AAMI
Advancing Safety in Healthcare Technology

Checklists for Preventing Healthcare-Associated Infections (HAIs)

Key Considerations for the Purchase and Use of Reusable Medical Devices

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A Collaborative, Coordinated Effort to Prevent Device-Related HAIs

A variety of stakeholders are accountable for each aspect in the life span of any reusable medical device: from its design, use, processing validation (cleaning, disinfection, and/or sterilization) to its maintenance, transportation, and storage. Every reusable medical device has the potential to be related to transmission of pathogenic agents due to contamination. Contamination of a reusable medical device with subsequent patient transmission is an important risk factor for healthcare-associated infections (HAIs) and continues to be a serious threat to patient safety. HAIs have increased morbidity and even mortality among patients, concurrently increasing healthcare delivery costs.

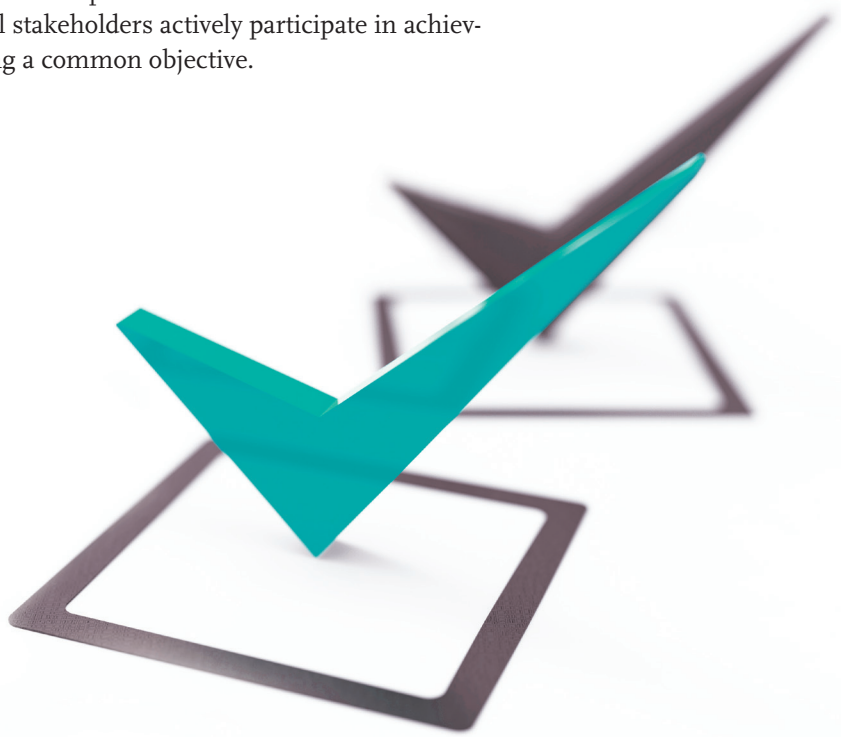
It was due to these considerations that AAMI and its partners convened a Sept. 29–30, 2016, forum that brought together more than 100 stakeholders concerned with the use of medical devices and HAIs—healthcare administrators, clinicians, researchers, instrument processing personnel, and device manufacturers—to explore how and why device- and equipment-associated transmissions occur, and to identify solutions to the problem. The considerations, lessons, and outputs of that forum are available online at **www.aami.org/HAIs.**

Preventing reusable medical device contamination has become an essential public health issue. Since device contamination can occur at any time, infection prevention must be a shared responsibility—a collaborative, coordinated process in which all stakeholders participate. Such participation involves effective communication, education, proper usage, transportation and storage, cleaning and disinfection, and overall maintenance of often expensive and very delicate reusable equipment essential for proper care of the most important stakeholder: the patient.

In the following pages, checklists are provided to reinforce and facilitate the successful acquisition and adoption of a reusable medical device with an eye on identifying, managing, and mitigating contamination risks; thereby reducing the likelihood of disease transmission and subsequent HAIs.

Preventing reusable medical device–related HAIs begins with the active and committed participation in the purchasing process to identify the resources that each stakeholder must have in order to prevent contamination. Once the medical device has been selected, leaders must prepare the personnel and environments for optimal use of the device.

Facility culture and compliance requirements help to set adherence expectations for all employees. Adhering to standards and best practices will promote opportunities for improvement in the delivery of patient care. Infection prevention is most effective when all stakeholders actively participate in achieving a common objective.



Selecting the Device

Purchase decisions should be made with a facility perspective. Ensure that the role of each stakeholder is considered in infection prevention.

Describe the device (What is it? What does it do? How is it used?)

What is the need for the device?

What prompted the request for the device?

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Who within the organization will/could use the device?

How frequently will the device be used?

Is there a target date for placing the device in service?

Within the organization, what type of purchase is this?

- ☐ First-time purchase
- ☐ Repeat purchase of an existing device (e.g., same model, manufacturer)
- ☐ Upgrade or change from existing device (e.g., different model, manufacturer)

If it is purchase of an identical device, is it

- ☐ A replacement for a device no longer in service?
- ☐ An addition (ensure documentation of increased demand for the device is available)?

If it is a purchase of an upgraded or changed device, why is it being purchased?

- ☐ Replacing an old device (no longer in service)
- ☐ Internal process improvement (preferred over existing device or replacement of an old device?)
- ☐ More modern technology, smaller instrument, or ease of processing
- ☐ Alignment with new modality or method of processing
- ☐ Not applicable

Assessing the Manufacturer

Purchase decisions and device adoption should include comprehensive, relevant information and support from the manufacturer. The manufacturer's input and support can make a valuable contribution to preventing medical device–related HAIs.

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Who is the device manufacturer?

What is the facility's history with this manufacturer?

Who is the facility's primary contact person with this manufacturer?

Ensure that the following components are in place prior to the purchase of a new device

- ☐ Facility can gain ready access to manufacturer personnel who can address all stakeholders' device-related questions, concerns, and troubleshooting needs
- ☐ Manufacturer is prepared to deliver service after the sale as needed by all stakeholders
- ☐ On-site inservice is available for all departments and all shifts
- ☐ Manufacturer advanced technical support is available
- ☐ Tools (e.g., posters, videos, checklists) are provided to enhance education and training
- ☐ Administrative work instructions, policies, and procedures are provided to enhance the standard of work to be accomplished as well as dictate and measure the required level of competency
- ☐ Manufacturer IFU meets the needs of all stakeholders
- ☐ Manufacturer IFU is readily available and accessible at the processing area
- ☐ Manufacturer does not have a history of postmarket revisions without clear communication to customers

Instructions for Use (IFU)

Manufacturers should provide an IFU that meets the needs of all stakeholders and serves as a primary onsite resource.

Ensure the following components are part of the IFU

- ☐ Document focuses on providing clear and graphic information for the end user (as opposed to simply meeting regulatory requirements)
- ☐ Document includes all of the information needed (e.g., explicit steps to reprocess)
- ☐ Document is organized so that information sought is easily found
- ☐ Font size is large enough for easy reading
- ☐ Document is written in plain language (i.e., at a reading level of an eighth-grade education) to ensure understanding of the information without need for interpretation by the customer
- ☐ Revisions or updates will be provided by the manufacturer to all the facilities that carry the reusable medical device

Training and Inservicing

The rollout and use of a new reusable medical device requires well-designed training and inservicing. Employees must be capable of learning to use the device as well as motivated to assume the responsibilities for managing the device and preventing contamination.

Structure of the program

- ☐ Materials are written and presented at an appropriate learning level
- ☐ Learning activities incorporate a variety of learning styles
- ☐ Visuals (PowerPoint presentations, videos) are provided as appropriate
- ☐ Components include narration, lecture, discussion, question/answer
- ☐ Study materials (e.g., IFUs, handouts) are provided
- ☐ Hands-on/lab/simulation is incorporated as appropriate
- ☐ Instructor is well trained to comprehensively deliver the materials

Environment is conducive to learning

- ☐ Staff is provided sufficient time to cover the material
- ☐ Learning sessions do not conflict with daily workload assignments
- ☐ Classroom is appropriate
- ☐ Comfortable seating is provided
- ☐ Audio/visual support is available
- ☐ Potential for distractions is minimized (avoid high-traffic areas such as the cafeteria or the employee lounge)

Capable learners

- ☐ Academic preparation is appropriate to the material for physicians, nurses, sterile processing department technicians, environmental technicians, and/or supervisors
- ☐ Course level is directed to the particular audience
- ☐ Learners are fluent in the language of the course
- ☐ Learners are culturally prepared to assume responsibility for assertiveness when required

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Device orientation

- [ ] Is mandatory
- [ ] Is delivered by a trained instructor
- [ ] Describes the device application
- [ ] Describes any unique characteristics that differentiate the device from similar devices (if learners have experience with similar devices)
- [ ] Defines responsibilities related to preventing contamination and device-related HAIs
- [ ] Introduces other stakeholders and their responsibilities for the device
- [ ] Defines roles and responsibilities of all stakeholders related to device-specific contamination risks

Criteria for demonstrating competence with the training material

- [ ] Verbalizes critical information related to the device
- [ ] Verifies competency in the classroom setting
- [ ] Shows competency with processing or use of device
- [ ] Can verbalize behaviors that facilitate success
- [ ] Demonstrates behaviors that prevent contamination of the device and device-related HAIs
- [ ] Documents individual mastery of material and competent performance

Successful implementation of the device

- [ ] Policies/standard operating procedures (SOPs) are in place and enforced
- [ ] Clinician users are trained and understand their responsibility to prevent HAIs
- [ ] Appropriate clinical use is verified
- [ ] Infection prevention practices are verified
- [ ] Behaviors that promote the success of other stakeholders are verified
- [ ] Resources are available for remediation
- [ ] Processes are in place for recognizing success

Stakeholder Checklist

Sterile Processing

Risk assessment

- ☐ Published evidence documents the risk of improper processing associated with the device (or device type)
- ☐ Published best practices and/or practice standards are associated with proper use of this device (or device type)
- ☐ Findings are followed up to ensure that they can be addressed (or an alternate device is selected)

Personnel considerations

- ☐ Device can be processed with current staff
  OR
- ☐ Additional staffing is available for processing
- ☐ Current staff has the necessary expertise to process the device
- ☐ Among current staff, language barriers or cultural issues will not interfere with learning to process the new device

Resources

- ☐ Resources (equipment, personnel, time) exist to process the device appropriately
  IF NOT, THEN
- ☐ Required additional resources are understood, and a plan is in place to acquire the needed resources

Policies/procedures

- ☐ Site-specific procedures are in place for processing this device
- ☐ SOPs are distributed to staff by supervisors and/or other authorities
- ☐ SOPs are dated and signed by responsible staff
- ☐ If policies and procedures need to be created, the necessary resources (individuals and information) are defined to write, review, approve, and update them (e.g., IFU, technical data sheets, safety data sheets, evidence-based best practices, manufacturer competency-based training)
- ☐ Policies, procedures, and SOP revisions are part of the maintenance of the reusable medical device

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Education/training

- [ ] A user certification/recertification/validation process is required for processing the device
- [ ] Entire staff will be trained to process the device
- [ ] Staff attends a collaborative education/training event involving all stakeholders
- [ ] Education and training materials are in place for training staff to process this device
  OR
- [ ] Resources (individuals and information) exist to write, review, and approve the education/training programs as needed
- [ ] Regular refreshers and assessments exist to ensure continuous adherence to policies

Processing

- [ ] If a limited number of personnel are prepared to process the device, procedures are in place to ensure that appropriately trained individuals are available when needed
- [ ] If the device is a limited resource, it can be processed in place to ensure availability
  - [ ] *Quality of processing is maintained regardless of the location*
- [ ] A procedure is in place to ensure sufficient time for processing the device between uses
- [ ] Processing is done in an appropriate place following the validated procedures from the IFU and following policies and SOPs from the facility

Storage (for device and consumables)

- [ ] A specific location is identified where the device and consumables will be stored
- [ ] Special handling or storage requirements are understood (e.g., fire safety, temperature, humidity, ventilation, or refrigeration)
- [ ] A mechanism is in place to ensure that stakeholders (specifically end users) report the depletion of consumables for restocking
- [ ] Improvisation of temporary solutions or "quick fixes" is discouraged (as breaches in the manufacturers' design and usage may introduce contamination)

Staff consistently implement infection prevention protocols

- [ ] Hand hygiene practices are observed
- [ ] Personal protective equipment (PPE) is used appropriately
- [ ] "Clean conscience" (e.g., staff assesses for functionality and processes or discards an item that falls on the floor)
- [ ] Staff maintains a clean environment
- [ ] Staff members suspected of having, or known to have exposure to a transmissible infectious disease (or are in a carrier state) must follow appropriate guidelines to prevent transmission in the workplace or in areas with handling of reusable medical devices

If the device is used by more than one department or processed by a different department from where it is used

- [ ] All departments are involved in developing point-of-use and transfer protocols
- [ ] Clear lines of communication are established to forestall or resolve any issues that arise

Infection control department

- [ ] Is kept abreast in a timely fashion if a breach in the processing of a reusable medical device is identified
- [ ] Is involved in policy writing for medical device acquisition, maintenance, and processing
- [ ] Maintains a schedule for monitoring the cleaning/disinfection/sterilization process and environment
- [ ] Documents in the healthcare facility's incident reporting system any variance, or result, of improperly processed devices (contamination is present)
- [ ] Investigates the root cause of reusable medical device malfunction (e.g., contamination, infection transmission)
- [ ] Reports reusable medical device malfunctions to the Food and Drug Administration (FDA) and the manufacturer using the Medical Device Reporting system

Stakeholder Checklist

Infection Prevention

Risk assessment

- ☐ Published evidence documents the potential risks associated with this device (or device type)
- ☐ Published best practices exist for this device (or device type)

Cleaning and disinfection or sterilization

- ☐ Process for cleaning/disinfection or sterilization of the device is understood
- ☐ Specific challenging issues related to processing are defined
- ☐ Required equipment is available
- ☐ Training opportunities are available for processing personnel
- ☐ Competency validation process is in place
  - ☐ *Initial competency validation*
  - ☐ *Periodic ongoing validation of competency*

Disinfection/sterilization issues to consider prior to purchase

- ☐ Disinfection/sterilization information is provided in the IFU
- ☐ Information is clear to understand and follow
- ☐ Manufacturer provides a validated method for disinfection of the reusable medical device
- ☐ Manufacturer provides recommended (and validated) solutions for low-, intermediate-, or high-level disinfection
- ☐ If sterilization is involved, manufacturer indicates the validated method and appropriate parameters to follow (e.g., industrial versus hospital sterilization method)
- ☐ Facility has the resources (in-house or by contracting out) for the adequate sterilization of the device

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Use

- [ ] Device training includes infection prevention behaviors
- [ ] Initial and ongoing periodic competency validation has been developed
- [ ] Frequency of credentialing for people working with reusable medical device is established

Storage

- [ ] Device storage conditions are conducive to preventing infection
  - [ ] *Limited access*
  - [ ] *Routine cleaning*
  - [ ] *Appropriate parameters (temperature/humidity/airflow, if applicable)*

Oversight/maintaining an infection control presence

- [ ] High-risk equipment is cultured periodically to assess for contamination on fully processed devices
- [ ] Documentation of sterilization/disinfection monitoring is maintained appropriately
- [ ] Infection control department
  - [ ] *Is kept abreast in a timely fashion if a breach in the processing of a reusable medical device is identified*
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  - [ ] *Reports reusable medical device malfunctions to the FDA and the manufacturer using the Medical Device Reporting system*

Stakeholder Checklist

Environmental Services

Equipment and supplies

- ☐ A mechanism is in place to determine the best product for each application ("one size does not necessarily fit all")
- ☐ A process is in place to ensure the cleanliness of cleaning supplies (e.g., no dirty rags or mops)

Process

- ☐ A schedule exists for cleaning areas (e.g., patient rooms) in a timely fashion (to avoid rushing and doing a less-than-optimal job)
- ☐ A mechanism exists for assessing the effectiveness of the cleaning procedures

Staffing

- ☐ Staff is competent to ensure the implementation of "best practices"
- ☐ Staff is knowledgeable of the infection prevention implications of cleaning activities
- ☐ Dry time is sufficient for a disinfectant to achieve microbial kill
- ☐ Procedures are in place to prevent aerosolization of microorganisms
- ☐ Hand hygiene practices are maintained
- ☐ Importance of changing gloves when contaminated is emphasized
- ☐ Language barriers and/or cultural norms will not interfere with complete comprehension and performance (e.g., not understanding responsibilities in sufficient detail to make competent performance decisions, unwillingness to be assertive when there is an opportunity to improve one's own or another's practice)

Training programs

- ☐ Are sensitive to the learning level of employees
- ☐ Are sensitive to language barriers that might interfere with mastery of the material
- ☐ Include an assessment of competency/mastery of material to demonstrate successful completion
- ☐ Include infection prevention principles and practices
- ☐ Emphasize the need for assertiveness in promoting infection prevention
- ☐ Include a process for ongoing and performance validation

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Stakeholder Checklist

Healthcare Technology Management

Equipment and supplies

- ☐ A mechanism is in place to determine the best product for each application ("one size does not necessarily fit all")
- ☐ A process is in place to ensure the tools, equipment, and supplies are available to provide support for the maintenance and repair of medical devices used, and for air-handling and utilities used in the healthcare environment

Process/protocols

- ☐ Appropriate manuals and guidance are available for maintenance and repair of utilities, air-handling, and medical equipment
- ☐ A schedule exists for preventive maintenance of utilities, air-handling equipment, and medical equipment
- ☐ A mechanism exists for assessing the effectiveness of the repair and maintenance services provided
- ☐ Preventive maintenance and cleaning activities are conducted according to device/equipment manufacturer IFU
- ☐ There is a formal documentation process for all services provided

Staffing

- ☐ Staff certification/training is appropriate for maintenance and repair of equipment to be purchased
- ☐ Staffing levels are sufficient to ensure the implementation of "best practices"
- ☐ Staff is knowledgeable of the infection-prevention implications of their activities
  - ☐ *Water purification processes*
  - ☐ *Air handling (e.g., air exchanges, high efficiency particulate arrestance filtration and negative or positive pressure suited to function of service provided)*
  - ☐ *Appropriate PPE in relation to service provided*
  - ☐ *Repair and/or preventive maintenance of equipment (e.g., steam sterilizers, low-temperature sterilizers, water purification systems, medical devices)*
- ☐ Language barriers and/or cultural norms will not interfere with complete comprehension and performance (e.g., not understanding responsibilities in sufficient detail to make competent performance decisions, unwillingness to be assertive when there is an opportunity to improve one's own or another's practice)

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Training programs

- [ ] Are appropriate to the learning level of employees
- [ ] Include infection prevention principles and practices
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