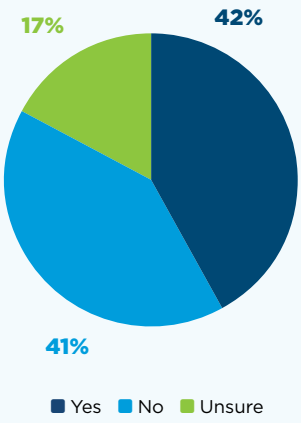
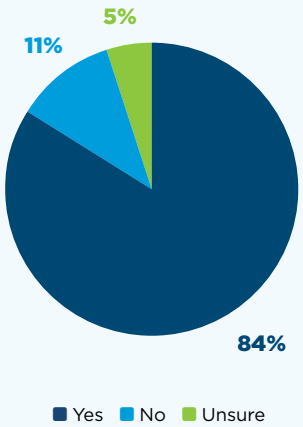
Modernizing Medical Device Instructions for Use (IFUs): Infection Preventionists (IPs) Speak Up for Patient Safety

CITED FOR FAILURE TO FOLLOW IFU



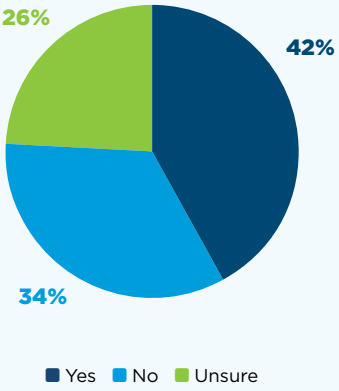
42 percent of IPs had their facilities cited by a surveyor for failure to follow an IFU.

HAD TO REACH OUT TO MANUFACTURER FOR CLARIFICATION OF AN IFU



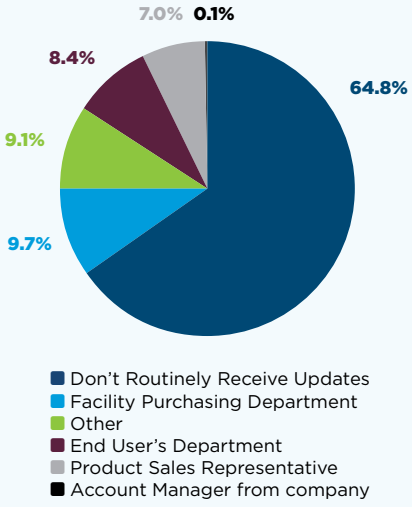
84 percent of IPs indicated the need to reach out to a manufacturer for clarification on an IFU.

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



Our focus group and survey respondents indicated that there were devices in use that lacked clarity about whether the item is disposable (single-use) or reuseable (multi-use).

HOW IPs ROUTINELY RECEIVE 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.

MOST COMMON IFU PROBLEMS

Below are the top 10 problems identified in our focus groups and survey. (Statements in order of those with the highest percentage of agreement as determined by the combined strongly agree and agree responses.)

70.6% IFU has instructions that are unnecessarily complex, difficult, or time-consuming to follow.

70.2% IFU includes inadequate cleaning/disinfection/sterilization instructions that seem more designed to address product lifespan and warranty rather than preventing the transmission of infectious diseases.

68.3% IFU lacks specificity or clarity about how to appropriately clean the product to prevent the transmission of infectious diseases.

66.5% IFU seems to be out-of-date or inconsistent with currently available products or technologies for cleaning/disinfection/sterilization.

66.0% IFU is difficult to locate.

63.7% IFU lacks clarity about how long a product can safely be used (e.g. number of uses) and still be safe for use with patients.

60.4% IFU is inconsistent with clinical flow (e.g. clean with soap and water in a mammography area where there are no sinks).

59.9% IFU seems unnecessarily targeted to a specific brand of cleaner.

59.5% IFU contains internal consistencies in which if you follow one part of the instructions, it is difficult or impossible to comply with another part of the instructions. (e.g. contact/wet time).

55.5% Device IFU contradicts the disinfectant IFU.

APIC Call to Action:

1. **Develop tools to help IPs** and other healthcare personnel navigate the current less-than-optimum process, for cleaning, disinfection, and sterilization of medical instruments.

2. Bring **problematic IFUs to the attention of manufacturers** and the FDA.

3. **Educate 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.

4. Convene 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.

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About the Survey: *The information in this infographic is based on responses by 1,198 infection preventionists who responded to a survey fielded in March and April of 2023. Click here to access the full results.*