Healthcare
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Device and Drug Recalls: Enhancing Preparedness, Reducing Risk

Healthcare-related recalls have reached historic levels, encompassing regulated products that range from drugs, blood and basic medical supplies to complex biomedical instruments, implantable devices and biologics, including cellular- and tissue-based products.[1] There were 3,202 medical device recalls in fiscal year 2017, up from 2,303 in 2013. Pharmaceutical recalls also occur relatively frequently, with 84 U.S. drug companies reporting at least one recall in the first quarter of last year.

If a medical product poses a substantiated threat to patient safety, it may be recalled by the manufacturer or the U.S. Food and Drug Administration (FDA), the federal agency that oversees the safety of medical devices, implants, and prescription and over-the-counter drugs, as well as food and other consumer products. Recall notices are assigned one of three classes, based upon the severity of threat that a defective product may pose. (See "Recall Classification Levels" at right.) The majority of "recalls" are actually safety notifications requiring no emergency measures on the part of the recipient. However, a formal process must be in place even for low-level recalls, in order to implement the indicated actions.

Clinicians and healthcare organizations may be exposed to legal action and potential loss if they fail to notify patients of a recall situation after being instructed to do so by the FDA. They can also be held legally accountable for patient injury due to other associated lapses, such as neglecting to remove a recalled item from the facility's inventory, failing to respond appropriately to a recall notification, or lacking effective recall-related policies and procedures.[2]

Recall Classification Levels

When a product under FDA jurisdiction is deemed defective or contaminated, the agency may issue one of three types of recall:

Class I – There is significant and immediate danger of death or serious injury associated with use of the product.

Class II – No immediate danger of death or serious injury is linked to the product, but it may cause temporary or reversible health problems.

Class III – The product poses no immediate or perceived threat to health, but it is in violation of FDA manufacturing or labeling regulations.

In addition to these three main classifications, the FDA recently established an interim "not-yet-classified" category, which permits product information to be released via the FDA's weekly Enforcement Report before a classification category has been determined. The move is part of the FDA's effort to increase transparency and alert the public to potential threats as quickly as possible.

Source: FDA Recalls

1 See Sweeney, E. "Medical Device Recalls Reach Historic Levels in 2018 with Software as Leading Cause." *FierceHealthcare*, May 9, 2018.
2 See Healy, E., Braender, L. and Zalewski, T. "A Provider's Guide to Managing a Medical Device Recall." *Journal of Health and Life Sciences Law*, February 2018, volume 11:2, pages 88-102.

Regardless of their level, recall notices typically arrive with little warning to the user facility and require a coordinated, multistage response. (See "Staying Informed About Medical Product Recalls" at right for a listing of recall notice information sources.) Healthcare facilities must be ready to disseminate recall-related information to providers and (sometimes) patients in a clear and timely manner, as well as to properly identify, track, retrieve, and return or dispose of affected items.

One of the major obstacles to an effective recall response is the presence within the facility of unauthorized or undocumented medical products, which have been obtained without the knowledge of the supply-chain team. This problem is often the result of such risky practices as manufacturers providing devices and implants on consignment, or pharmaceutical sales representatives dropping off medication samples. To ensure an accurate inventory and effective recall process, *all* drugs and devices, whatever their provenance, must be registered.

A centralized inventory and recall management system, anchored by well-defined policies/procedures and a dedicated coordinator or team, can enhance patient safety, efficiency and accountability. This edition of *inBrief*® presents a self-assessment guide to help healthcare facilities evaluate their degree of readiness for negotiating recall situations. It examines major phases of the process – from receiving the initial recall notice and alerting staff to sequestering affected products and documenting steps taken – as well as key preparatory and follow-up measures.

Staying Informed About Medical Product Recalls

Healthcare organizations are encouraged to subscribe to more than one source for product safety and recall notifications. The following industry partners, among others, provide safety alert and recall information:

Ambulatory Surgery Center Association:

- Recall Information Center

ECRI Institute:

- Healthcare Product Alert RSS Feeds

U.S. Food and Drug Administration:

- Center for Biologics Evaluation and Research
- Center for Devices and Radiological Health
- Enforcement Reports
- Industry Guidance for Recalls
- Medical Devices
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program
- Recalls, Corrections and Removals (Devices)
- Recalls, Market Withdrawals, & Safety Alerts
- Subscription Management Center (to receive FDA email updates)

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Gauging Organizational Readiness for Medical Device or Drug Recalls

Measures	Present (Yes/No)	Comments
Oversight		
Liability exposures associated with the recall process are reviewed by facility leadership, including failure to track devices, remove affected products from clinical areas and implement patient notification protocols.		
A recall coordinator is named and assigned responsibility for overall management of the recall response process. Typically, the facility's safety officer, materials manager, biomedical engineer or other person conversant with the supply chain and purchasing processes is appointed to this position.		
The designated recall coordinator is given ongoing, documented training in regulations, policies and procedures pertaining to medical device and drug recalls.		
The chief responsibilities of the recall coordinator are outlined in written policy and include, but are not limited to, the following:		
• Compiling and interpreting pertinent product data from multiple sources.		
• Reviewing recall instructions and determining what actions need to be taken.		
• Disseminating relevant information to indicated medical staff and department heads.		
If resources permit, a recall team is appointed to oversee and improve recall-related processes. The team should include representatives of affected departments, such as nursing, purchasing, clinical engineering and quality/risk/safety management, as well as surgical, pharmacy, laboratory and/or imaging suites, if relevant.		
The recall coordinator and/or team are given responsibility for verifying the accuracy of information received in recall notices, as well as confirming and conveying the following points, among others:		
• The name of the recalled product and its item and lot numbers.		
• A clear description of the reported problem.		
• Dates when the defective product was manufactured, distributed and received by the facility.		
• Product order history.		
• Availability of replacements.		
The recall coordinator and/or team are granted ready access to a computerized inventory of all medical devices and drugs that are purchased, stored, used and/or prescribed by the organization.		

Measures	Present (Yes/No)	Comments
Planning and Protocol		
A centralized procedure is established for receiving and interpreting product alerts and safety notices from manufacturers and the FDA, as well as for disseminating information about recalled devices and medications.		
The procedure is designed to guide staff in responding appropriately to each level of recall, i.e., Class I, II and III. (See page 1.)		
Specific recall-related tasks are delineated in writing and assigned to specific staff members.		
An action plan template is created for recall notices that are received at inopportune times, such as weekends and holidays.		
A protocol is in place outlining steps to take if recall notices are deficient in information, including contacting the manufacturer, distributor and/or wholesaler for additional details.		
A process is instituted for monitoring and implementing medical technology recalls, including notification of clinical engineering personnel.		
A list of pre-approved rental vendors is prepared in advance, in the event that clinical equipment must be replaced quickly following a device recall.		
Staff members are instructed not to bill patients for recalled products, or for procedures involving complications caused by recalled drugs or devices, until approval is granted by management.		
Liability claims involving recalled products are addressed with broad organizational input, including consultation with legal counsel, as well as with representatives of the risk management and quality improvement departments.		
Staff Education and Assessment		
Staff are trained in recall management practices and safety alert regulations upon hire and annually thereafter, or in response to legal or process changes.		
Recall simulations are conducted annually, in order to reinforce staff members' working knowledge of critical processes, such as identifying recalled devices, notifying providers and affected patients, and removing defective products from the inventory.		
Proficiency tests are administered regularly to assess staff members' understanding of recall procedures and documentation requirements, including properly completing product return cards and sending them to the manufacturer or wholesaler.		

Measures	Present (Yes/No)	Comments
Inventory Management		
A computerized inventory management system is adopted, which integrates clinical, purchasing and distribution processes; identifies and locates affected products; and tracks chain of use.		
The supply and device inventory system is designed for ease of use, and lists manufacturer, trade name, and serial and lot number.		
A current, comprehensive inventory list is maintained, which includes disposable supplies, rented or leased items, on-loan and provider-owned equipment, devices vulnerable to cyber-threats, etc.		
Products from satellite sites are included in the central inventory, as are items not procured by the purchasing department.		
A standard nomenclature for medical items is utilized, such as the Universal Medical Device Nomenclature System™, in order to facilitate inventory searches for recalled devices.		
Bar codes are used to improve product inventory and tracking capabilities, and other technologies are adopted that interface with the electronic healthcare record.		
A current directory is maintained of unit and department heads who will receive safety notices following the recall of any inventoried item.		
Responsibility for "crossover" devices is delegated to a single unit/department; for example, a drug-emitting device that administers a preprogrammed dose may be assigned to pharmacy, nursing, information technology or materials management in the event of a recall notice.		
Special Considerations for Drug Recalls		
All medications are accurately registered in the pharmacy inventory management system, including samples as well as medication supplies and products supplied by vendors and contractors.		
Stock medications and supplies are maintained in secure locations with a lockout feature, for use in the event of recalls.		
A flowchart is compiled of all parties involved in the drug recall process, including, among others, providers, nurses, dialysis technicians, therapists and pharmacists.		
Medications are identified by product name, and the inventory entry also includes dosage, route of administration, manufacturer, lot number and expiration date.		
A designated individual is authorized to secure the medication supply throughout the facility in case of a recall.		
Adverse drug reactions are monitored and reported for patients who have been provided with recalled medications.		
Following notice of a drug recall, a thorough search is conducted for affected medications and related records, including prompt inspection of medication storage facilities, imaging and procedural areas, automated dispensing cabinets, stock lists, purchasing records, medication sample logs, etc.		

Measures	Present (Yes/No)	Comments
Medical Implants		
In the event of future recalls, a medical implant log is maintained, which includes the following information:		
• The implant's product and brand name, as well as its generic equivalent name, if applicable.		
• The implant's lot batch, model and serial number, as well as its bar code and other tracking data.		
• Name and contact information of the physician who implanted the device.		
• Patient identification information.		
• The date the device was implanted.		
• The date the patient was informed of the recall, plus a description of how the patient was notified and by whom.		
• The resolution of the recall, e.g. implant left in place, removed, out of use due to patient death (note date of death) and/or returned to manufacturer (note shipment date).		
Staff Notification		
A standard message template is developed for notifying staff of a recall, in order to promote thorough, timely and uniform communication.		
Staff-directed recall notifications are reviewed by leaders prior to release, in order to ensure that they accurately identify the product and the problem, note the level of the recall and clearly describe the actions to be taken.		
A range of communication methods are used to notify staff of recalls, including email, text messaging, face-to-face meetings, and posters/flyers in clinical and staff areas.		
Product Tracking and Sequestration		
Incoming product shipments are monitored for possible recalls on an ongoing basis.		
All medical devices are checked to ensure that they display a unique device identifier (UDI), as mandated by the FDA for tracking purposes.		
UDIs are included in patients' electronic healthcare records, in compliance with the Centers for Medicare & Medicaid Services Final Rule.		
Location-sensing hardware or asset-tracking software is utilized to quickly find and retrieve affected products.		
Large and built-in devices are prominently labeled, including the location of the appropriate technical service bulletin and the scheduled date of repair.		

Measures	Present (Yes/No)	Comments
Product Tracking and Sequestration (continued)		
Manufacturers, distributors and/or recycling companies are consulted early in the recall process, so they can assist with the return or disposal of recalled items.		
Only designated staff are authorized to remove recalled products from clinical areas, in order to ensure accountability and control.		
Recalled devices are quarantined in a secure area and clearly marked with their model, lot and serial numbers, as well as their recall status (e.g., "Recalled – Do Not Use"), in order to prevent accidental reintroduction to clinical areas.		
Items requiring disposal are specially marked and listed in the inventory, including their location, dimensions, weight and final disposition.		
Recalled devices involved in an adverse event are not released to the manufacturer until the insurance carrier's representative signs off.		
The policy governing sequestration of recalled devices is routinely reviewed and, if necessary, updated by risk managers and other leaders, as is the procedure for securing items that may become the subject of litigation.		
Patient Notification		
Patients are notified of recalls according to a defined communication protocol, in a manner suited to the severity of the situation, and in compliance with the recall notice requirements sent by the manufacturer or FDA.		
Manufacturer-supplied information, directions and guidance are conveyed to patients in a thorough and timely manner.		
Patient notifications are fully documented, including the name of the recalled drug or device.		
As part of the notification process, patients are urged to consult their physician in regard to obtaining a comparable drug or device.		
Physicians and other providers are instructed what to tell patients about recalled products, based upon the manufacturer or FDA recall notice.		
The organization's risk manager is included in the recall notification process.		
All patient follow-up is documented and tracked.		

Measures	Present (Yes/No)	Comments
Documentation Requirements		
Compliance with the recall plan is thoroughly documented, especially in regard to the following dates and actions:		
• Date of the initial recall notice.		
• Major actions taken, including inspections, product removals, patient notifications, and disposal or return of recalled products to the manufacturer, distributor or wholesaler.		
• Date recall notifications are sent to staff, physicians and other prescribers.		
• Date patients are notified of the recall, if applicable.		
• Description of how patients are notified of the recall and by whom, if applicable.		
• Additional actions taken in response to instructions from the manufacturer, as well as the FDA, state board of pharmacy, health department and/or other government agencies.		
Receipt of recall-related information is verified in writing, including confirmation that devices have been removed from clinical settings and corrective actions taken.		
Electronic copies are retained of recall notices and related documents submitted to manufacturers, distributors and/or wholesale suppliers.		
Process Improvement		
Post-event debriefing sessions are held, noting any recall-related problems or challenges and calculating the time elapsed from recall notice to completion of all relevant tasks.		
Debriefing findings are shared and discussed with staff members in formal training sessions, in order to strengthen the recall management process.		
Recall drills are conducted, analyzed and documented, in order to evaluate and enhance the readiness and performance of administrators and staff, as well as the effectiveness of electronic systems.		
Device and drug inventory systems are audited regularly to ensure that all recalled items have been removed from clinical use and securely sequestered.		
On a monthly basis, recall activities are reported to leadership and unit/departmental leaders, including, at a minimum, the following information:		
• Listing of manufacturer and FDA recall notices affecting the facility and its patients.		
• Number and description of manufacturer and FDA recall notices received requiring action.		
• Length of time between receipt of notification and response.		
• Types and number of recalled products located on site.		

Measures	Present (Yes/No)	Comments
Contractual Protections		
During contract negotiations, vendors are notified in writing of the facility's recall policies and procedures, as well as vendor obligations relating to recalls.		
Vendors are contractually required to include product name on invoices, as well as lot and serial numbers, to aid in tracking recalled devices.		
Vendors' liability insurance limits and terms are reviewed during contract negotiations.		
The name of the specific individual or department that manages recall notifications is included in vendor purchase agreements, as well as departmental contact information.		

This checklist serves as a reference for organizations seeking to evaluate risk exposures associated with medical device or drug recalls. The content is not intended to represent a comprehensive listing of all actions needed to address the subject matter, but rather is a means of initiating internal discussion and self-examination. Your clinical procedures and risks may be different from those addressed herein, and you may wish to modify the tool to suit your individual practice and patient needs. The information contained herein is not intended to establish any standard of care, serve as professional advice or address the circumstances of any specific entity. These statements do not constitute a risk management directive from CNA. No organization or individual should act upon this information without appropriate professional advice, including advice of legal counsel, given after a thorough examination of the individual situation, encompassing a review of relevant facts, laws and regulations. CNA assumes no responsibility for the consequences of the use or nonuse of this information.

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