Guidance on Medication Recalls

Created by the Section Advisory Group on Medication Safety

ASHP Section of Inpatient Care Practitioners (SICP)

Background

Drug recalls occur when the quality of a drug product has been compromised rendering the drug no longer safe for human use. Quality and safety standards are defined into law and enforced by the Food and Drug Administration (FDA) for drug manufacturers and pharmacies. Although most drug recalls are voluntarily initiated by the drug manufacturer, the FDA can request or mandate a drug recall. Recall notices are externally communicated to healthcare organizations and consumers for a response. A recall of a drug can also be internally initiated within a healthcare organization when the quality of a drug no longer meets organizational standards for use.

In health-systems, the pharmacy department plays a key role in the procurement and management of drug inventory. The pharmacy department, through drug procurement services, is often first to be notified of external drug recall notices. Additionally, it has internal oversight to determine when quality standards were breached for drugs used or prepared in the organization. Therefore, pharmacy department has direct authority and ultimate responsibility to respond to external and internal recall notices.

Effective response to recall notices, both external and internal, requires a proactive, multidisciplinary approach. At a minimum, representatives from nursing, medicine, pharmacy services and administration should be involved in efforts to develop, implement, and coordinate execution of strategies, policies, and procedures related to drug recalls. The pharmacy department should take a leadership role in this planning. The health-system leadership must support the pharmacy department in the leadership and execution of these duties.

Purpose

The purpose of this document is to provide a framework for pharmacy departments and healthcare teams in health-system settings that can be used to develop policies and procedures that address externally or internally initiated drug recalls. These guidelines are focused on minimizing the impact on patient care because it is impossible for healthcare organizations to prevent drug recalls from occurring. There are other recalls that affect health-systems, these guidelines focus only on drug recalls and not on recalls related to medical devices.

Definitions

External recalls: Recalls of any priority level that originate from outside entities, e.g., FDA or manufacturer-initiated recall.

Internal recalls: Any recall or quarantine process due to concerns originating from inside an organization, e.g., recall of a product due to increase of ADRs in the organization or particulates discovered in batched compounded sterile medications.

Planning for Drug Recalls

The pharmacy department plays an integral leadership role in drug recall management as the primary procurer of drugs and through drug inventory management for the organization. Effective recall management in any organization requires several essential elements of infrastructure that must be in place before a recall occurs: a drug recall team and team leader and established processes.

Recall Team Structure. The first step is to identify an interdisciplinary team of key staff who can make decisions, access, and assess recall information. For many healthcare settings, a dedicated and trained Recall Team that knows all the policies, procedures and pertinent regulations will provide best support to the hospital by responding and managing recalls in a consistent manner. Members of the Recall Team should reflect the applicable stakeholders for the organization (See *Table 1. Examples of Drug Recall Stakeholders*)

Table 1. Examples of Drug Recall Stakeholders

Within the Pharmacy	Within the Hospital	Within the Health System	Ancillary Services

• Drug Procurement Service Line
• Medication Safety Pharmacist
• Clinical Pharmacy
• Drug Information
	• Pharmacy
	• Nursing
	• Providers
	• Patient Safety
	• Ad Hoc Departments
	  ○ Central Supply
	  ○ Radiology
	  ○ Biomedical Engineering
		• Hospital Team
		• Outpatient Team
		  ○ Enterprise Safety
		  ○ Community Pharmacy
		  ○ Ambulatory Services (e.g., Clinics, Home Care, Oncology Centers)
		  ○ Private Providers
			• Patient Safety
			• Quality Assurance
			• Risk Management
			• Legal
			• Public Relations
			• Infection Prevention

A specific point person should be designated to lead recall efforts, but no single person can manage all recall response activities alone. The medication safety officer role lends itself well as a Recall Team leader because medication safety officers are inherently a conduit between clinical teams and pharmacy operations. The Recall Team and the leader will be responsible for:

- Determining the method of the response and including additional clinicians in the response, e.g., including central material supply if the recall is related to fluids or outpatient providers when a recall involves drug samples
- Creating organizational situational awareness
- Briefing executive and department leaders on the occurrence and progress
- Concluding if the recall requires patient level follow-up and defining the clinical monitoring needed
- Determining additional actions and situational monitoring needed
- Establishing therapeutic alternatives
- Establishing means for continuous monitoring of the recalls

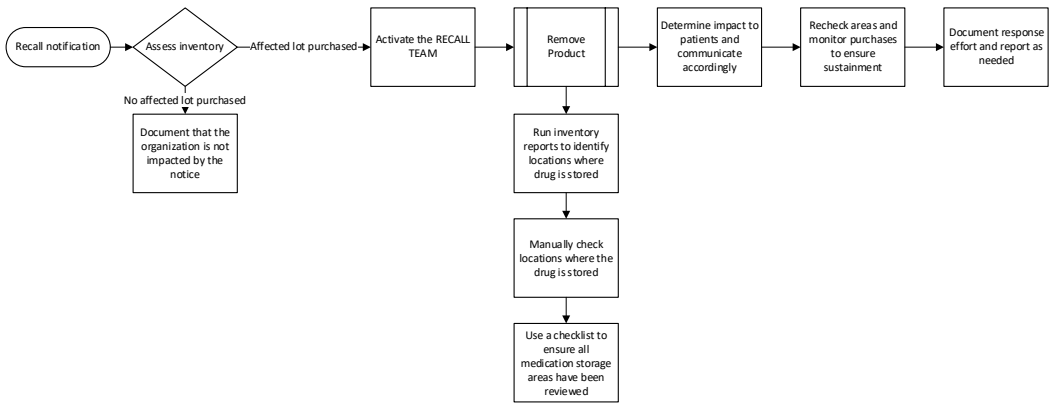
Policies and Procedures. The policies and procedures must be established to ensure a standard process to address recalls within the health-system. Policies and procedures should encompass all patient care areas, including outpatient services. Effort should be made for established policies and procedures to be the centralized for the enterprise. Proposed contents for policies and procedures for recalls:

1. Identify the roles and responsibilities of all personnel involved in the recall process in sufficient detail to ensure maximum compliance
2. Define the process to review external recall notifications at the organization, including which sources of recall information are reviewed
3. Define the process of how and when internal recall is initiated
4. Identify which recalls require action for the organization and define the organization's process for what to do for various recall levels (e.g., CLASS I, CLASS II, CLASS III, UNCLASSIFIED, internally initiated recall)
5. Define the process for escalating recalls that are not yet classified as CLASS I by the FDA for commercially available products (e.g., contaminated product recall that is not yet classified)
6. Identify methods for continuous monitoring of drug recalls
7. Determine a central documentation repository, manual or electronic, for all recall-related records
8. Develop education that is provided to stakeholders and their departments on a regular schedule that covers the organization's recall process, including:
    a. Federal and state regulations governing drug product
    b. Various communication methods throughout the organization to disseminate information regarding recalls (including email, fax inter-campus, interoffice mail, flyers, hospital newsletter – some of these methods are too slow but can serve as reminders).
        i. Including context about information shared in the organizational recall notices, its applicability to stakeholders, and what actions must be taken
    c. Location of central repository of recall notices applicable to the organization

Responding to a Recall Notice

The recall process is similar for both external and internal recalls. The identification of a drug recall initiates a cascade of events surrounding drug inventory management (Figure 1). When a drug recall is initiated, the Recall Team should conduct an assessment to evaluate its potential impact. The Recall Team should use that impact analysis to develop an action plan for approval and implementation.

Figure 1. Sample Recall Process Map



Recall Notification. The procurement service line can manage the receipt of recall notices in collaboration with a safety officer.

Redundant notification systems should be established to ensure the facility receives recall notices. Organizations are encouraged to subscribe to more than one method available for product recalls. Recall notices can arrive to hospitals via fax, certified letter, standard mail, emails from manufacturers, wholesalers, or notices with invoices for other drugs. Sole reliance on recall notification via the US Postal Service is not acceptable. Appropriate sources of external recalls include:

- http://www.fda.gov/Safety/MedWatch/default.htm
- FDA list-serves
- Patient safety and healthcare professional organizations (e.g., NAN, ISMP)
- Wholesalers
- 503B Pharmacies

For internal recalls, a review of voluntary safety reports and/or expert determinations by qualified clinicians should serve as notice of potential recall. These notices should be reviewed by the Recall Team or at minimum by medication and/or patient safety officers. If the notice warrants product removal, the process for an internal recall should be activated. Examples of internal recall notices include:

- Example #1: Ocular lubricant that has been linked to increased corneal ulcerations by the ophthalmology group (ADE)
- Example #2: Preparation error identified in a centrally compounded product (batched medications with or without extended BUD) after the product was released for use

Inventory Assessment. When an external recall notice is received, a purchase history can quickly help the procurement service line determine if affected product has been procured. Some external recalls may be applicable for drug samples; therefore, it is important that all sources of drug procurement are reviewed. Internally initiated recalls are related to drugs already available within the organization.

If the recall does impact an organization, the identified Recall Team must be activated to lead the process, as needed based on the recall type, external or internal, CLASS I, CLASS II, CLASS III, UNCLASSIFIED.

Locating Affected Drugs. Occasionally, drug recall notices do not require removing the drug from stock. When the drug removal is necessary, inventory reports can expedite location of drugs stored in automated dispensing cabinets and inventory storage solutions. Automated pharmacy kit processing software collects drug information which can guide response to drugs in prepared kits, medication boxes, and emergency carts that are stored outside of the pharmacy. At times, these kit systems are equipped with RFID technology which can expedite locating of affected carts and/or trays within the organization.

Checklists are an effective tool to ensure all drug storage locations have been reviewed. Organizational checklists should be created and cross-checked during a recall response to ensure all locations have been reviewed. For each location, the checklist should include the removal was complete and/or if area does not have affected product (see Documentation, Auditing, and Tracking). A completed checklist is

confirmation of the organizational response, and it should be maintained as record. Locations that should be considered for inclusion on an organizational list include:

- Inpatient pharmacies (central and decentralized)
- Outpatient pharmacies
- Patient care units
- Ambulatory clinic departments pharmacies
- Procedural areas (e.g., floor stock)
- Automated dispensing cabinets
- Medication boxes/kit (e.g., code drug trays, emergency carts, kits)

In order to ensure a thorough sweep, consider reviewing impacted areas at a defined period of time to ensure no affected lots remain where drugs are stored. Additionally, continue to monitor incoming purchases for defined period of time (e.g., 2 to 4 weeks) to ensure no affected lots are delivered.

Quarantine of Affected Drugs. Establishing a central location to collect removed affected drugs is essential to assess the impact of the recall and to prepare affected product for return to the manufacturer or to be internally wasted. A quarantine should be established in a centralized location that can be easily identified. The quarantine location should allow for segregation and physical separation from locations used to store other drugs. The space should be locked, and access should be restricted, if possible. For hazardous medications, the hazardous drug receiving room can serve for this purpose.

For large health-systems and organizations, a central location quarantine may not be feasible, and a local quarantine location may be utilized. For local quarantine, staff should be made aware of the quarantine location and the status of the drugs. Periodic verification of counts can help validate if quarantined product has been removed or used when stored locally.

Quarantine use should include documentation and outward communication. Any drug placed into the quarantine location should be accompanied with information about the drug (Table 2). This information should be maintained on the bin or bag in which the drug is contained, and it should be logged into the central documentation system maintained by the Recall Team. Additionally, communication, written information paired with in-person huddles, to frontline providers and staff is important to bring awareness in pharmacies with local quarantine supply to prevent comingling of drugs.

Table 2. Recommended Information to Document for Recalled Drugs

Quarantine Details	Sample Affected Drug Bag or Bin Label

• Quarantined Drug- NOT FOR PATIENT USE
• Drug Information
  ○ Name
  ○ NDC
  ○ lot number
  ○ expiration number
• Recall information
  ○ Effective Date: <date> until <date>.
• Count of items <number>
	Quarantined Drug
	NOT FOR PATIENT USE
	
	epinephrine (*Pharmaceutical Co)*
	NDC:1234-234-12 lot: ABC123
	
	MANUFACTURER RECALL
	Effective Date: 1/1/21 to TBD

• Contact information	Removed from: Central Pharmacy Count: 51 vials Contact: Director of Pharmacy

Communication. Creating awareness with stakeholder groups is necessary and the level of communication is dictated by recall level (see Consumer Level Recall). Internal stakeholders, i.e., departments within the health-system, should be notified of the recall when a determination has been made that affected drugs are stored or in the custody of that department. For products that may be widely distributed, notification of product removal from use should be shared with nursing and procedural units through email and safety huddles.

In addition to communicating to internal stakeholders (i.e., departments within the organization), reporting of the incident to appropriate regulatory bodies, i.e., FDA through MedWatch, should be completed especially for internally initiated recalls related to adverse drug reactions. Manufacturer reports can supplement Med Watch reports.

Communication within peer networks, local hospitals or regional organizations, is effective in identifying ADR trends. Safety networks can serve as a forum for sharing ADR trends for non-officially recalled products. These platforms should be used strategically and sparingly and should not replace official ADR-modes of reporting. Examples of patient safety organizations include ASHP Connect Community, ISMP and MSOS links.

Table 3. Guidelines for sharing ADE or Recall Information through Professional Forums

Do	Avoid
• Include generalized description of a safety story • Ask if others have seen similar reactions (or recent increase in reactions) • Do take conversations off-line ○ Include an ISMP representative when a possible trend is identified	• Including manufacturer (or details that can point to a manufacturer) • Lengthy back-and-forth conversations on thread (take off-line) • Sharing of identifiable patient information

Documentation. All activities related to external and internal recall notice response must be documented, even if no affected product was identified at the organization. Documentation should be maintained centrally. Electronic recall documentation systems helpful to manage workload and capture documentation digitally.

Consumer Level Recall Process. Healthcare organizations should establish policies and protocols regarding the disclosure of drug recall information to patients and the extent of these disclosures. Disclosure may vary depending on the type of recall and the exposure of the patient to the recalled drug. Some recommendations for patient notification about recalled products include:

> For all consumer level, every effort should be made to contact patient by phone or mail. Recalls may initially be categorized as a lower level and updated to consumer level later. The clinical

leadership or legal department and the Recall Team should review collected recall information, impact, and plan of address, prior to any patient notification.

To investigate exposure, a patient contact list can be compiled through a prescription list report for affected drug over the affected period to create. For recalls related to microbial contamination, infection prevention personnel should be included in the evaluation of impact, execution of a global infection search within the medical record, and the drafting of patient notices.

The method of patient contact should be reviewed by consulted stakeholders including community or patient relations. The FDA offers resources and templates, written and phone scripts, for communication of recall information to patients. Match the method of patient contact to the volume of patients identified. For small numbers, contact by phone (see attached Phone Script). For moderate patient numbers, mail may be a more feasible. If contacting greater numbers, investigate a mail service (see attached Sample Letter). The legal and public relations departments can aid in determining modes of communication for widespread recalls, e.g., shelf-talkers, or announcements near point of sale.

Additional Considerations for Internal Recalls. Guidelines for determining drugs not permitted for use in the organization following an internal recall related to adverse drug reactions can ensure a standard approach when internal recalls are triggered. The inclusion of standard adverse drug reaction assessment tools, such as Naranjo probability assessment, can aid in the decision-making. Key stakeholders in safety and clinical are important to include in the final determination. These stakeholders include the Patient Safety Officer and/or Medication Safety Officer, the Chief Medical Officer, and Pharmacy Operations Director and/or Director of Pharmacy. A trigger reminder for follow-up is a helpful tool ensure all internally initiated recalls are reviewed and determination on the use of the product in the organization is made. Triggers can be embedded into the recall documentation repository.

When a drug is not permitted for use in the organizations following an internal recall related to an adverse drug reaction, steps must be taken to avoid the reintroduction of the drug into the inventory. Forcing functions can decrease the risk of reintroduction of affected drugs through the application a "do not purchase" list within the procurement service line. Some wholesalers are capable of programming an organizational "do not interchange" list so products are not recommended for substitution even if the product is cost effective, available, or not on shortage.

If a drug is determined to not be definitively linked to an adverse drug reaction and it will be continued to be used in the organization following an internal recall, a plan for a controlled release of the suspected affected drug should be developed and implemented. A controlled release aids in the monitoring for additional adverse drug reactions.

Quality Assurance and Process Improvement

The Recall Team should implement periodic reporting of recall activities to patient safety or pharmacy and therapeutics committees. An ongoing monitoring and reporting program can provide benefits to the

organization, pharmacists, health care professionals, and patients. Specific benefits include an indirect measure of the quality and incidence of ADRs related to drug recalls, supplement to organizational risk-mitigation activities, and as a measure of the economic impact of drug recall response on the organization.

Data collections Data that should be considered for collection and dissemination on an organizational level could include:

- The number of recalls received by the organization.
- The number of recalls requiring action by the organization.
    - May be listed by action type
- The length of time from receipt of the recall notice until closure is attained.
- The number of patients affected or potentially affected, including any adverse outcomes.
- The location and quantity of recalled product returned.
- Identification of any problems encountered with the recall process.

Key Takeaways and Summary

Key Takeaways

- Identify a multidisciplinary Drug Recall Team Structure and clearly define roles and responsibilities
- Develop policies and procedures that outline drug recalls processes including notification, escalation pathways, continuous monitoring, communication, and documentation.
- Report drug recall activities to patient safety and/or pharmacy and therapeutics committees on a regular cadence

Summary

In summary, drug recalls can impact the medication use process by potentially resulting in adverse drug reactions or creating temporary shortages of medications. A proactive and multidisciplinary approach is required to effectively manage drug recalls. The pharmacy department plays a key role, but must be supported by health-system leadership. Pharmacy departments and healthcare teams can use this document as a framework to develop policies and procedures to manage drug recalls.

References

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2. Flowers P, Dzierba S, Baker O. A continuous quality improvement team approach to adverse drug reaction reporting. Top Hosp Pharm Manage. 1992; 12(Jul): 60–7.
3. American Society of Hospital Pharmacists. ASHP Guidelines on Adverse Drug Reaction Monitoring and Reporting. Am J Health-Syst Pharm. 1995; 52:417–9.

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To report an adverse drug event to the FDA, use the MedWatch program. Reports can be completed online or mailed (MedWatch, 5600 Fishers Lane, Rockville, MD 20852–9787), faxed (800-FDA-0178), called in (800-FDA-1088). An easy-to-use FDA form 3500 can be used. This form is available for access on the FDA website www.accessdata.fda.gov/scripts/medwatch/index.cfm

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Appendices

Includes a sample drug recall script and a sample recall letter.

Sample Drug Recall Phone script to patients:

Quinapril and Hydrochlorothiazide Tablets, 20 mg/12.5 mg

Our records indicate you had a prescription filled at _____ that may be part of a nationwide recall. The generic ingredients are Quinapril and Hydrochlorothiazide Tablets, 20 mg/12.5 mg and was filled on _____

- The company is recalling certain lots of the product because testing found that certain lots may have exceeded levels of a contaminant greater than allowed by FDA for a carcinogen called a nitrosamine*.
- None of the BJC pharmacies had recalled drug on their shelves, but in abundance of caution, we are calling.
- The risk is minimal, however we recommend getting a new supply and that you stop taking your current supply, if any.
- If you think you have experienced any problems related to the product, please contact your doctor.

***More about nitrosamines:**

Nitrosamines are common in water and foods, including cured and grilled meats, dairy products and vegetables. Everyone is exposed to some level of nitrosamines. These impurities may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time.

Sample Recall letter to patients:

Date

Dear Pharmacy Patient,

Our records indicate you had a prescription filled at _____ Pharmacy that may be part of a nationwide recall.

The prescription drug name was labeled Citrate of Magnesia or Magnesium Citrate and was dispensed in a 10-ounce clear round plastic bottle.

The prescription was filled between Jan 1st, 2022 and now.

The manufacturer is voluntarily recalling the product as a precautionary measure due to potential contamination with a bacterium. These bacteria are unlikely to cause infection in individuals without serious medical conditions. Patients at a slightly higher risk of infection may include patients with medical conditions such as cystic fibrosis or decreased immunity. To date, the manufacturer is aware of 3 reports of possible adverse events related to this recall.

If you have any of this medication remaining, please stop using the product.

If you have not used this product, do not use and discard it.

If you need a replacement, please contact your prescriber for an alternative.

If you have questions regarding this recall can contact Vi-Jon, LLC by e-mail (Recalls@Vijon.com) or Phone: 314-592-1400, Monday-Friday, from 7:30 am to 4:30 pm, Central Time.

Please contact your physician or healthcare provider if you have experienced any problems that may be related to taking or using this drug product.

If you have any additional questions, please contact XXX Pharmacy at XXX-XXX-XXXX