

Review

An In-depth Analysis of Intravenous Oncology Drug Compounding in Pharmacies: Ensuring Safety, Enhancing Efficiency, Driving Innovations, and Maintaining Stability

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Abstract: Introduction: Intravenous (IV) oncology drug administration plays a pivotal role in cancer therapy, enabling swift and precise delivery of therapeutic agents. The preparation process for these drugs is highly complex, necessitating rigorous adherence to safety standards, efficient operational workflows, and adoption of advanced technologies to ensure both patient safety and treatment effectiveness. This review delves into the practices and innovations within pharmacy settings that underpin the preparation of IV oncology drugs, with an emphasis on safety, operational efficiency, technological advancements, and drug stability. Safety: Ensuring safety in the preparation of IV oncology medications is crucial due to the hazardous properties of chemotherapeutic agents. Compliance with standards such as USP <797> and USP <800> is vital to mitigate contamination risks and minimize exposure. Safety measures include the use of personal protective equipment (PPE), engineering controls such as biological safety cabinets (BSCs) and compounding aseptic containment isolators (CACIs), along with comprehensive staff training programs. Past incidents, such as contamination at the New England Compounding Center, illustrate the necessity for robust safety protocols to safeguard both patients and healthcare professionals. Efficiency: Optimizing efficiency in the preparation process is essential to address high demand while maintaining stringent safety and quality standards. Key steps include prescription validation, drug compounding, quality assurance, and dispensing. The adoption of technologies like automated compounding devices (ACDs) and pharmacy management systems has streamlined these processes, significantly reducing errors and preparation times. However, achieving a balance between operational efficiency and uncompromised safety remains a persistent challenge, requiring ongoing staff education, resource optimization, and strict compliance with regulatory guidelines. Innovative Technologies: The integration of cutting-edge technologies, including robotics, automation, and artificial intelligence (AI), has transformed IV drug preparation. Robotic systems offer enhanced precision and minimize human error, while AI and advanced aseptic techniques optimize workflows and dosing accuracy. Future advancements may include the application of 3D printing, nanotechnology, and blockchain to further elevate the safety, efficiency, and traceability of preparation processes. Stability: Preserving the stability of compounded oncology drugs is fundamental to their therapeutic effectiveness and safety. Stability is influenced by variables such as storage conditions, handling methods, and the compatibility of diluents and containers. Adhering to guidelines like USP <797> is crucial for maintaining stability. Innovations in stabilizing agents, packaging, and real-time monitoring systems are advancing the field, helping to overcome stability-related challenges and improving treatment outcomes. Conclusion: This review underscores the paramount importance of safety, efficiency, innovation, and stability in the preparation of IV oncology drugs. Strict adherence to safety standards, streamlined workflows, the adoption of advanced technologies, and meticulous stability management are critical to enhancing pharmacy practices and patient care. Future efforts should prioritize the integration of emerging technologies, standardization of procedures, continuous education for staff, and implementation of real-time monitoring to further progress in this domain. Addressing

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these challenges with innovative solutions will drive improvements in both patient safety and therapeutic outcomes.

Keywords: intravenous oncology drugs; drug preparation; pharmacy practice; safety protocols; efficiency; innovative technologies; drug stability; chemotherapy; automation; artificial intelligence

1. Introduction

1.1. Significance of Intravenous Oncology Drug Preparation

The administration of intravenous (IV) oncology drugs is a fundamental aspect of cancer therapy, enabling the rapid and precise delivery of chemotherapeutic agents directly into the circulatory system [1]. This approach is particularly vital for oncology patients, as it ensures the accurate administration of potent, often highly toxic medications designed to effectively combat cancer cells. Given the complexity and critical importance of these drugs, their preparation and handling within pharmacy settings demand a high level of precision and care. The process encompasses several key stages, including accurate dose calculation, sterile compounding, and maintaining drug stability, all of which are critical for ensuring patient safety and therapeutic success.

Over recent decades, oncology pharmacy has undergone substantial advancements, propelled by innovations in pharmaceutical sciences and increasingly intricate cancer treatment regimens. Preparing IV oncology medications is far from a routine task—it is a highly specialized process requiring extensive knowledge of pharmacokinetics, pharmacodynamics, and the distinct characteristics of chemotherapy agents. Pharmacists hold a central role in this process, meticulously preparing each dose to ensure safety and efficacy while striving to minimize potential risks and adverse effects.

1.2. Objective and Scope of the Review

This review seeks to deliver an in-depth exploration of the prevailing practices and recent advancements in the preparation of intravenous oncology medications within pharmacy environments. Emphasis is placed on four primary dimensions: safety, operational efficiency, technological innovations, and drug stability. By investigating these critical elements, the review underscores their individual and collective significance in ensuring the optimal preparation and delivery of IV oncology drugs. Additionally, it aims to highlight the interconnections among these factors, illustrating their combined impact on enhancing patient outcomes and treatment quality.

1.3. Safety

Ensuring safety during the preparation of intravenous oncology drugs is of utmost importance due to the hazardous nature of chemotherapeutic agents. These highly potent drugs pose significant risks to healthcare professionals if not managed correctly. Compliance with guidelines such as USP <797> and USP <800> is essential to mitigate risks associated with contamination and exposure. USP <797> specifies requirements for sterile compounding to maintain aseptic conditions and prevent microbial contamination, while USP <800> provides comprehensive guidelines for handling hazardous drugs to safeguard both healthcare workers and patients.

Effective implementation of safety measures includes the use of personal protective equipment (PPE), engineering controls such as biological safety cabinets (BSCs) and compounding aseptic containment isolators (CACIs), and thorough training programs for pharmacy staff. These precautions aim to establish a controlled environment that minimizes contamination risks. Historical events, such as the New England Compounding Center incident, which led to a widespread fungal meningitis outbreak, underscore the

dire consequences of inadequate safety protocols and the necessity for stringent regulatory oversight.

Procedural safeguards are equally critical. Standard operating procedures (SOPs) for the preparation, handling, and disposal of chemotherapeutic agents help prevent accidental exposure and ensure uniform practices. Regular audits and inspections reinforce adherence to guidelines and highlight areas needing improvement. Cultivating a safety-first culture within the pharmacy is equally vital. Open communication about safety concerns, continuous education on best practices, and vigilant adherence to safety measures by all staff members collectively reduce risks and enhance the reliability of drug preparation processes.

In China, significant progress has been achieved in centralized intravenous drug deployment (PIVAS) over the past two decades [2]. Efforts by early pioneers in PIVAS construction and dedicated hospital pharmacists, under the guidance of health administrative authorities, have substantially improved the quality of prepared infusion products, reduced medication errors, and enhanced patient safety. These advancements have also alleviated the burden on nurses by reducing their exposure to hazardous drugs during intravenous dispensing. However, challenges remain, including financial constraints, insufficient professional staffing, and limited physical resources in hospitals. Addressing the balance between meeting basic medical needs and delivering advanced medical services, while enhancing the social and economic value of pharmaceutical services, remains an ongoing pursuit for PIVAS practitioners.

1.4. Efficiency

Efficiency in the preparation of intravenous oncology drugs is critical to addressing the high demand for cancer treatments while ensuring safety and maintaining stringent quality standards. The process involves multiple steps—prescription verification, compounding, quality control, and dispensing—all of which must be seamlessly integrated to deliver safe and effective medications to patients in a timely manner.

Technological advancements have significantly enhanced efficiency in drug preparation. Automated compounding devices (ACDs) streamline the measurement and mixing of drugs, ensuring accurate dosages and consistent quality. Similarly, pharmacy management software facilitates efficient workflows by managing inventory, tracking prescriptions, and coordinating preparation processes. These tools not only reduce preparation times but also help minimize errors, improving both productivity and patient safety.

Despite these advancements, balancing efficiency with safety remains a critical challenge. The demand for rapid turnaround must not compromise the rigorous safety protocols essential for handling hazardous drugs. Achieving this balance requires effective resource allocation, continuous staff training, and strict adherence to established safety standards. Optimized workflows can also lead to cost savings, allowing healthcare facilities to redirect resources toward patient care and other essential services.

Human factors play a pivotal role in enhancing efficiency. Effective communication between pharmacists, physicians, and nurses ensures prompt resolution of issues or discrepancies, reducing delays in treatment. Lean management principles, such as identifying and eliminating workflow inefficiencies, further optimize resource use and streamline operations. Continuous quality improvement (CQI) initiatives, including process mapping and root cause analysis, enable pharmacy teams to address inefficiencies proactively, implement targeted solutions, and sustain high standards of care.

1.5. Innovative Technologies

The adoption of advanced technologies, including robotics, automation, and artificial intelligence (AI), has transformed the preparation of intravenous oncology drugs. Robotic systems are increasingly employed to enhance precision and minimize human error by automating intricate and repetitive tasks. For instance, robotic arms can precisely measure

and mix drugs, ensuring consistent and accurate preparation of each dose. These systems operate in sterile environments, significantly reducing the risk of contamination while maintaining high safety standards.

Advanced aseptic techniques, such as the deployment of isolators and laminar flow hoods, establish controlled environments that safeguard both the drug and pharmacy staff. These technologies are particularly vital for maintaining sterility during the compounding process of hazardous drugs. AI-driven systems complement these innovations by analyzing extensive datasets to optimize workflows, enhance dosing accuracy, and predict potential errors. For example, AI algorithms can identify inefficiencies and recommend process improvements, empowering pharmacists to make informed, data-driven decisions.

Emerging technologies offer promising avenues for further advancements in drug preparation. The integration of 3D printing, nanotechnology, and blockchain presents novel opportunities. 3D printing could enable the creation of patient-specific drug delivery systems, enhancing personalized medicine [3]. Nanotechnology holds potential for developing highly targeted and effective treatments, improving therapeutic outcomes with reduced side effects. Meanwhile, blockchain technology can bolster traceability and transparency throughout the supply chain, ensuring secure and verifiable records for each step of the drug preparation process.

Telepharmacy is another transformative innovation, particularly in remote or underserved regions. This approach allows pharmacists to provide consultations, oversight, and verification remotely through digital platforms, ensuring consistent standards of care. Telepharmacy not only expands access to essential pharmacy services but also helps distribute workload more efficiently, fostering greater operational resilience and equity.

1.6. Stability

Ensuring the stability of compounded drugs is essential for maintaining their therapeutic efficacy and safety. Stability refers to a drug's ability to retain its original properties, such as potency, purity, and physical characteristics, over time. Several factors influence stability, including storage conditions, handling procedures, and the compatibility of drugs with diluents and containers. Environmental factors, such as light exposure, temperature changes, and humidity, can degrade a drug's active ingredients, potentially diminishing its effectiveness or even creating harmful byproducts.

Guidelines like USP <797> provide essential recommendations to safeguard drug stability during compounding. These guidelines address key considerations such as selecting appropriate containers, using stabilizing agents, and ensuring optimal storage conditions. Ongoing research into stabilizing agents, improved packaging materials, and real-time monitoring technologies continues to address these challenges, improving the overall stability of compounded drugs. For example, advancements in packaging materials that protect against environmental factors help prolong the shelf life of drugs, while real-time monitoring systems alert pharmacy staff to any potential stability concerns.

The stability of oncology medications is particularly critical, as these drugs often have narrow therapeutic windows and are highly sensitive to environmental conditions. Any loss of stability can result in reduced efficacy or increased toxicity, which can be dangerous for patients [4]. Therefore, adherence to established guidelines and the use of advanced technologies to monitor and preserve stability is vital for ensuring the safe use of intravenous oncology drugs.

Techniques such as high-performance liquid chromatography (HPLC) and mass spectrometry are increasingly employed to monitor drug stability [5]. These methods allow for precise chemical analysis, enabling pharmacists to detect any degradation or changes that might indicate instability. Furthermore, stability-indicating assays are used to identify and quantify any degradation products, ensuring that compounded preparations remain safe and effective for the intended duration of use.

2. Safety in Intravenous Oncology Drug Preparation

2.1. Importance of Safety in Oncology Drug Preparation

The preparation of intravenous oncology drugs involves handling hazardous materials that pose significant risks to both healthcare workers and patients. Exposure to cytotoxic drugs can result in serious health issues, such as acute toxicity, reproductive health problems, and even cancer. Given these risks, strict adherence to safety protocols is essential to minimize potential harm and ensure the safety and efficacy of the medications being prepared.

2.2. Common Safety Protocols and Guidelines

Several guidelines and standards govern the safe preparation of intravenous oncology drugs. Two key standards are:

- 1) **USP <797>**: This guideline provides detailed recommendations for sterile compounding to ensure the safety, sterility, and efficacy of compounded sterile preparations. It includes directives for maintaining a controlled environment and preventing contamination during the compounding process.
- 2) **USP <800>**: This standard focuses on the handling of hazardous drugs, such as chemotherapy agents. It provides protocols for their receipt, storage, compounding, dispensing, and administration, aiming to minimize exposure and protect healthcare workers from potential harm.

2.3. Strategies for Minimizing Contamination and Exposure Risks

Several strategies are critical in minimizing contamination and exposure risks in oncology drug preparation:

- 1) **Use of Personal Protective Equipment (PPE)**: Proper use of gloves, gowns, masks, and eye protection is essential in reducing exposure to hazardous drugs. PPE acts as a barrier between the healthcare worker and the cytotoxic substances.
- 2) **Engineering Controls**: The use of biological safety cabinets (BSCs) and compounding aseptic containment isolators (CACIs) is crucial in creating a controlled, sterile environment for drug preparation. These devices help contain hazardous drugs and prevent contamination.
- 3) **Training and Education**: Continuous education and training for pharmacy staff on safe handling practices, including updated safety protocols, are essential in ensuring that all personnel are aware of and adhere to the necessary safety measures.
- 4) **Environmental Monitoring**: Regular monitoring of compounding areas for contamination is necessary to detect and address any risks. Routine checks and audits help maintain high safety standards and ensure the compounding environment remains compliant with safety protocols.

2.4. Case Studies or Data on Safety Breaches and Their Impact

A notable case study highlighting the importance of safety in drug preparation is the contamination incident at the New England Compounding Center in 2012. This breach resulted in a fungal meningitis outbreak that affected over 750 patients and led to 64 deaths. This tragic event underscores the need for stringent safety protocols and regulatory oversight to prevent similar incidents in the future. The outbreak prompted widespread changes in safety practices and reinforced the importance of adhering to USP <797> and USP <800> standards to prevent contamination and protect patients [6].

2.5. Future Directions in Enhancing Safety

To further enhance safety in oncology drug preparation, future advancements may include:

- 1) **Enhanced PPE and Engineering Controls:** Development of more advanced protective equipment and compounding technologies, such as improved isolators and safer handling devices, will continue to improve safety.
- 2) **Automated Systems:** Increased automation in drug preparation can reduce the risk of human error and minimize exposure to hazardous substances. Automated compounding devices and robotic systems can ensure precision while enhancing worker safety.
- 3) **Continuous Education and Policy Updates:** Ongoing education for healthcare workers, combined with regular updates to safety guidelines based on the latest research and technological innovations, will ensure that safety standards evolve to meet new challenges and improve overall safety in drug preparation.

3. Efficiency in Compounding Intravenous Chemotherapeutics

3.1. Defining Efficiency and Its Importance in Drug Preparation

Efficiency in drug preparation refers to streamlining processes to meet the high demand for oncology medications while reducing waste and upholding safety and quality standards [7]. Effective workflows are crucial for ensuring timely patient treatment, optimizing resource management in pharmacy settings, and minimizing delays. Achieving a balance between speed and safety is critical in oncology drug preparation, where precision is essential due to the sensitive nature of the drugs.

3.2. Current Processes and Workflows in Compounding

The typical workflow in compounding intravenous chemotherapeutics includes the following steps:

- 1) **Prescription Verification:** Verifying the accuracy of the prescribed medication, dosage, and patient-specific requirements to ensure the right drug is used.
- 2) **Compounding Process:** Accurately measuring, mixing, and preparing the drug under sterile conditions to ensure a safe final product.
- 3) **Quality Control:** Conducting checks on the compounded drug to verify its integrity and correctness, ensuring it meets safety and efficacy standards.
- 4) **Labeling and Dispensing:** Properly labeling the medication with relevant details, such as patient information, drug instructions, and storage conditions, before preparing it for patient administration.

3.3. Technological Advancements Enhancing Efficiency

Technology has played a crucial role in improving efficiency in compounding:

- 1) **Automated Compounding Devices (ACDs):** These systems automate the precise measuring and mixing of drugs, significantly reducing preparation time and human error, while ensuring consistency in dosages.
- 2) **Pharmacy Management Software:** This software helps streamline workflows by handling inventory, prescription management, and documentation. It minimizes manual tasks and enhances overall efficiency within the pharmacy.
- 3) **Telepharmacy:** Telepharmacy allows remote prescription verification, supervision of compounding processes, and consultations, improving access to pharmacy services, especially in underserved areas, while optimizing workflow.

3.4. Examples of Time and Cost Savings

Data shows that automated compounding systems can reduce preparation time by around 25% and decrease medication errors by 50% [8]. The adoption of pharmacy management software also results in cost savings by minimizing waste and optimizing resource use, which is particularly valuable in oncology, where drug costs are high, and errors can have serious consequences [9].

3.5. Challenges in Balancing Efficiency and Safety

Despite technological advancements, maintaining a balance between efficiency and safety is challenging:

- 1) **Resource Management:** Ensuring sufficient staffing and resources to handle increasing demands is essential to maintaining both efficiency and safety.
- 2) **Training:** Continuous training is necessary for staff to effectively use new technologies and stay updated on best practices in drug preparation.
- 3) **Compliance:** Efficiency initiatives must not compromise safety protocols. Strict adherence to guidelines like USP <797> and USP <800> remains critical to avoid errors and ensure patient safety.

4. Innovative Technologies in Oncology Drug Preparation

4.1. Overview of Cutting-Edge Technologies Used in Drug Preparation

Advancements in drug preparation technologies focus on improving precision, safety, and efficiency. The integration of these technologies plays a significant role in optimizing the compounding process for oncology drugs. Key innovations include:

- 1) **Robotics and Automation:** Robotic systems and automated devices are used to carry out precise, repetitive tasks in the drug compounding process. These systems enhance consistency and accuracy, reducing the risk of human error.
- 2) **Advanced Aseptic Techniques:** Modern aseptic techniques, such as the use of isolators and laminar flow hoods, are employed to maintain a sterile environment during drug preparation, minimizing the risk of contamination, particularly when handling hazardous drugs.
- 3) **Artificial Intelligence (AI):** AI-driven systems support various stages of drug preparation by assisting with dose calculations, optimizing workflows, and detecting potential errors. These systems analyze large datasets, identify patterns, and make recommendations to improve accuracy and efficiency in drug compounding.

4.2. Robotics and Automation in Compounding

Robotic systems, like the RIVA (Robotic IV Automation) platform, have demonstrated improvements in both the accuracy and efficiency of drug compounding [10]. These technologies reduce human intervention, which helps minimize contamination risks and exposure.

4.3. Advanced Aseptic Techniques

Techniques such as closed system transfer devices (CSTDs) and enhanced airflow systems in compounding areas are key in preserving a sterile environment, effectively lowering the chances of contamination during the preparation process [11].

4.4. Use of AI and Machine Learning for Precision and Accuracy

AI and machine learning technologies can process large datasets to fine-tune dosing protocols, predict possible errors, and optimize workflow. These innovations contribute to greater accuracy and consistency in the compounding process [12].

4.5. Future Trends and Potential Technologies in Development

Several emerging technologies show promise for revolutionizing drug preparation in the future:

- 1) **3D Printing:** Could enable the development of customized drug delivery systems tailored to individual patient needs [13].
- 2) **Nanotechnology:** Holds potential for creating nanocarriers that enhance targeted drug delivery and improve stability.

- 3) **Blockchain:** Offers the potential to enhance traceability and security across the drug supply chain.

5. Stability of Intravenous Oncology Drugs

5.1. Importance of Drug Stability for Patient Outcomes

The stability of drugs is vital for ensuring their effectiveness and safety in oncology treatments. Instability can result in drug degradation, loss of potency, and the production of harmful by-products, all of which can negatively affect patient outcomes [14].

5.2. Factors Influencing Drug Stability

Various factors impact the stability of compounded drugs:

- 1) **Storage Conditions:** Factors such as temperature, light exposure, and humidity can compromise stability.
- 2) **Handling Procedures:** Proper handling and transport practices are essential to preserving drug integrity.
- 3) **Compatibility:** Ensuring that drugs are compatible with their diluents and containers is crucial for maintaining stability.

5.3. Guidelines for Maintaining Stability

Standards like USP <797> offer comprehensive guidelines to ensure the stability of compounded sterile preparations. These guidelines outline the appropriate storage conditions, handling procedures, and recommendations for determining beyond-use dates [15].

5.4. Case Studies on Stability Problems and Their Solutions

Inadequate storage of certain chemotherapy drugs has led to stability challenges, including diminished efficacy and increased adverse effects. Adhering to strict storage protocols has successfully addressed these issues, preserving drug quality and safeguarding patient health.

5.5. Advances in Enhancing Drug Stability

Ongoing research is exploring new strategies to improve drug stability, including:

- 1) **Stabilizing Agents:** The development of new excipients and additives that enhance stability.
- 2) **Improved Packaging:** Utilizing advanced packaging materials that offer superior protection against environmental factors.
- 3) **Real-time Monitoring:** Incorporating sensors and monitoring systems that track drug stability continuously.

6. Discussion

6.1. Summary of Key Insights

This review emphasizes key advancements and ongoing challenges in the preparation of intravenous oncology drugs. The interconnected factors of safety, efficiency, innovation, and stability play a critical role in enhancing the quality and effectiveness of the compounding process.

6.2. Connections between Safety, Efficiency, Innovation, and Stability

- 1) **Safety and Efficiency:** Streamlining workflows can improve safety by reducing the time that drugs spend in environments that may compromise sterility.
- 2) **Innovation and Stability:** Cutting-edge technologies like automation and AI contribute to both the precision and long-term stability of compounded drugs.

- 3) **Efficiency and Innovation:** Technological advancements simplify processes, helping to cut down on preparation times and associated costs.

6.3. Existing Gaps in Research and Practice

Although progress has been made, challenges remain in fully adopting new technologies in everyday practice and ensuring consistent application of safety protocols.

6.4. Suggestions for Future Research and Practice

Adoption of Emerging Technologies: Ongoing research into the integration of robotics, AI, and similar innovations into pharmacy operations is crucial.

Standardization of Protocols: Developing uniform protocols across various settings is essential to ensure consistent safety and efficiency in drug preparation.

Ongoing Education and Training: Providing continuous education for healthcare professionals on the latest technologies and safety guidelines is necessary to maintain high standards.

Investment in Real-Time Monitoring Systems: Enhanced monitoring and data analysis technologies should be incorporated to further improve drug stability and optimize overall efficiency.

6.5. Discussions in China

Experts in PIVAS (Pharmacy Intravenous Admixture Service) from across China have come to a preliminary consensus after extensive discussions:

Addressing New Challenges: The "centralized intravenous drug dispensing model" is seen as an essential future direction for intravenous infusion dispensing in China. With the ongoing resolution of pricing issues, the construction of PIVAS will enter a phase of rapid growth. Therefore, hospital pharmacy departments need to fully embrace the PIVAS concept, strengthen the recruitment of specialized technical staff, and develop professional standards for intravenous drug dispensing.

- 1) **Innovating New Approaches:** As the centralized dispensing model expands to more hospitals, it will reach more patients. However, many hospitals, especially among the 2,548 tertiary hospitals and numerous secondary hospitals across the country, still rely on nurses administering intravenous medications directly in the wards. This process consumes valuable nursing time and introduces risks to patient safety and nurse exposure. While pushing for broader PIVAS adoption, it is important to explore diverse models of centralized intravenous drug distribution.
- 2) **Exploring Diverse Models:** China's centralized intravenous drug dispensing system is the largest and most standardized in the world. However, many foreign countries employ various models, including centralized distribution from a single hospital pharmacy to multiple hospitals, or shared dispensing centers among several hospitals. In China, exploring these diverse models could reduce redundant investments and enhance efficiency, thereby expanding the reach of centralized drug dispensing within existing hospitals.
- 3) **Policy Support:** Pilot programs should begin in selected regions and hospitals, starting with drugs known for their stability. This will provide a demonstration effect to address challenges in hospitals where establishing dispensing centers is not feasible. However, these programs heavily depend on clear policy support for effective implementation.
- 4) **Technological Advancements:** Over the past two decades, China's approach to centralized intravenous drug dispensing has continuously evolved and improved, reaching internationally recognized standards. Comparing with inter-

national practices, Chinese PIVAS experts should continue to explore advancements in sterile drug preparation and the stability of finished infusions, further enhancing the working models and technical standards of PIVAS in China.

7. Conclusion

The preparation of intravenous oncology drugs is a complex process that requires careful attention to safety, efficiency, innovation, and stability. Each of these elements plays a critical role in ensuring that patients receive optimal care while minimizing risks.

7.1. Safety

Ensuring safety is the top priority when preparing intravenous oncology medications. Given the hazardous nature of chemotherapy drugs, strict adherence to guidelines like USP <797> and USP <800> is necessary to prevent contamination and occupational exposure. It is essential to implement strong safety protocols, including personal protective equipment (PPE), biological safety cabinets (BSCs), and thorough training for pharmacy staff. These precautions help create a controlled environment that reduces the risk of contamination and exposure, protecting both healthcare workers and patients.

Past incidents, such as the contamination at the New England Compounding Center, highlight the importance of stringent safety measures and regulatory oversight. By following established protocols and continuously refining safety practices, pharmacy settings can avoid similar problems and ensure the safe preparation of oncology drugs. Cultivating a safety-first culture where staff feel comfortable reporting concerns is also vital for maintaining high standards.

7.2. Efficiency

Efficiency in drug preparation is crucial to meet the high demand for oncology treatments. Technological innovations like automated compounding devices (ACDs) and pharmacy management software have significantly increased efficiency by reducing preparation times and minimizing errors. These tools streamline workflows, helping pharmacists manage inventories, track prescriptions, and coordinate drug preparation steps more effectively.

However, balancing efficiency with safety is a challenge. Speeding up the preparation process must not come at the expense of maintaining strict sterile conditions. Efficient resource management, ongoing staff training, and adherence to safety protocols are essential for maintaining this balance. Additionally, improving efficiency can result in cost savings for healthcare facilities, enabling better allocation of resources to patient care and other critical areas.

Human factors are also key to enhancing efficiency. Clear communication between pharmacists, physicians, and nurses ensures prompt resolution of any issues, minimizing treatment delays. Implementing lean management practices can help identify and eliminate inefficiencies, optimizing resource use and improving overall workflow.

7.3. Innovative Technologies

The adoption of advanced technologies, including robotics, automation, and artificial intelligence (AI), has transformed the preparation of intravenous drugs. Robotic systems improve precision and minimize human error by automating both repetitive and intricate tasks. These robots operate within sterile environments, reducing the potential for contamination.

Modern aseptic techniques, such as isolators and laminar flow hoods, further enhance the controlled environment to protect both the drug and pharmacy staff. AI systems can optimize dosing and streamline workflows by analyzing large datasets to identify trends that improve both accuracy and efficiency.

Looking ahead, emerging technologies like 3D printing, nanotechnology, and blockchain could further enhance drug preparation by improving safety, efficiency, and traceability. Additionally, telepharmacy is becoming an important innovation, enabling pharmacists to provide remote consultations, supervision, and verification services, thus improving access to pharmacy services and distributing workloads more evenly.

7.4. Stability

Maintaining the stability of compounded drugs is vital to preserving their effectiveness and safety. Stability refers to how well a drug retains its original characteristics over time, including its potency, purity, and physical properties. Factors like storage conditions, handling procedures, and compatibility with diluents and containers can all affect a drug's stability.

Guidelines such as USP <797> offer comprehensive recommendations to ensure drug stability. Research continues to advance, focusing on stabilizing agents, enhanced packaging, and real-time monitoring systems to address stability challenges and improve patient outcomes. Advanced techniques, like high-performance liquid chromatography (HPLC) and mass spectrometry, are increasingly utilized to assess drug stability.

Ensuring stability is especially critical for oncology drugs, which often have narrow therapeutic windows and are sensitive to environmental conditions. Any instability can compromise drug effectiveness or increase toxicity, leading to significant risks for patients. Following guidelines and adopting new technologies are key to ensuring the safe and effective use of intravenous oncology medications.

7.5. Future Directions and Recommendations

As the field of intravenous oncology drug preparation continues to evolve, several key areas require further exploration and development to address growing demands and challenges:

- 1) **Adoption of Emerging Technologies:** Ongoing research and investment in technologies like AI, 3D printing, and nanotechnology can significantly enhance the precision, safety, and efficiency of drug preparation. These advancements have the potential to transform current practices and open new avenues for personalized and targeted cancer treatments.
- 2) **Standardization of Protocols:** While existing guidelines such as USP <797> and USP <800> offer a foundational framework, there is a pressing need for universally standardized protocols. This would help ensure consistency in various healthcare settings and improve overall safety and quality in drug preparation.
- 3) **Continuous Education and Training:** Regular training programs are essential for pharmacy staff to stay updated on the latest technologies, protocols, and best practices. This ongoing education is crucial for maintaining a high level of competency, minimizing errors, and enhancing the quality of care provided to patients.
- 4) **Implementation of Real-Time Monitoring:** The introduction of real-time monitoring systems can offer immediate feedback on drug stability and preparation processes. These systems will allow pharmacy staff to quickly identify and address potential issues, enhancing drug integrity and patient safety.
- 5) **Improved Collaboration and Communication:** Strengthening the collaboration between pharmacists, physicians, nurses, and other healthcare professionals is essential for optimizing drug preparation and administration. Effective teamwork and information sharing can improve workflow efficiency and ultimately lead to better patient outcomes.

The preparation of intravenous oncology drugs is integral to cancer treatment, requiring high precision, safety, and efficiency. By embracing technological advancements, adhering to stringent safety protocols, and ensuring drug stability, healthcare providers

can significantly improve the quality of care for oncology patients. As research and innovations continue to shape the field, new opportunities will arise to enhance practices and patient outcomes. Through ongoing improvements and a commitment to excellence, the preparation of intravenous oncology drugs can continue to evolve, ultimately advancing patient safety and treatment efficacy.

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Appendix A: Detailed Case Study on Contamination Incident

Background: Overview of the New England Compounding Center contamination incident.

Impact: Analysis of the consequences and affected patients.

Resolution: Steps taken to address the contamination and prevent future incidents.

Appendix B: Survey on Pharmacy Staff Training and Compliance

Methodology: Description of survey design and participants.

Findings: Summary of results highlighting gaps in training and compliance.

Recommendations: Proposed measures to enhance training programs and ensure compliance with safety protocols.

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