APIC
Association for Professionals in Infection Control and Epidemiology

MAY 2024

Modernizing Medical Device Instructions for Use (IFUs):

INFECTION PREVENTIONISTS SPEAK UP FOR PATIENT SAFETY

Preface

This manuscript is a project of the Association for Professionals in Infection Control and Epidemiology (APIC) and was developed by APIC staff with input from the APIC Public Policy Committee and subject matter experts in the field of infection prevention and control (IPC).

APIC

APIC is the leading professional association for infection preventionists, with more than 15,000 members. Our mission is to advance the science and practice of infection prevention and control. Most APIC members are nurses, physicians, public health professionals, epidemiologists, microbiologists, or medical technologists who:

- Collect, analyze, and interpret health data to track infection trends, plan appropriate interventions, measure success, and report relevant data to public health agencies.
- Establish scientifically based infection prevention practices and collaborate with the healthcare team to ensure implementation.
- Work to prevent healthcare-associated infections (HAIs) in healthcare facilities by isolating sources of infections and limiting their transmission.
- Educate healthcare personnel and the public about infectious diseases and how to limit their spread.

Many infection preventionists are employed within healthcare institutions. They may also serve as educators, researchers, consultants, and clinical scientists. Although the majority of APIC members are affiliated with acute care settings, an increasing number practice in ambulatory and outpatient settings, where they direct programs that protect patients and personnel from HAIs. APIC members are also involved in long-term care, home health, and other practice settings where infection prevention and control is an increasing area of responsibility for nurses and other healthcare personnel. Visit us at www.apic.org.

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APIC wishes to thank Shanina C. Knighton, PhD, RN, CIC who provided direction on the survey questions.

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Background

Most people do not think of the requirements for cleaning, disinfection, and sterilization of medical devices unless something tragic occurs. For example, stories in the news media of outbreaks related to specific types of medical devices have led to improvements in device reprocessing. These stories have led to focused policy conversations about how devices could be better designed to make safe reprocessing more likely. This paper is intended to focus on the little-known process that guides the current requirements for cleaning the medical devices used daily in healthcare facilities. We believe the current system is inefficient. It creates challenges for healthcare staff striving to comply with CDC cleaning and disinfection guidance, and does not adequately take into account the need to protect patients from healthcare-associated infections.

We believe the current system is inefficient. It creates challenges for healthcare staff striving to comply with CDC cleaning and disinfection guidance, and does not adequately take into account the need to protect patients from healthcare-associated infections.

First, it is important to outline the current regulatory framework related to the cleaning, disinfection, and sterilization of medical devices. The Centers for Medicare and Medicaid Services (CMS) Conditions of Participation (CoPs) require healthcare facilities to appoint an infection preventionist (IP) to oversee the facility's infection prevention and control program (IPCP). The IPCP includes "surveillance, prevention, and control of healthcare-associated infections (HAIs), including maintaining a clean and sanitary environment to avoid sources of transmission of infection..."[1] CMS interpretive guidelines define this as "appropriate monitoring of all hospital departments..." and includes monitoring of housekeeping, maintenance, supply storage, equipment cleaning, and other areas.[2] CMS monitors compliance with these requirements through relationships with several survey entities.

The Centers for Disease Control and Prevention (CDC) provides evidence-based guidelines for infection control in healthcare facilities—including environmental infection control and disinfection and sterilization—based on the Spaulding classification system. The Spaulding classification is a system that categorizes medical devices and instruments according to the risk of infection transmission they pose and determines the level of disinfection or sterilization they require. Spaulding classifications are:

- **"Critical"** devices enter sterile tissue or the vascular system—these devices must be **sterilized** (e.g., surgical forceps).
- **"Semicritical"** devices come into contact with mucous membranes or nonintact skin—these devices must be disinfected using **high-level disinfection** (e.g., endoscopes).
- **"Noncritical"** devices or patient care equipment come into contact with intact skin or do not contact the patient directly (e.g., indirect contact via the hands of the healthcare worker)—these items are disinfected by **intermediate-level or low-level disinfection** (e.g., stethoscopes).[3]

The 1976 amendments to the Federal Food, Drug, and Cosmetic Act require the Food and Drug Administration (FDA) to regulate medical devices and ensure their safety and effectiveness. The FDA oversees many steps in the approval process for medical devices, including providing strict guidelines for labeling and the inclusion of instructions for the device user. Labeling is important to medical devices as without the label intact on a medical device, misuse can occur.[4] The IFU's purpose is to inform the user how to safely use the device and must include procedural steps to follow in setting up, using, cleaning, troubleshooting, and storing a device. For devices which can be reused, instructions for reprocessing (e.g. cleaning, disinfection or sterilization) are included to be compliant with FDA standards for reuse (e.g. low-level disinfection, intermediate-level disinfection, high-level disinfection or sterilization).[5]

Finally, the FDA provides guidance for the formulation and scientific validation of reprocessing instructions for reusable medical devices in "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling—Guidance for Industry and Food and Drug Administration Staff." Within this document, the FDA provides complex requirements for the development of reprocessing instructions. Importantly, these complex instructions do not include clear guidance highlighting the difference between the cleaning needs of reusable devices which come into contact with intact skin (Spaulding classification non-critical) and those that come into contact with mucous membranes, non-intact skin, body fluids or enter sterile areas (Spaulding classification semi-critical and critical). Within the body of the document, the FDA

recommends the cleaning instructions for all types of medical devices should include the following six criteria for reprocessing:

1. Intended use,
2. Cleaning guidance,
3. Appropriate disinfection steps for that device (based on Spaulding classification),
4. Reprocessing directions that should be technically feasible for the intended location and use readily available products,
5. Instructions should be comprehensive, and finally
6. Instructions should be understandable.[6]

With all this guidance there are several elements which direct the manufacturer, who may not have a specialty in infection prevention, to make decisions without providing adequate background. These omissions include choice of disinfectant; for example: "[for non-critical devices…] always consider the worst-case microbes to which the device may be exposed during clinical use, the likelihood of significant organic soiling of the device during use, and the ability of the device material to repeatedly withstand disinfectant contact when selecting a disinfectant to validate and then recommend for use with your device. Also consider the products that are frequently used in health care settings when selecting a disinfectant to study and validate. If a product or class of products can damage the materials in your device, your device label should include a warning not to use that product or class of products to reprocess your device."[7] Additionally, this document does not direct the manufacturer to consider the disinfectant's IFU or the CDC's requirement for hospitals to select and implement EPA approved disinfectants. Guidance refers to complex processes outlined by CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities[8] and/or Association for the Advancement of Medical Instrumentation (AAMI) Standards 79 and 91[9] for devices which require high level disinfection or sterilization, but does not provide supplemental guidance directing the manufacturer to understand the implications of use of certain disinfectants or processes on the user's safety as outlined in guidelines or standards from the Facility Guidelines Institute (FGI), American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE), or Occupational Safety and Health Administration (OSHA).

CMS-approved survey entities defer to the FDA regulation and guidance when they are reviewing compliance with cleaning, disinfection, and sterilization of medical devices. During a facility survey, IPs are often asked to verify that they are following manufacturers' IFUs. However, the survey process does not

[I]nstructions are often not available, difficult to locate, out-of-date, overly complex, brand specific, and/or provide instructions that seem focused on protecting medical devices and their warranties rather than protecting patients from being exposed to pathogens.

distinguish between devices for which there are FDA standards for inclusion of validated cleaning instructions (Class III) and those for which such standards may not be required due to exemption or through the 510(k) premarket approval process (Class I and Class II).[10]

As part of their broader role within healthcare facilities, IPs establish scientifically-based infection prevention practices within their facilities and collaborate with the broader healthcare team to ensure their implementation. This includes preventing HAIs in healthcare facilities by isolating sources of infections, recommending interventions to prevent transmission, and educating healthcare personnel on their role in preventing the spread of infection. To accomplish this, one of the IP's many roles includes monitoring and overseeing adherence to IFUs, although responsibility for carrying out cleaning, disinfection and sterilization likely falls under a variety of individuals. For example, complex medical devices may go to an in-house or an external sterile processing department, while other equipment, such as glucometers or blood-pressure cuffs, are cleaned or disinfected by other personnel at the point of care.

For many years, IPs have raised concerns about medical device IFUs. Specifically, IPs have said that the instructions are often not available, difficult to locate, out-of-date, overly complex, brand specific, and/or provide instructions that seem focused on protecting medical devices and their warranties rather than protecting patients from being exposed to pathogens including multidrug-resistant organisms such as carbapenem-resistant *Enterobacteriaceae* (CRE) and *Candida auris (C. auris)*. Further, manufacturers may update an IFU without routinely informing customers. Nevertheless, surveyors frequently cite facilities for failure to comply with IFUs, which requires IPs to undergo a complex process that involves contacting the manufacturer of the device to obtain clarity on cleaning protocols, or reaching out to the FDA if they cannot get adequate information from the manufacturer. APIC conducted a survey to quantify problems identified in their qualitative assessments of difficulties IPs may have with medical device IFUs. The survey results indicate that difficulties with device IFUs are widespread and should be revised so that healthcare facilities have clear and concise instructions necessary to comply with appropriate cleaning, disinfection, and sterilization of medical instruments to keep patients safe.

Executive Summary

IPs from a broad array of facility types, sizes, and locations in the United States struggle with manufacturers' instructions for use (IFU) that are overly complex, time consuming, unclear, out of date, or difficult to locate. In our survey, 65 percent of IPs agreed or strongly agreed that the primary challenges they faced were for devices that fall into the low and intermediate levels of disinfection based on the Spaulding criteria.

IPs in facilities with one or two IPs on staff were especially likely to make their views known on these issues through our survey. Additionally, IPs at all experience levels, from 0-2 years to 16-plus years, were equally likely to weigh in on these issues.

The reason becomes clear when you realize that, after removing the 17 percent of respondents who were not sure of their citation status, half of the respondents have been cited for failure to follow an IFU. Thirty-five percent of those IPs were able to successfully challenge the citation by providing surveyors with evidence for their practice.

An overwhelming majority of IPs—84 percent—had to reach out to a manufacturer for clarification of an IFU. Another 8 percent of IPs took the additional step of reaching out to the FDA for clarification of an IFU.

To avoid citations and potential patient harm, IPs are currently required to follow a burdensome process which may include seeking input from manufacturers and/or the FDA in real-time to determine how to safely clean, disinfect, and/or sterilize medical instruments. APIC believes this is an unacceptable burden that does not support the goal of preventing the transmission of HAIs.

Data collection is the first step in determining the scope of problems and identifying the initiatives needed to solve them. With the results of this survey APIC calls for the following:

- Developing tools to help IPs and other healthcare personnel navigate the current less-than-optimum process for cleaning, disinfection, and sterilization of medical instruments.
- Bringing problematic IFUs to the attention of manufacturers and the FDA.

- Educating policymakers and healthcare organizations about flaws in the current regulatory framework that limit IPs' ability to protect patients from transmission of HAIs via medical devices.
- Convening stakeholder organizations to work with APIC to propose a new regulatory framework for cleaning, disinfection, and sterilization of medical devices that includes (but is not limited to):
  - A standardized format for IFUs;
  - IFU language which takes into account the needs of infection prevention and control, sterile processing, environmental services, and end users to protect patients;
  - Device labels which are easily accessible to users for the duration of the product's lifespan, indicate when the IFU was last updated, and provide information on who users may contact in case of questions;
  - A public repository for IFUs so that users will have access to appropriate information for devices that are no longer manufactured and/or when the manufacturer is no longer in business.

Introduction

IPs have informed APIC about the difficulty of complying with cleaning instructions in IFUs for many years and have noted that they spend a significant amount of time tracking down IFUs, determining how to appropriately comply with cleaning instructions and ensuring staff are properly educated. Further, they have indicated that IFUs do not seem to be developed with an awareness of current infection prevention and control practices and/or products.

Anecdotal evidence from IPs informed us that this lack of clarity, coupled with surveyors deferring to the FDA on this issue (e.g., requiring use of a specific disinfectant brand because other brands are not listed as approved), resulted in excessive citations and failure to improve outcomes for patients. Instead of clear, updated reprocessing instructions within IFUs that take infection prevention into account, the current system fails to apply current regulatory requirements (e.g., CMS CoPs) and scientific evidence related to preventing risk to patients from HAIs.

Because citations for failure to properly clean, disinfect, or sterilize equipment according to an IFU fall under infection prevention and control, IPC staff must routinely track down IFUs, reach out to manufacturers and/or regulatory agencies and provide recommendations for updates to outdated IFUs to fit current practice and expectations. This puts the onus for proper cleaning, disinfection, and sterilization practices on healthcare personnel and takes infection prevention staff away from other potentially lifesaving work to prevent HAIs.

As a result of these concerns, APIC held focus groups to gain a better understanding of the difficulties IPs experienced with IFUs. With the information gathered in the focus groups, APIC developed and fielded a survey intended to understand the issues/concerns that IPs face with medical device IFUs and quantify the results. The survey will be utilized to inform regulatory agencies, healthcare institutions, and other stakeholders.

Methodology

APIC hosted two focus groups with infection preventionists to document the primary difficulties IPs were having with IFUs for medical devices and hear their recommendations to improve the situation. One focus group was held in-person at the APIC Annual Conference on June 14, 2022, and the second was held virtually on July 27, 2022.

The results of the focus groups were compiled by APIC staff and a survey was developed to quantify problems identified in the qualitative assessments of difficulties IPs were having with IFUs. The survey was advertised via an APIC membership database of active members and was successfully delivered to 12,863 individuals in the database. It was also shared via articles in APIC's eNews weekly newsletter and on social media to facilitate responses from IPs who may not be APIC members.

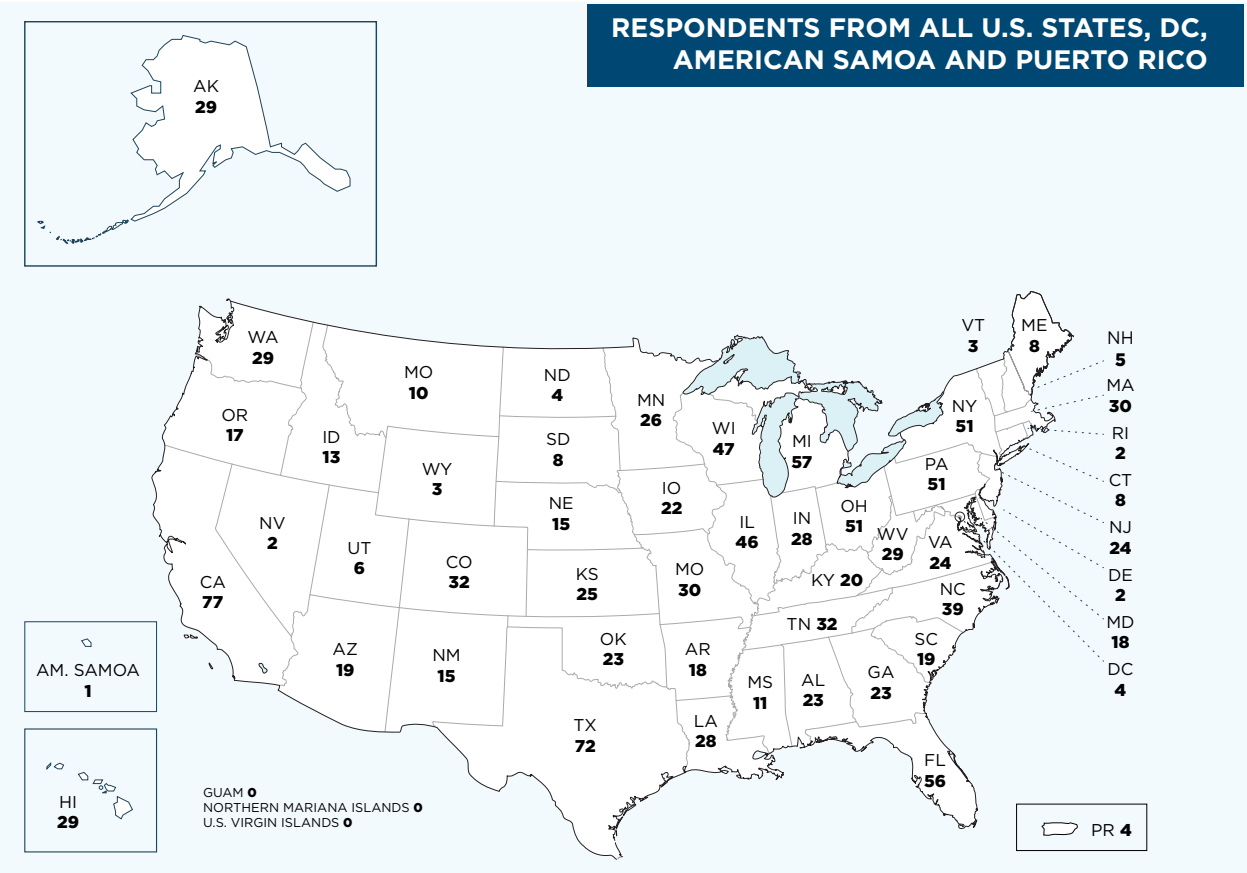
All currently practicing IPs were invited to complete the survey, but instructions stated that only one survey per facility should be completed. Participants were informed that facilities would not be identified in the survey reports. The survey was fielded via Microsoft Forms during the period from March 14 to April 24, 2023.

Of the 1,310 individuals who accessed the survey, 1,198 (91 percent) were eligible to answer the survey by indicating that they were IPs currently practicing in a U.S. healthcare facility.

Demographics

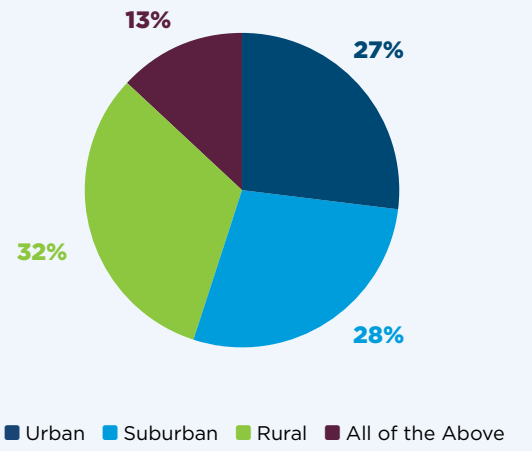
Respondents were asked to indicate the state in which they resided and were provided with a pull-down menu of all 50 states and territories as well as the District of Columbia.

Individuals from all U.S. states, the District of Columbia, American Samoa and Puerto Rico responded.



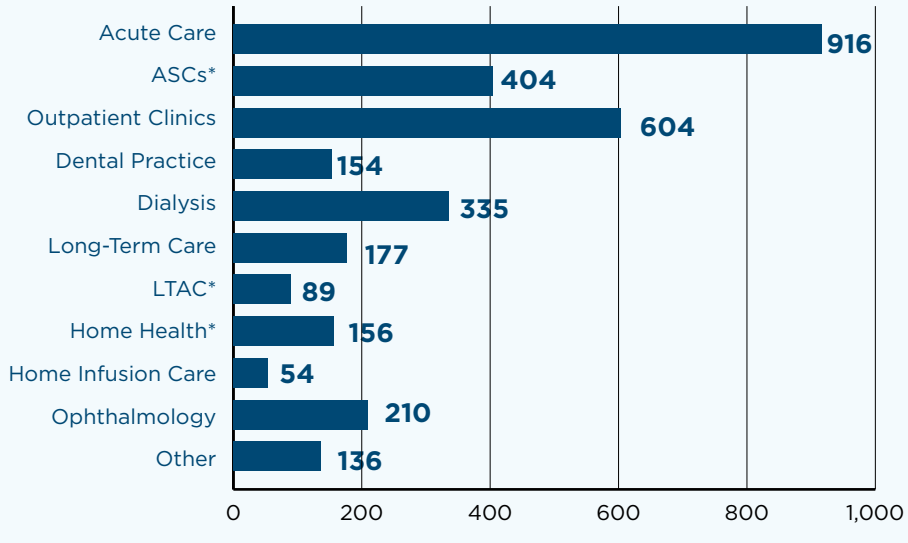
IPs from all settings, urban, rural, suburban, and mixed settings (all of the above) were well-represented in the survey, with urban, suburban, and rural being nearly evenly represented indicating 27 percent, 28 percent, and 32 percent of respondents respectively.

LOCATION OF FACILITES



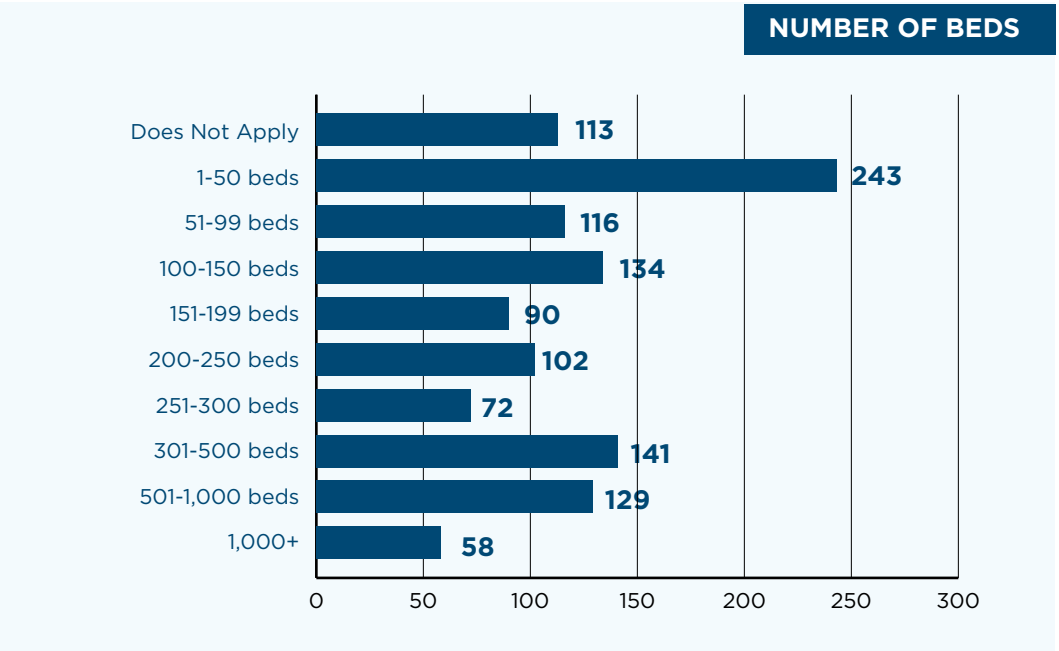
Additionally, individuals from a wide range of practice settings responded to the survey. Respondents could choose as many practice settings as applied. The top three settings represented were acute care, ambulatory surgical centers, and outpatient clinics.

PRACTICE SETTINGS

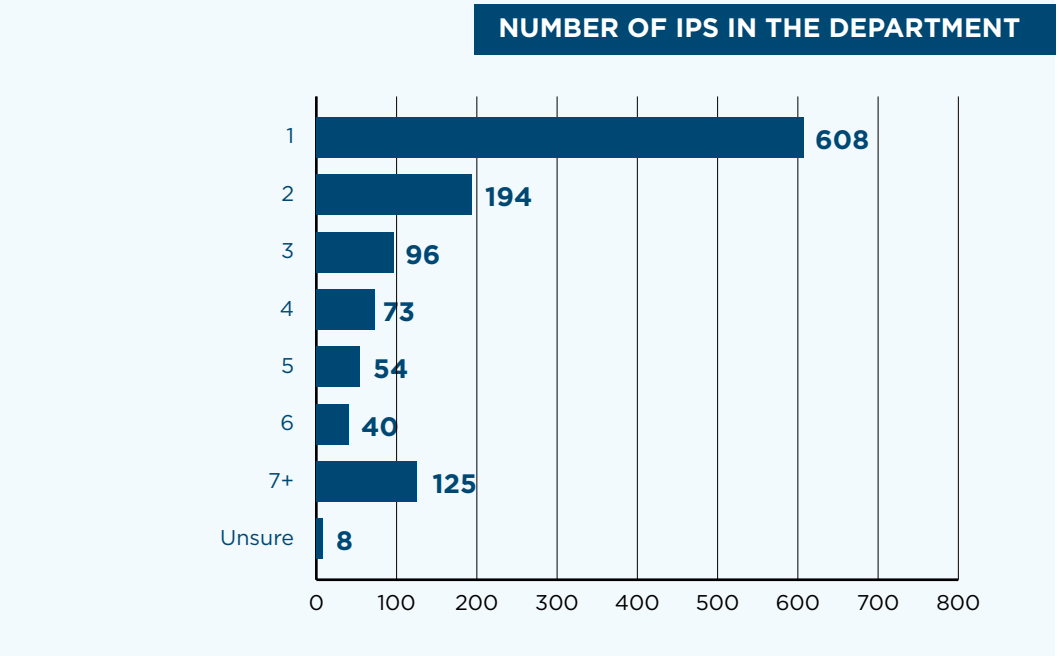


**Home Health includes personal care homes; Ambulatory Surgical Centers are abbreviated ASC; Long Term Acute Care facilities are abbreviated LTAC.*

Respondents were asked to indicate bed-size covered by their infection prevention and control department to the extent that the measure applied to their practice settings. This measure was chosen because it was believed to be the easiest number for IPs to estimate while responding to a survey. Facilities with 1-50 beds were the most well represented in the survey (20.3 percent).

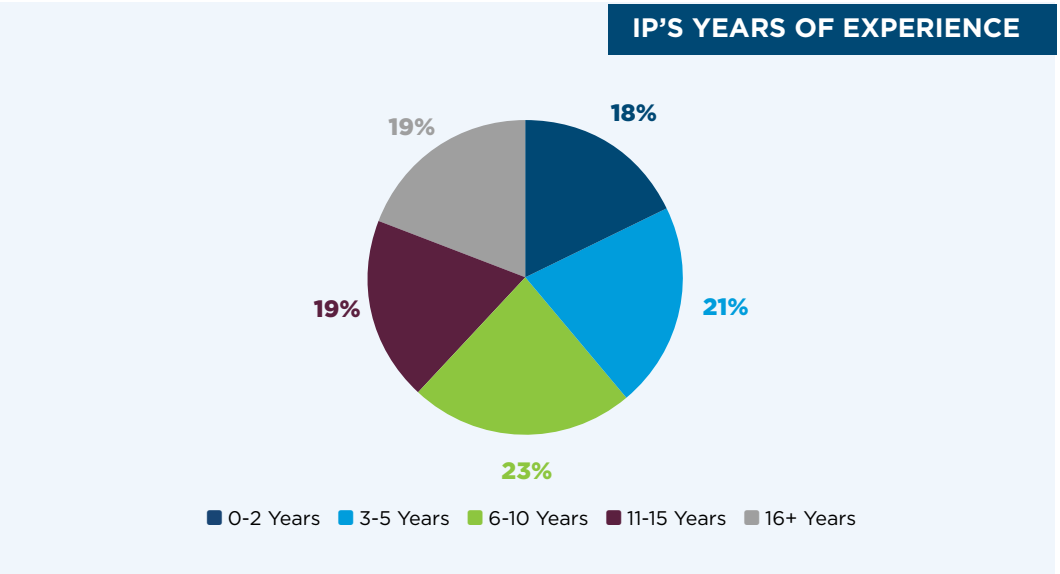


Individuals were also asked how many infection preventionists worked in their department and 50.8 percent (608) indicated that they were the only IP in their department. The second category chosen, two IPs in a department, represented 16.2 percent of respondents.



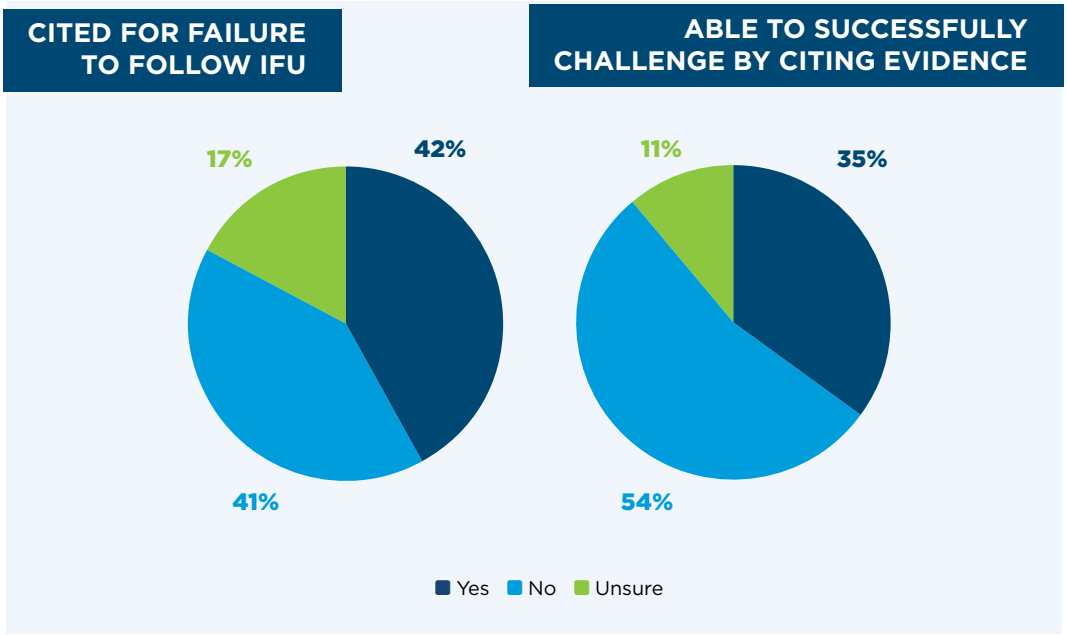
We cannot be certain why facilities with fewer IPs and smaller facilities were over-represented in the survey. However, it stands to reason that a solo practitioner would lack appropriate resources to both track down accurate IFU information to avoid a citation and continue their other essential IPC work required to keep staff and patients safe. This could be a strong motivating factor for completing a survey that seeks to find solutions to IFU problems.

IPs from a wide range of experience levels responded to this survey, with respondents in all categories spanning from 0-2 years to 16+ years of experience being nearly equally represented.



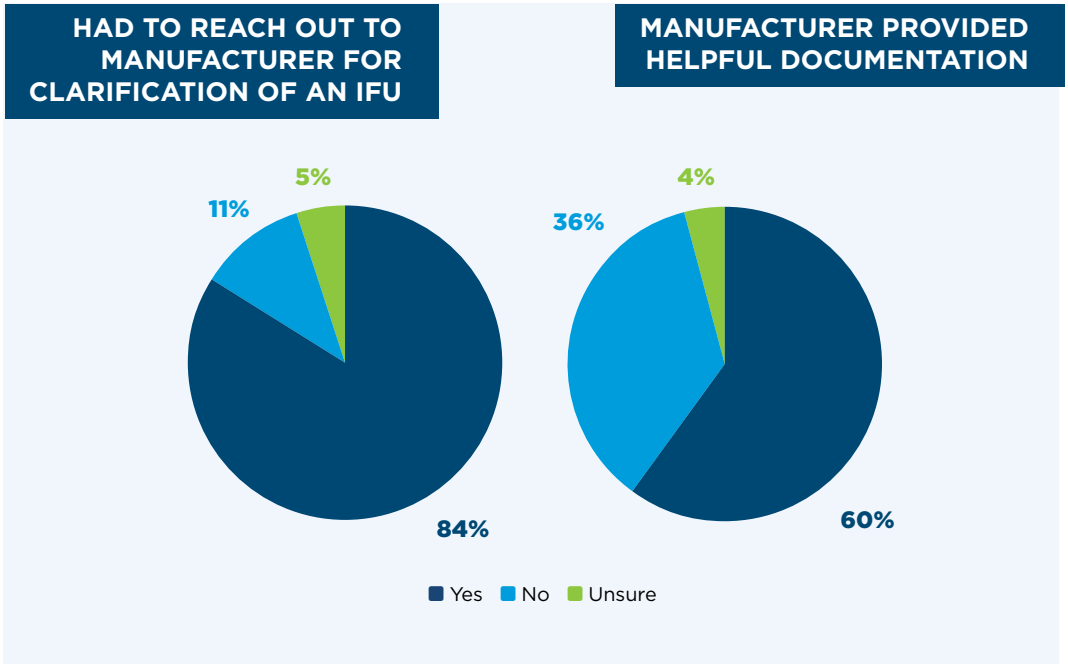
Compliance Problems/Issues

Our focus groups indicated it is common for facilities to be cited for failure to follow an IFU. Our survey confirmed that 42 percent of the respondents had been cited by a surveyor for failure to follow an IFU, 41 percent had not been cited, and 17 percent were not sure. Of those individuals cited by a surveyor, 54 percent were unable to successfully challenge the citation by providing evidence for their practice, while 35 percent were able to successfully challenge the citation.



42 percent of the respondents had been cited by a surveyor for failure to follow an IFU

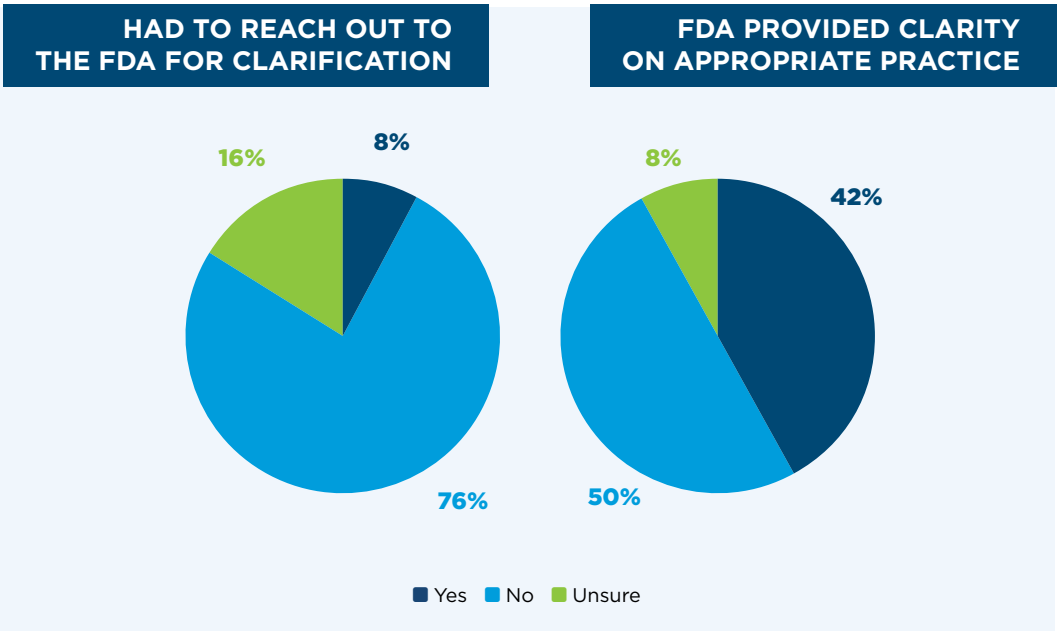
Our survey identified 84 percent of respondents indicated the need to reach out to a manufacturer for clarification on an IFU. Of that group, 60 percent said the manufacturer provided them with helpful documentation to verify the appropriate cleaning/disinfection/sterilization practice, but 36 percent did not receive helpful information.



(The sample size was slightly smaller for this question due to an error that had this question inadvertently turned off for all participants for the first two hours the survey was open. N = 1,040 on this question.)

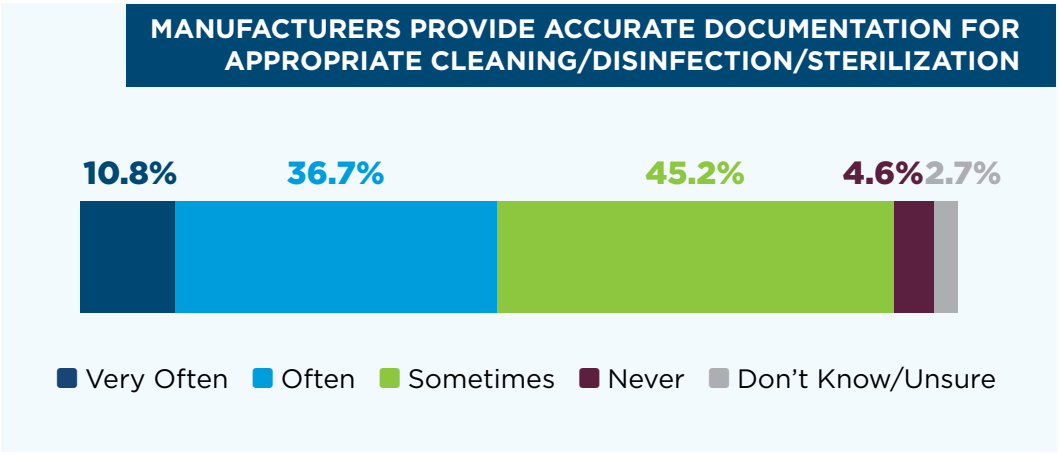
84 percent of respondents indicated the need to reach out to a manufacturer for clarification on an IFU.

Eight percent of IPs went as far as reaching out to the FDA for clarity on an IFU. Of that group, 42 percent said the FDA provided greater clarity on the appropriate cleaning, disinfection, and sterilization practice. However, more concerning is that 50 percent said they did not.



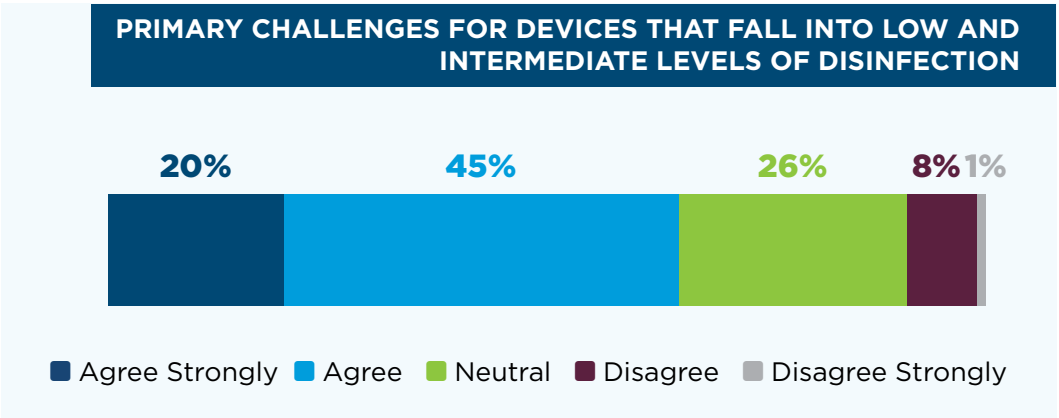
When asked whether manufacturers provided accurate documentation for appropriate cleaning, disinfection or sterilization, nearly 48 percent of IPs said they very often or often provide accurate documentation.

Approximately 45 percent said they sometimes provided such information, and approximately 7 percent said they never provided such documentation or the IP was unsure.



Specific Issues Identified

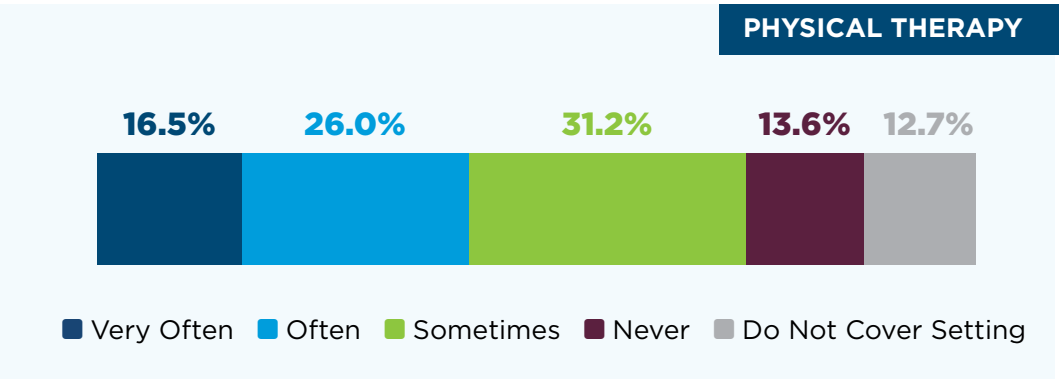
Our focus groups indicated that IPs had the most challenges with IFUs for devices that fell into the "noncritical" classification on the Spaulding system, requiring low and intermediate levels of disinfection. Sixty-five percent of respondents to the survey either agreed strongly (20 percent) or agreed (45 percent) that the primary challenges experienced with IFUs are for devices that fall into low and intermediate levels of disinfection, with only 9 percent saying they disagree (8 percent) or strongly disagree (1 percent) with that statement. (Total does not equal 100 percent due to rounding.)



Two practice settings were identified in the focus groups as having particularly problematic IFUs regarding cleaning, disinfection, and sterilization: physical therapy and ophthalmology.

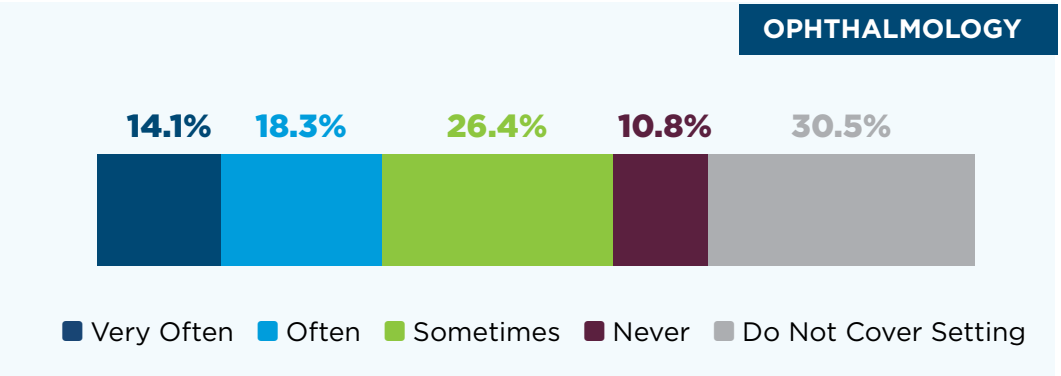
Physical Therapy

Our survey indicated that nearly 43 percent of IPs felt physical therapy equipment cleaning, disinfection, and sterilization instructions were very often (16.5 percent) or often (26 percent) a problem, with 31.2 percent saying they were sometimes a problem, 13.6 percent saying they were never a problem and 12.7 percent saying the respondent did not cover that practice setting.



Ophthalmology

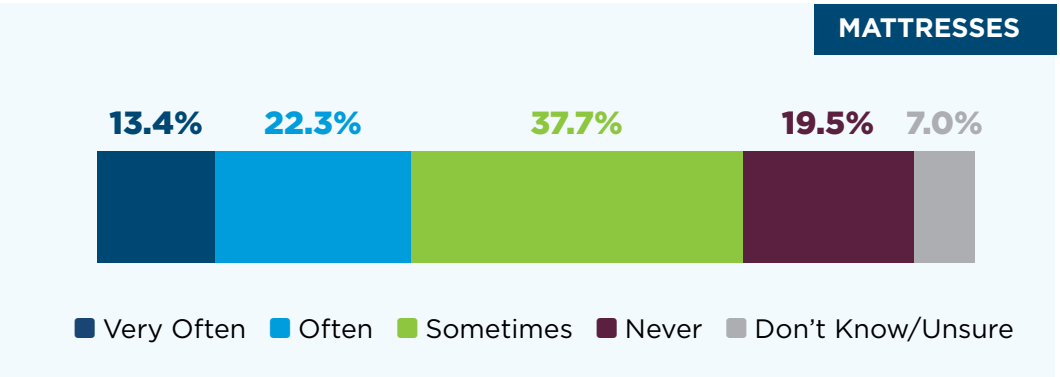
Our survey indicated that 32.4 percent of IPs felt ophthalmology equipment IFUs were very often a problem (14.1 percent) or often a problem (18.3 percent), with 10.8 percent saying they were never a problem and 30.5 percent saying they did not cover that practice setting or item.



Mattresses

Mattresses were cited enough in our initial focus group that we added a question to our survey to determine how often IPs have difficulty with instructions for cleaning and disinfecting this type of medical equipment.

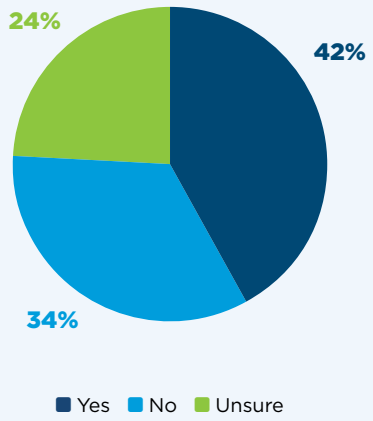
Our survey indicated that nearly 36 percent of IPs felt mattress cleaning and disinfection instructions were very often (13.4 percent) or often (22.3 percent) a problem, with nearly 38 percent saying they were sometimes a problem, nearly 20 percent saying they were never a problem, and 7 percent saying the respondent did not cover this practice setting or item.



Reusable (Multi-use) vs. Disposable (Single-use) Devices

Among the specific problems identified in our focus groups was having devices in use for which there was a lack of clarity about whether the item is disposable (single-use) or reusable (multi-use) due to the similarity in appearance of the disposable and multi-use items. Forty-two percent of IPs answering the survey said there were devices in their facility for which there was a lack of clarity, while 34 percent said there was not. One specific item mentioned in the focus group, that was confirmed by our open-ended survey questions, was oxygen "Christmas trees," named for their shape. These devices are widely utilized to connect oxygen tubes to medical gas ports which supply oxygen to patients.

LACK OF CLARITY ABOUT WHETHER AN ITEM IS DISPOSABLE OR MULTI-USE



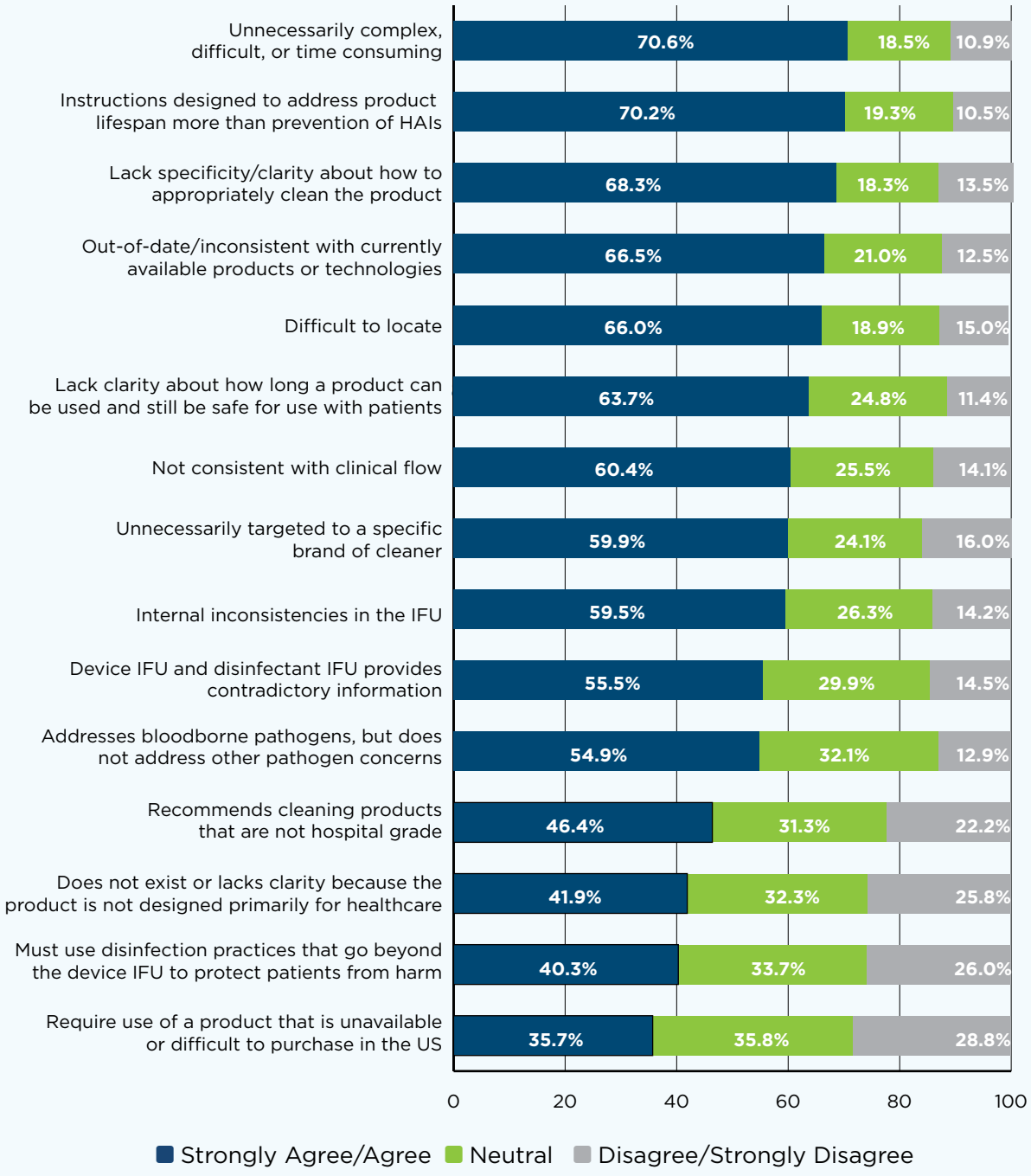
[T]he complexity of the IFU, inadequate instructions designed to address product lifespan...and lack of specificity are the most common problems the IP faces when trying to manage appropriate cleaning/disinfection.

Most Common IFU Problems

We summarized the most common problem statements we received related to IFUs during our focus groups and asked IPs to rate the statements using the following scale: Strongly Agree, Agree, Neutral, Disagree or Strongly Disagree.

Below we have listed the problem statements in order of those with the highest percentage of agreement as determined by the combined strongly agree and agree responses. As you will note, the complexity of the IFU, inadequate instructions designed to address product lifespan (i.e. difficult to manage instructions like "may only disinfect 30 times"), and lack of specificity are the most common problems the IP faces when trying to manage appropriate cleaning/disinfection.

COMMON IFU PROBLEMS



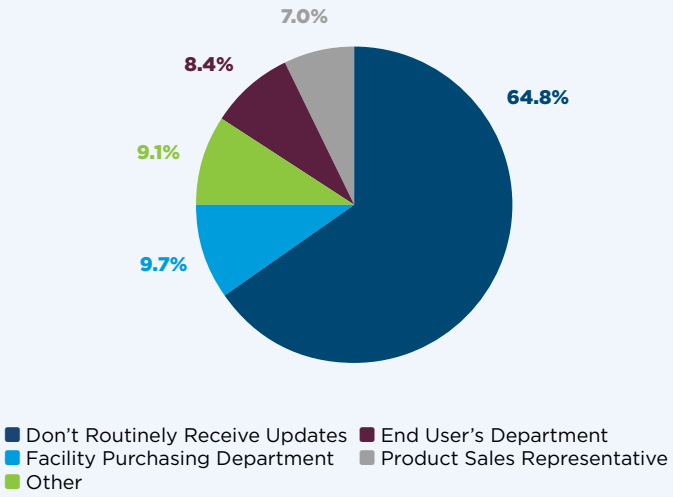
Access to IFU Updates/Information

On a question asking how IPs receive updates on IFUs, nearly 65 percent of IPs indicated they do not routinely receive IFU updates. However, individuals who did report routinely receiving information indicated the following sources:

- facility purchasing department 9.7 percent
- other 9.1 percent
- end user's department 8.4 percent
- product sales representative 7.0 percent

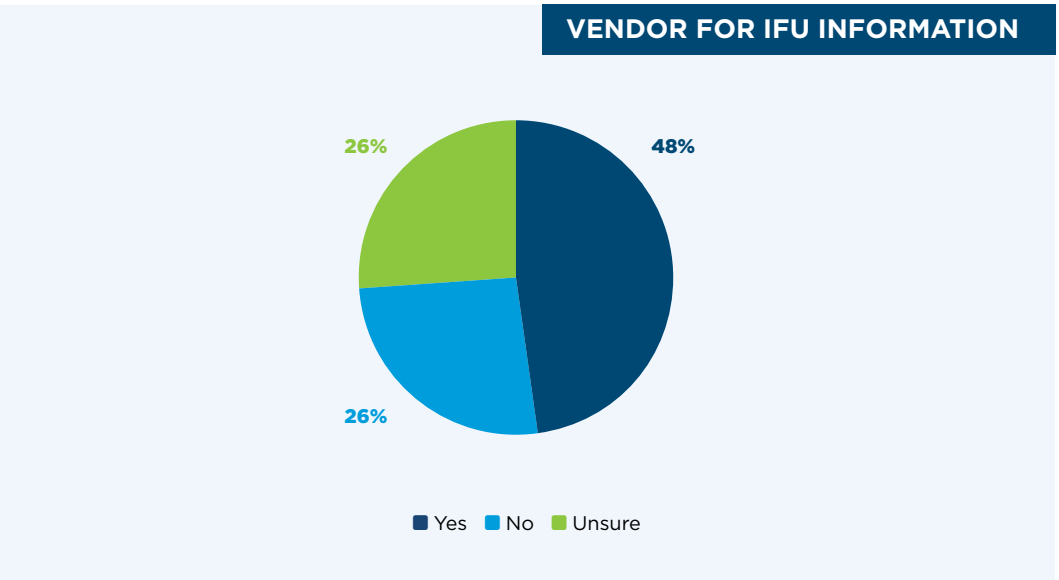
(Total does not equal 100 percent due to rounding.)

HOW IPs ROUTINELY RECEIVE UPDATES/INFORMATION



Access to a Vendor for IFU Information

Nearly one half of IPs (48 percent) indicated that their facility or system has a database/vendor for accessing IFU information. The remaining respondents either did not have a database/vendor or were unsure or didn't know whether such a database was available (26 percent each). Of the 531 individuals who provided a vendor name on an open-ended question about which vendor or service they used, 95 percent indicated they use the oneSource document management company or its parent company RLDatix. There were a smattering of other vendors and individual notations about vendor or in-house processes for accessing information about IFUs. Further, several respondents indicated that the system was limited to certain equipment and/or departments such as sterile processing. Although almost half of the respondents had access to one primary vendor for accessing IFU information, IPs felt the need to indicate in our open-ended question that access to a database/vendor did not solve the problem of missing, dated, or overly complicated IFUs. It is definitely an important tool, but many of the primary problems we documented still need to be addressed.



Summary and Recommendations

To avoid citations and potential patient harm from medical devices that are not being properly cleaned, disinfected, and/or sterilized, IPs are currently required to follow a burdensome process which may include seeking input from manufacturers and/or the FDA in real-time to clarify the IFUs and ensure compliance with the intended process. APIC believes this is an unacceptable and unnecessary burden that is inadequate to prevent the transmission of HAIs.

Data collection is the first step in determining the scope of problems and identifying the initiatives needed to solve them. With the results of this survey APIC calls for the following:

- Developing tools to help IPs and other healthcare personnel navigate the current less-than-optimum process for cleaning, disinfection, and sterilization of medical instruments.
- Bringing problematic IFUs to the attention of manufacturers and the FDA.
- Educating policymakers and healthcare organizations about flaws in the current regulatory framework that limit IPs' ability to protect patients from transmission of HAIs via medical devices.
- Convening stakeholder organizations to work with APIC to propose a new regulatory framework for cleaning, disinfection, and sterilization of medical devices that includes (but is not limited to):
  - A standardized format for IFUs;
  - IFU language which takes into account the needs of infection prevention and control, sterile processing, environmental services, and end-users to protect patients;
  - Device labels which are easily accessible to users for the duration of the product's lifespan, indicate when the IFU was last updated, and provide information on who users may contact in case of questions;
  - A public repository for IFUs so that users will have access to appropriate information for devices that are no longer manufactured and/or when the manufacturer is no longer in business.

Endnotes

1. Centers for Medicare & Medicaid Services. (2019). Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care, 42 CFR Parts 403, 416, 418, 441, 460, 482, 483, 484, 485, 486, 488, 491, and 494 [CMS–3346–F; CMS–3334–F; CMS–3295–F]. Department of Health and Human Services. https://www.govinfo.gov/content/pkg/FR-2019-09-30/pdf/2019-20736.pdf.
2. Centers for Medicare & Medicaid Services. (2022). Infection Prevention and Control and Antibiotic Stewardship Program Interpretive Guidance and Update. Department of Health and Human Services, Center for Clinical Standards and Quality/Quality Safety and Oversight Group. https://www.cms.gov/files/document/qso-22-20-hospitals.pdf.
3. Centers for Disease Control and Prevention (2008). A Rational Approach to Disinfection and Sterilization. Department of Health and Human Services. https://www.cdc.gov/infectioncontrol/guidelines/disinfection/rational-approach.html.
4. Food and Drug Administration. (1997). Labeling Regulatory Requirements for Medical Devices. Department of Health and Human Service. https://www.fda.gov/media/74034/download?attachment.
5. Food and Drug Administration. (2001). Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers. Department of Health and Human Services. https://www.fda.gov/media/71030/download.
6. Food and Drug Administration. (2017) Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff. Department of Health and Human Service. https://www.fda.gov/media/80265/download.
7. Food and Drug Administration. (2017) Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff. Department of Health and Human Service. https://www.fda.gov/media/80265/download.
8. William A. Rutala, Ph.D., M.P.H., David J. Weber, M.D., M.P.H., and the Healthcare Infection Control Practices Advisory Committee (HICPAC). (2019 Update) Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Centers for Disease Control and Prevention, Department of Health and Human Services. https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf.
9. American National Standards Institute (ANSI)/Association for the Society of Medical Instrument (AAMI). (2017) Comprehensive Guide to Steam Sterilization and Sterility Assurance in Healthcare Facilities. ST79:2017. https://www.aami.org/standards/featured-standards/ansi-aami-st79.
10. Food and Drug Administration. (2023) Premarket Notification 510(k). Department of Health and Human Services https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k#intro.