Lost in Translation: Ethical Dilemmas in Medical Manufacturing Instructions

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Learning Objectives

1. **Analyze the operational and ethical challenges posed by ambiguous, impractical, or inaccessible Instructions for Use (IFUs) in medical device reprocessing.**
2. **Discuss how unclear IFUs increase the burden on healthcare facilities, leading to non-compliance, errors, and potential harm to patients.**
3. **Recommend strategies for manufacturers to improve IFU clarity, accountability, and collaboration with healthcare providers to enhance patient safety and operational efficiency.**
4. **Promote partnerships between manufacturers, healthcare facilities, and regulatory bodies to ensure that IFUs are practical, accessible, and tested for real-world conditions.**

Instructions for Use (IFUs) are essential for guiding healthcare providers in reprocessing medical devices. However, many IFUs remain vague, impractical, or inaccessible, presenting challenges that facilities must navigate without adequate support. Many specify chemistries or products that are not manufacturer-neutral, forcing facilities to adapt to instructions that may not align with their resources. Some IFUs also fail to account for real-world conditions, leaving sterile processing departments (SPDs) and healthcare teams to navigate unclear guidance that was never tested in collaboration with end-users.

Currently, hospitals and manufacturers have regulatory options to ensure some level of postmarket oversight and compliance. In the United States, the FDA mandates programs such as Medical Device Reporting (MDR) to monitor device-related adverse events and product issues, such as those regarding IFUs (FDA, 2024). Facilities are also subject to postmarket surveillance orders under Section 522 of the Federal Food, Drug, and Cosmetic Act, which allows the FDA to require studies addressing specific safety or effectiveness concerns for certain devices (FDA, 2024).

While these mechanisms are important for ensuring safety, they often fall short in addressing the practical challenges posed by IFUs in real-world scenarios. The industry needs actionable change and real-time support from manufacturers, who have a moral obligation to prioritize patient well-being. In healthcare, ethical principles such as beneficence, non-maleficence, and justice should guide the evaluation and improvement of processes affecting patient care. These ethical dilemmas, their impact on healthcare providers and patients, and actionable steps to improve IFU usability, reduce compliance burdens, and prioritize patient safety are examined here.

The Ethical Dilemma of IFUs and Real-World Challenges

IFUs are intended to ensure the safe and effective use of medical devices, yet their inadequacies often create ethical dilemmas. These dilemmas arise when manufacturers produce IFUs that:

- Use complex or ambiguous language, leaving healthcare providers to interpret critical instructions.
- Require specific resources or chemistries that may be unavailable in many healthcare environments.
- Present unrealistic or impractical instructions that fail to account for real-world constraints.

Such shortcomings lead to confusion, non-compliance, and increased risks for both patients and healthcare facilities. At the heart of this issue lies the ethical principle of non-maleficence, which obligates manufacturers and healthcare providers to avoid causing harm. When unclear or impractical IFUs result in improper device usage, patient safety is directly compromised, violating this principle. Furthermore, justice, which

demands fairness and equitable access to safe and effective healthcare, is often neglected when facilities with limited resources are unable to comply with IFU requirements.

IFUs are crucial documents that guide healthcare providers in the safe and effective reprocessing of medical devices. However, many IFUs fall short in terms of practicality and accessibility. Their complexity often forces healthcare facilities to adapt processes that may not align with available resources. In some cases, IFUs do not account for real-world conditions or fail to involve end-users in their creation, leaving sterile processing departments (SPDs) and healthcare teams to navigate IFU's on their own.

Take, for example, the reprocessing of tracheostomy tubes. Some IFUs specify the exclusive use of a detergent that may not be available in home health settings or even in many healthcare facilities. In addition, these IFUs may require tracking reprocessing cycles without providing practical methods for doing so, as critical serial numbers are often printed on disposable packaging. As a result, caregivers and healthcare providers are left to rely on guesswork or improvisation, such as marking the devices themselves, which can raise additional concerns about accuracy and safety. These gaps in guidance create significant risks, leaving SPDs uncertain about how many times trachs have been reprocessed across different settings, and whether their sterilization efforts are truly doing more harm than good.

Another example is IFUs that specify differing limits for device usage and sterilization cycles but fail to offer practical solutions for tracking each of these. Facilities are often unable to attach labels, RFID codes, or other tracking mechanisms because IFUs either omit that these options are possible or explicitly prohibit them. This forces SPDs and caregivers to improvise, increasing the likelihood of errors, device degradation, and noncompliance during audits.

Unfortunately, many facilities are forced to invest in costly tracking systems or additional equipment to manage these devices. Yet even with these measures, critical gaps remain because such systems cannot account for the differing requirements of tracking device usage and sterilization cycles. For example, end-users in clinical settings might open a device five times for patient care but only use it three times. Both usage and sterilization cycles must be tracked at different intervals to ensure compliance and safety. End-users must know both the total number of uses and the number of sterilization cycles, as devices should be discarded based on whichever limit is reached first. However, SPDs can only monitor sterilization cycles, as they are not involved in direct patient care or device use. This disconnect leaves end-users, such as nurses or physicians, without a reliable mechanism to track usage accurately or determine when a device has reached its disposal threshold. Without alignment between end-users and SPDs, even the most advanced tracking systems fall short, creating ongoing risks to compliance, usability, and patient safety.

Manufacturers must prioritize patient safety by creating IFUs that are clear, universally applicable, and tested in diverse environments. Furthermore, manufacturers have an ethical obligation to offer ongoing updates and support as challenges emerge. By bridging the gap between theoretical guidelines and real-world implementation, they can safeguard patient outcomes while reducing the burden on healthcare providers.

Patient Safety and Compliance Risks

When IFUs are poorly written or impractical, the burden shifts to healthcare facilities. For example,

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1. A, 2. B, 3. C, 4. B, 5. B, 6. C, 7. C, 8. D, 9. C, 10. D, 11. C, 12. B

facilities may need to invest time and resources in reaching out to manufacturers and prompting them to invest in third-party sterilization testing to verify compatibility with sterilization methods not found on current IFUs. While necessary, this adds costs and administrative work on both the manufacturer and the healthcare facility that could be avoided if manufacturers partnered with facilities and SME's during the design and testing phases.

Additionally, healthcare facilities face tough decisions when patients arrive with custom or degraded devices that require sterilization. Should they reprocess a patient's only tracheostomy tube when an emergency arises away from their homes, not knowing if it may have been over-reprocessed in other facilities already? These challenges highlight the need for manufacturers to collaborate with facilities to provide actionable solutions that reduce ambiguity and prioritize patient safety.

Ambiguous or impractical IFUs can have significant implications for both patient safety and facility compliance. One common example involves sterilization chemistries, such as the use of vaporized hydrogen peroxide versus hydrogen peroxide gas plasma. Some IFUs authorize the use of only one of these sterilization methods while neglecting to include guidance for the alternate method frequently employed in healthcare settings.

This lack of clarity often leads to confusion, with healthcare providers mistakenly assuming that similar sterilization methods, such as the two types of hydrogen peroxide, are interchangeable. However, using an unapproved sterilization process could compromise the device's integrity and safety, ultimately putting patients and hospitals at risk. This leaves facilities who do not have the appropriate equipment unable to process or follow IFUs for specific devices. Furthermore, those life-saving devices that could potentially be used on patients, cannot be obtained due to these IFU limitations.

When auditors visit healthcare facilities, they frequently review sterilization processes and request the corresponding IFUs to verify compliance. If a facility has used a sterilization method not explicitly outlined in the IFU, auditors may question the validity of the process, prompting facilities to conduct detailed risk assessments to justify their decisions. This process often involves obtaining written addendums, testing updates, or verification from manufacturers that alternative sterilization methods are safe and effective. Many facilities go even further, gathering consensus documents, white papers, and published research to substantiate their practices and ensure compliance with safety standards. While these efforts are critical for safeguarding patient outcomes, they fall outside the scope of the original IFUs and require sterile processing leaders to create extensive documentation to address auditor concerns.

Proving compliance under such circumstances is both labor-intensive and resource-draining. Teams must conduct thorough risk assessments, coordinate with manufacturers, and maintain meticulous records to demonstrate validation of their processes. Even with these exhaustive efforts, facilities may face scrutiny if auditors find the documentation insufficient, putting compliance and accreditation at risk. For instance, transitioning from High-Level Disinfection to an alternative sterilization method necessitates manufacturer-supplied verification, including testing or written guidance, all of which must be diligently maintained to prove that the process was validated, patient safety was prioritized, and the standard of care was upheld. This reactive approach highlights the pressing need for manufacturers to proactively update and include comprehensive, flexible sterilization guidelines in their IFUs, alleviating the burden on healthcare providers and ensuring a more efficient pathway to compliance.

Collaboration and Accountability

Effective collaboration between healthcare facilities and manufacturers is essential to addressing the challenges posed by inadequate IFUs. Facility leaders must work closely with manufacturers to request updated IFUs, obtain addendums, and develop practical solutions tailored to their specific operational needs. This effort includes ensuring that sterilization compatibility matrices provided by sterilization equipment manufacturers align with the unique requirements of medical device manufacturers, fostering seamless integration between processes and devices. Proactive communication between both parties not only helps healthcare facilities enhance patient safety but also ensures compliance with industry standards, reducing the risk of errors and inefficiencies.

Manufacturers have a moral obligation to provide this guidance and distribute it broadly across the healthcare industry. If one facility identifies a gap or requires clarification, it is likely that others face similar challenges. By sharing solutions and updates proactively, manufacturers can reduce knowledge gaps, foster transparency, and prevent errors or adverse events caused by unclear or impractical IFUs. This collaborative effort can build trust between manufacturers and healthcare providers while creating a safer, more effective system for all stakeholders.

Building Partnerships for Testing and Compatibility

Collaboration must extend beyond documentation to include comprehensive testing and compatibility efforts. Manufacturers and healthcare facilities should work together to ensure that devices are compatible with various sterilization methods used in diverse healthcare settings,

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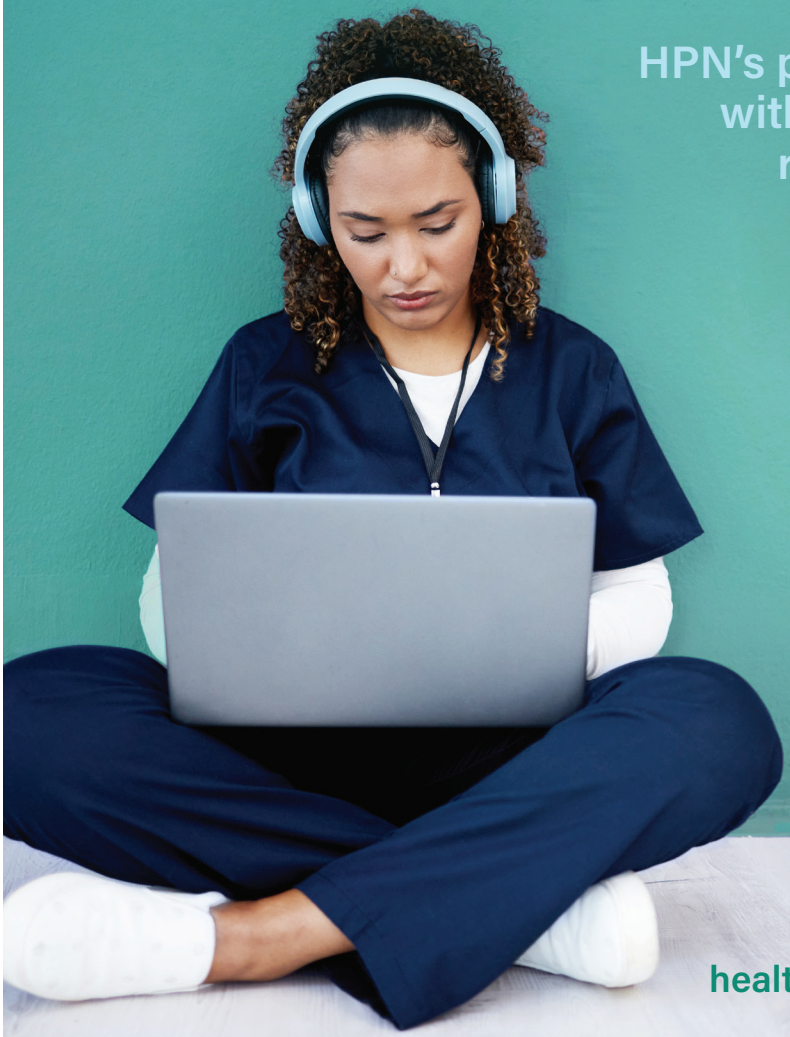

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from steam to low-temperature processes. By partnering with third-party testing companies, manufacturers can validate their devices' compatibility and provide healthcare facilities with clear, actionable guidelines.

While facilities have a responsibility to select devices that align with their reprocessing capabilities, manufacturers play a pivotal role in ensuring the usability of their devices aligns with the diverse and practical needs of healthcare facilities and patients. Innovation and market competition drive advancements, but it is equally essential to prioritize the accessibility and clarity of IFUs. Comprehensive testing and collaboration ultimately serve the shared goal of safeguarding patient outcomes and streamlining healthcare operations while driving innovation.

By fostering these partnerships, the healthcare and manufacturing industries can close critical gaps, ensuring that devices and reprocessing methods align seamlessly with real-world needs. This cooperative approach not only enhances compliance but also strengthens the foundation of trust and reliability needed for optimal patient care.

Proposed Solutions and Recommendations

Addressing the challenges associated with vague, impractical, or inaccessible IFUs requires a multi-faceted approach involving manufacturers, healthcare facilities, and regulatory bodies. The following solutions aim to bridge the gap between theoretical guidelines and real-world application, ensuring patient safety while reducing compliance burdens.

Standardize IFU Language

Instructions for Use (IFUs) should feature clear, concise language to eliminate ambiguity and ensure comprehension across diverse healthcare environments. Engaging subject matter experts (SMEs) and sterile processing professionals in the design and testing phases is crucial to achieving this clarity. This collaboration can identify potential challenges early, ensuring the IFUs are practical, universally applicable, and easy to interpret.

Enhance Manufacturer Accountability and Transparency

Manufacturers must take proactive steps to address gaps in IFUs by providing regular updates, addendums, and supplementary materials to all stakeholders—not just those who request clarification. Solutions such as sterilization compatibility matrices, tailored to diverse methods and settings, should be made readily available.

Foster Industry Collaboration

Manufacturers and sterilization equipment companies should establish partnerships to address compatibility issues. By collaborating with third-party testing companies, manufacturers can verify device compatibility with a range of sterilization methods, from steam to low-temperature processes.

Expand Access to Resources and Support

Manufacturers must prioritize the development of IFUs that recommend manufacturer-neutral chemistries and processes to increase accessibility. Additionally, they should offer training materials, online resources, and live support to guide facilities in implementing IFUs effectively.

Leverage Technology for Tracking and Compliance

To address the challenge of tracking reprocessing and usage cycles for certain devices, manufacturers should implement innovative solutions, such as embedding serial numbers directly on the devices and offering online tracking solutions for these items. These technologies should be included in the Instructions for Use (IFUs) with clear guidance on proper usage and compatibility, enabling healthcare facilities and families to meet compliance and safety requirements.

Proactive Risk Assessment and Adaptation

When IFUs are inadequate or incomplete, healthcare facilities must conduct risk assessments in collaboration with manufacturers to validate alternative processes. Facilities should maintain thorough documentation of any deviations, including manufacturer-supplied addendums or third-party testing results, to safeguard compliance during audits.

Develop a Shared Accountability Framework

Regulatory bodies, manufacturers, and healthcare providers must work together to establish benchmarks for IFU clarity, accessibility, and flexibility. These benchmarks should be enforced through audits and certification programs to ensure widespread adoption.

Conclusion

IFUs are more than instructional documents; they are the foundation of patient safety and compliance in healthcare. The responsibility for navigating unclear or inadequate IFUs cannot rest solely on healthcare facilities. Manufacturers have both an ethical and practical obligation to uphold non-maleficence by producing IFUs that are clear, comprehensive, and adaptable to the complexities of modern healthcare environments, minimizing potential harm to patients. Simultaneously, we must all advocate for the resources, training, and systems that support the ethical principle of justice, ensuring equitable access to safe and effective processes across all healthcare settings without compromising the highest standards of care.

The path forward demands shared accountability and immediate action. By fostering collaboration among

manufacturers, healthcare facilities, and regulatory bodies, we can transform IFUs into reliable, user-friendly resources that protect patient safety, enhance compliance, and empower healthcare providers to deliver optimal care. These changes are not merely necessary, they are essential to uphold the ethical principles of our industry and advance patient care standards. **HPN**

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1. **What is the primary ethical issue discussed in the article regarding IFUs?**
   A. Ambiguity and impracticality of IFUs
   B. Misuse of medical devices
   C. Excessive regulatory requirements
   D. Lack of technological innovation
2. **How do unclear IFUs affect healthcare providers?**
   A. They increase the efficiency of operations
   B. They lead to non-compliance and errors
   C. They reduce the cost of medical equipment
   D. They improve patient outcomes
3. **Which of the following is NOT a consequence of inadequate IFUs?**
   A. Delayed procedures
   B. Increased burden on healthcare staff
   C. Improved understanding of medical devices
   D. Potential harm to patients
4. **What is one key recommendation for manufacturers regarding IFUs?**
   A. To make IFUs as long as possible
   B. To ensure IFUs are clear, practical, and accessible
   C. To reduce the number of IFUs per device
   D. To require patients to read IFUs
5. **Why is collaboration between manufacturers and healthcare providers essential?**
   A. To increase profits
   B. To ensure IFUs are tested under real-world conditions
   C. To avoid regulatory oversight
   D. To reduce the number of devices used
6. **What role does regulatory oversight play in IFU clarity?**
   A. It is not relevant to IFUs
   B. It ensures IFUs are not tested in real-world settings
   C. It helps maintain the clarity and effectiveness of IFUs
   D. It focuses on the marketing of medical devices
7. **What is one solution to the problem of ambiguous IFUs?**
   A. Simplifying all medical procedures
   B. Limiting the use of medical devices
   C. Improving the design and usability of IFUs
   D. Relying solely on staff experience
8. **What does the article suggest about the relationship between healthcare providers and medical device manufacturers?**
   A. It should be one-sided, with manufacturers solely responsible
   B. It should focus only on cost reduction
   C. It is irrelevant to patient safety
   D. It should involve ongoing communication and collaboration
9. **How does the ambiguity in IFUs affect patient safety?**
   A. It does not affect patient safety
   B. It reduces the chances of medical errors
   C. It increases the risk of errors and harm to patients
   D. It helps improve patient care
10. **Which of the following is a proposed benefit of clear, practical IFUs?**
    A. Higher healthcare costs
    B. Decreased efficiency in device reprocessing
    C. More complex procedures
    D. Enhanced operational efficiency and compliance
11. **What is the main goal of addressing the issues with IFUs according to the article?**
    A. To reduce the cost of medical devices
    B. To promote medical device innovation
    C. To ensure better patient safety and operational efficiency
    D. To increase the number of medical devices used
12. **How can industry-wide collaboration improve IFUs?**
    A. By reducing the number of medical devices available
    B. By creating standard practices that prioritize clarity and usability
    C. By focusing only on regulatory compliance
    D. By increasing the complexity of instructions