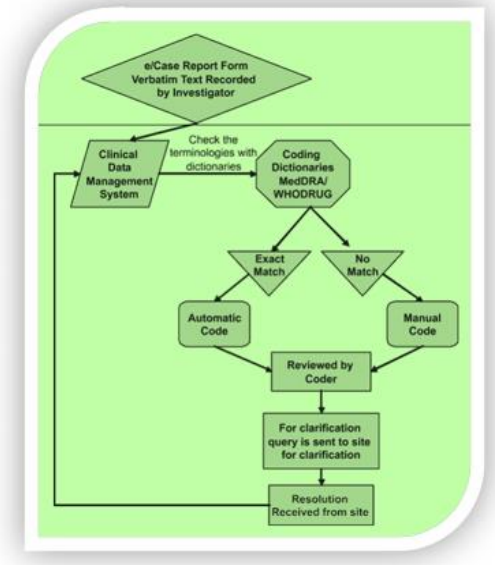

Fig No.1Medical Coding Process

Common Challenges Faced by Medical Coding Experts

Medical coding experts encounter several difficulties when coding medical data. These challenges can impact the accuracy and completeness of the coded information. Here are some of the common problems they face:

1. Illegible Verbatim Terms:

One of the most significant challenges is dealing with handwritten notes or poorly typed entries that are hard to read. Illegible terms can lead to misunderstandings or incorrect interpretations of a patient's condition. When coding experts cannot decipher what the term is, it may result in the coding of inaccurate or inappropriate diagnoses.

2. Spelling Errors:

Spelling mistakes in the terms entered can create significant hurdles for coders. Even minor errors can result in the failure of the auto-coding process, requiring manual intervention. If a term is misspelled, it may not match any entries in the medical dictionary, causing delays and potential inaccuracies in data coding.

3. Use of Abbreviations:

The use of abbreviations can complicate the coding process significantly. While abbreviations can save time, they often lack clarity and can mean different things in different contexts. If a coder is unfamiliar with a particular abbreviation or if the abbreviation is ambiguous, it may lead to errors in coding. Coders must have a comprehensive understanding of common medical abbreviations to ensure accurate interpretation.

4. Multiple Signs and Symptoms Logged as Separate Events:

Patients often present with a variety of symptoms that may collectively point to a single diagnosis. However, when these symptoms are recorded as separate events, it can complicate the coding process. For instance, if a patient has both a fever and cough recorded separately, it could mislead coders and result in the individual coding of each symptom rather than recognizing them as part of a broader diagnosis (like pneumonia). This fragmentation can skew data and lead to an

inaccurate representation of a patient's clinical picture.

5. Multiple Medical Concepts Documented Together:

Sometimes, medical records include several distinct medical concepts listed together without clear separation. For effective coding, it is necessary to break these terms down into individual components. For example, if a record states "diabetes mellitus with hypertension and hyperlipidemia," the coder must separate these into distinct codes for each condition. This process can be time-consuming and requires careful attention to ensure that no concepts are overlooked during the coding process.

6. Events Recorded Without Site Information:

In some cases, events such as ulcers are documented without specifying their location. For instance, if only the term "ulcer" is recorded, the coder cannot determine whether it refers to a mouth ulcer, a leg ulcer, or another type. This lack of specificity can lead to misclassification and incorrect coding. Coders must ensure that additional context about the site or type of event is provided to accurately assign codes.

7. Ambiguous Medical Concepts Involving Surgical Procedures:

Occasionally, records may document surgical procedures alongside the reasons for an injury, but the underlying cause, reason, or site of the injury is not clarified. For example, if a patient undergoes an appendectomy due to an unspecified abdominal pain, the coder faces the challenge of coding the procedure without adequate context for the initial condition. Without clear details, this can lead to incomplete coding and a lack of understanding of the patient's case.

8. Medication Terms Without Clarification of Allergies or Reactions:

When a medication is recorded, it is essential to also document any allergies or adverse reactions associated with that medication. If a term for a medication is reported, but there is no accompanying information about an allergy or its outcome, the coder is left with incomplete data. This oversight can hinder proper coding and affect patient safety, especially in instances where medication allergies could have serious implications for future treatments

Medical Dictionary for Regulatory Activities (MedDRA)

The Medical Dictionary for Regulatory Activities (MedDRA®) is a medical coding dictionary created by the Maintenance and Support Services Organization (MSSO). It is backed by the International Conference on Harmonisation (ICH), which sets technical guidelines for registering pharmaceuticals for human use. Before MedDRA was developed, there wasn't a globally recognized medical terminology for regulatory purposes in biopharmaceuticals.

Uses of MedDRA

MedDRA is used for coding various medical terms that arise during clinical trials, except for those related to animal studies. Specifically, it is employed to code:

- Therapeutic indications: This includes signs, symptoms, diseases, diagnoses, prevention methods, and changes in medical functions.
- Investigation results: Names and quantitative results from medical tests.
- Procedures and history: Coding for surgical procedures, as well as medical, social, and family histories.

MedDRA is updated twice a year, in March and September. Access to the MedDRA terminology requires an annual subscription, which includes all updates and changes approved during that period.

Structure of MedDRA

MedDRA organizes its terms into five hierarchical levels:

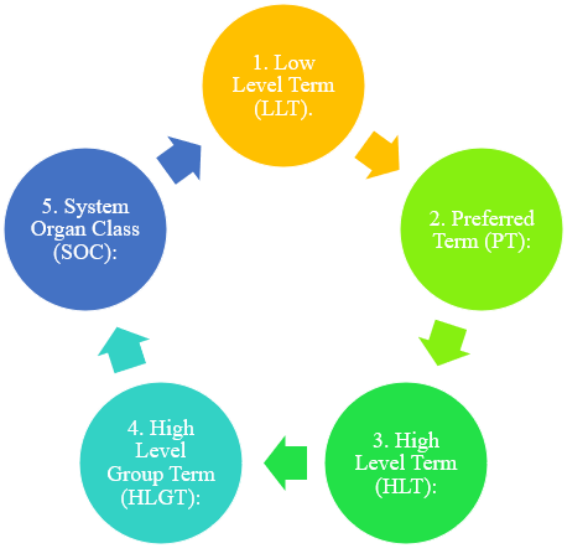

Fig no. `1. Structure of MedDRA

Frequently Used Medical Dictionaries

1. International Classification of Diseases (ICD): This is a global standard for diagnosing and classifying diseases and health conditions. It is used for health management, epidemiology, and clinical purposes.

2. Current Procedural Terminology (CPT): Developed by the American Medical Association, this dictionary provides a standardized system for coding medical procedures and services performed by healthcare providers.

3. National Drug Code (NDC): This is a unique identifier for medicines in the United States, used for identifying pharmaceuticals and monitoring safety and effectiveness.

4.Systematized Nomenclature of Medicine - Clinical Terms (SNOMED CT): A comprehensive clinical terminology system that provides standardized terms for a wide range of healthcare concepts, including diagnoses, findings, procedures, and medications.

5.Logical Observation Identifiers Names and Codes (LOINC): A coding system used to identify health measurements, observations, and documents. It standardizes laboratory and clinical observations to facilitate the exchange of health data.

6. Rx Norm: This is a standardized nomenclature for medications that provides consistent naming of drugs and their relationships, aiding in drug interaction checking and electronic prescribing systems.

These dictionaries serve different purposes within healthcare but collectively contribute to ensuring clear and consistent communication in medical documentation and coding.

World Health Organization Drug Dictionary (WHODRUG)

The World Health Organization Drug Dictionary, or WHODRUG, is a valuable resource managed and updated by the Uppsala Monitoring Centre (UMC). It contains detailed information about medicines and is one of the most comprehensive drug dictionaries available. WHODRUG is commonly used by drug regulatory agencies, pharmaceutical companies, and contract research organizations (CROs). It includes both brand names and generic names of medicines from over 90 countries WHODRUG has evolved over time and now includes three different types of dictionaries. These resources help ensure that medicines are accurately identified and classified around the world.

WHO Drug Dictionaries Overview

1. WHO Drug Dictionary (WHO-DD)
2. WHO Drug Dictionary Enhanced (WHO-DD Enhanced)
3. WHO Herbal Dictionary (WHO-HD)

The WHO Drug Dictionary (WHO-DD) and the WHO Drug Dictionary Enhanced (WHO-DD Enhanced) primarily provide information about conventional medicinal products. In addition to these, they also encompass various other types of products, such as:

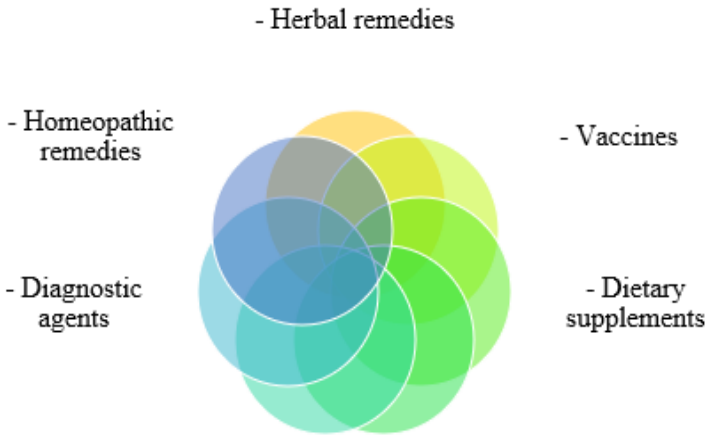

Fig. No 2 various other types of products

On the other hand, the WHO Herbal Dictionary focuses exclusively on herbal entries, containing almost all the herbal products that have been recorded in the WHO Drug Dictionary over the years. Since 2005, all new herbal entries have been included solely in the WHO Herbal Dictionary, which is organized according to the Herbal **Anatomical Therapeutic Chemical (HATC) classification.**

The WHO Drug Dictionaries provide details about medicinal products. This information is used to accurately identify a term (medicinal product) that closely corresponds to the term reported in the DCI (Drug Classification Identifier).

ATC classification is integral part of the dictionary. This is used to classify the medicinal product to the main therapeutic use of the active ingredient/s.

Fig. No 3 ATC classification is integral part of the dictionary

CONCLUSION: -

Medical coding involves converting procedures, healthcare diagnoses, medical services, and equipment into alphanumeric codes. Accurately managing and reducing errors in medical coding and billing is crucial for the accuracy and financial

health of an organization. Most errors stem from factors such as inadequate documentation, improper coding and modifiers, service unbundling, and a lack of familiarity with coding guidelines, anatomy, and medical terminology. To minimize these errors, it's essential to provide thorough training on coding standards, conduct regular audits and monitoring, and enhance knowledge in areas such as medical terminology, anatomy and physiology, medical abbreviations, and diagnoses. While coding and billing mistakes can be avoided, understanding their root causes is key to effectively reducing and managing them.

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