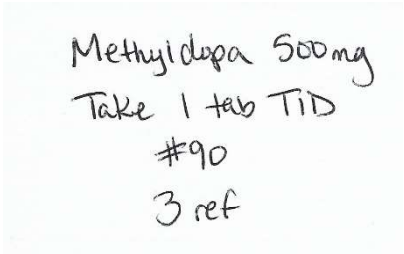
Technician Tutorial:
Managing Drug Shortages

Drug shortages are a common occurrence in pharmacies, and a burden for the healthcare system and patients. Drug shortages are time-consuming, frustrating, and can increase healthcare costs and the risk for medication errors. Sometimes patients can't get needed treatments when meds are in short supply. For example, almost two-thirds of hospitals reported that they changed patient care or delayed therapy due to drug shortages. It's important for pharmacy teams to have efficient strategies for managing drug shortages.



A 32-year-old pregnant patient with high blood pressure drops off a prescription for methyldopa 500 mg, take 1 tablet 3 times a day. You don't have methyldopa in stock, and it was unavailable from your wholesaler the last time you tried to order it.

What is a drug shortage?

The Food and Drug Administration (FDA) defines a drug shortage as a time when the total available supply of all versions of an approved product doesn't meet the current demand, and a registered alternative manufacturer is not able to meet the current and/or projected demands. To pharmacies, it simply means that despite ordering adequate amounts of a med, you can't get enough to fill all the prescriptions or orders you get.

Why do drug shortages happen?

Drug shortages can happen for a variety of reasons, including drug recalls or withdrawals, discontinuations, unavailability of raw materials needed for production, or ripple effects from shortages of other similar products. Drug shortages can be caused by natural disasters, such as when a manufacturing plant is damaged and cannot produce its usual supply. They can also be caused by global pandemics, such as COVID-19. Pandemics can lead to increased demand for meds used to treat patients affected by the disease or manufacturing delays caused by impacts of the disease on the workforce.

Recalls are the most common cause of drug shortages. You can find more details about recalls and withdrawals in the last section of this document. These are important for you to know about because they may have an additional impact on your workflow beyond what you'd need to do for a med in short supply.

Examples of drug shortages caused by a pandemic are hydroxychloroquine and chloroquine. These meds were being tried to prevent or treat COVID-19. Demand quickly went up. Unfortunately, this led to access issues for patients already taking hydroxychloroquine for chronic conditions, such as rheumatoid arthritis or systemic lupus erythematosus.

What are some examples of critical drugs that have been in short supply?

In the US, there's a lot of focus on shortages of hospital meds. These have consistently included injectable epinephrine (used for resuscitation of patients in cardiac arrest); propofol (used to sedate patients in critical care or during surgery); and injectable furosemide (used to help patients get rid of fluid build-up in the body so the heart and lungs can work normally). There have also been shortages of some chemotherapy drugs, such

as leucovorin and vincristine. These shortages have caused cancer treatment delays. Shortages of electrolyte solutions such as calcium salts have been troublesome for compounding parenteral nutrition. Even IV fluids (e.g., normal saline) and med diluents (e.g., sterile water) have been in short supply. All of these shortages are serious and could result in suboptimal patient care or in some cases, patient harm.

You inform the pharmacist that you saw a supply shortage update come in from your supplier for methyldopa. The notice said there's a shortage of the active ingredient, which is causing the med to be on backorder. There is no resolution date provided. You tell the pharmacist that the patient, who is pregnant, has an Rx for methyldopa. The pharmacist mentions methyldopa one of the preferred meds for pregnant patients with high blood pressure, but there are other options. He says that he'll speak with the patient.

What strategies can I use to prevent problems during drug shortages?

Monitor drug shortage lists. These can help you anticipate shortages that might affect your pharmacy and help you know when a shortage is expected to resolve. FDA has a list of drugs in shortage at https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm. FDA also has a mobile app called "DrugShortages" that might be useful to keep close tabs on shortages. The American Society of Health-System Pharmacists (ASHP) has a list at https://www.ashp.org/Drug-Shortages. Here you can find current and resolved shortages, the reason for a shortage, and more. In Canada, you can access https://www.drugshortagescanada.ca/ and https://medsask.usask.ca/professional-practice/drug-shortages.php to get details about current shortages and alternatives. Your wholesalers and distributors may also have lists of meds they usually stock that are in shortage.

Sometimes, pharmacy listservs will have information on drug shortages, and you can get automatic email updates if you subscribe online. Ask your pharmacist if you need help finding one to follow. In addition, your organization may share information such as email updates or newsletters about current drug shortages that are causing problems, which can be useful if you can't access other online resources.

If you work in the hospital, keep lines of communication open with your purchasing agent and your administrators to find out about potential drug shortages. This way, you can start thinking about how a particular shortage might affect your pharmacy or your practice area and consider ways to help.

Try to find out why the shortage is happening. This may affect your game plan. For example, you might be able to order a different strength of a med if one strength is short because of a discontinuation. Or you might need to order an alternative med if all strengths are short because of a manufacturing issue.

In the hospital setting, administrators could be making recommendations on how to handle drug shortages. However, your input is valuable, since your finger is on the pulse of what's happening with patient care.

Keep close tabs on your stock. It's important to know what's coming in and going out of the pharmacy. One big complaint about drug shortages is that they can happen with almost no notice. One day, a med simply won't come in from the wholesaler.

Check how much of a med your pharmacy is using by running usage reports. This information will help your pharmacy plan how to handle a specific shortage.

Also, when checking your stock, note expiration dates of meds in short supply. Use the ones with the shortest expiration first, to prevent waste. In the hospital, if your practice area doesn't move a med very quickly, contact someone in charge to see if you can trade your short-dated med for one with a longer expiration. That way, a practice area that uses the med more frequently can use the short-dated supply before it expires.

For meds in short supply, try to contact your supplier to get more details about availability. Ask about limits on the amount you can order, and when/if the med is expected to be available again.

Order sufficient supplies of alternatives. Having alternatives on hand can help ensure patients can be treated appropriately and avoid treatment gaps. You may be lucky enough to get a med in if you order a different generic or brand of what you need. Or, you may have to get a different product, such as a different strength or dosage form. In the community pharmacy setting, there will be times when an insurer does not cover an alternative product. This might require you to take additional steps, such as contacting insurers to get override or exception codes, or in the US, inputting certain dispense-as-written (DAW) codes. For example, DAW 4 can be used for a brand-name product when generic substitution is allowed, but the generic is not in stock. And DAW 8 can be used when the generic product is not available in the marketplace.

As an example, when certain strengths of injectable epinephrine are in short supply, such as 1 mg/10 mL prefilled syringes, other available strengths, such as 1 mg/mL vials, may have to be used instead. (Note that it's critical to use strategies to prevent dangerous mix-ups and errors with alternative products, and there is more information on this below.) Another example of an alternative is bumetanide, which is an option if the diuretic furosemide is unavailable. If bumetanide is available and furosemide is not available, it will be important to try to stock enough bumetanide to take up the slack.

Know when to allocate meds in short supply. Pharmacies may save shortage meds for certain patients. For example, during the COVID-19 pandemic, some community pharmacies saved hydroxychloroquine for lupus or rheumatoid arthritis patients. And hospitals saved metered-dose inhalers (MDIs), such as albuterol (or salbutamol in Canada), for COVID-19 patients, since nebulizer use can release large amounts of infectious airborne particles.

Refer questions about using meds past their expiration date to the pharmacist. Patients taking meds in short supply may wonder if they could take or use expired meds that they haven't disposed of. Send these questions to the pharmacist. FDA has a list of meds that can be used past their printed expiration date in an emergency. This list of extended use dates is at https://www.fda.gov/drugs/drug-shortages/search-list-extended-use-dates-assist-drug-shortages. For example, certain lots of *EpiPen* epinephrine auto-injector have an extended use date of four months.

Avoid hoarding drugs. Ordering excessive amounts of a med for your pharmacy, or even hoarding it in your hospital pharmacy satellite, can keep patients who need the med from getting it by creating "artificial shortages." Plus, hoarding can increase pharmacy costs. Instead, follow your pharmacy's guidance on how much you should stock, such as by running usage reports to find out how much you'll need. If you have no guidance, estimate how much you'll need over a certain period of time rather than ordering all you can get.

You can also help keep patients from hoarding meds. Be alert for large quantity prescriptions or unusual numbers of prescriptions for a shortage med. Patients may try to get meds "just in case," which can make drug shortages worse.

Communicate with other pharmacy staff, nurses, prescribers, and patients. This can help save time and avoid confusion. You might need to notify prescribers' offices that a particular med is temporarily unavailable and tell them what alternatives you do have. Or in the hospital, you might need to let nurses know a different strength of a med is being stocked instead of what's usually used, or that a shortage med is being dispensed from the pharmacy instead of from automated dispensing cabinets.

In some cases, you might be able to contact another pharmacy to see if they have a med a patient needs, if you don't have it. If a med is unavailable and a patient must be switched to another treatment, alternative options can be shared with prescribers.

Run a report to identify patients on a shortage med. Consider contacting them before they run out, especially when the shortage resolution date is unknown. It's a good idea to get ahead of things to avoid last-minute scrambling and treatment gaps. Help patients come up with a game plan, such as by offering to check with another pharmacy or having the pharmacist contact the prescriber to switch to an alternative.

Anticipate and safeguard against errors. As mentioned, an alternative product may have to be used during a drug shortage. Compared to the med you usually carry, alternative products may be made by different manufacturers, and have different appearances, strengths, package sizes, etc. Try to anticipate where errors might happen and suggest safeguards to prevent them. Watch for labels or packaging (e.g., cap color, vial size) that could lead to confusion. For example, the label for a product that you're using in place of a med that's short might look similar to a completely different product that's usually stocked in your pharmacy. This could cause mix-ups. Or stocking a different strength of a product, say a 2 mg/mL concentration, might confuse nurses accustomed to seeing a 1 mg/mL concentration. This could lead to an overdose. Consider measures such as using computer alerts, special labels, or shelf tags to avoid these problems.

Another activity that could lead to errors is when prepping individual doses of injectables in the pharmacy to prevent waste of meds in bulk vials. This requires drawing up individual doses into syringes. Ensure the labeling includes the total dose in the container, as well as the med concentration. This is what FDA requires for injectable med labels. Be sure an appropriate beyond-use date is also included on the label. For example, you wouldn't want to use the manufacturer's expiration date. Instead, you'd likely have a shorter date depending on whether doses are drawn up from single- or multidose vials.

Support your pharmacy's "go-to" person for managing drug shortages, if available. Some pharmacies have one person who coordinates everything surrounding drug shortages. Communicate effectively with this person, following any kind of guidance that's put into place. Also, give feedback on what's working and what's not. The intensity of drug shortages we've seen the last few years is greater than ever, so we're still learning better ways to reduce the impact on patient care.

You can learn more about drug shortages by reviewing our CE course, *Maintaining the Drug Supply Chain*.

The pharmacist speaks with the patient. The patient tells the pharmacist that methyldopa worked for her during her last pregnancy. She is open to another drug, as long as it will still be safe for her baby. The pharmacist spends time talking to her about labetalol and its use in pregnancy. The pharmacist then calls the prescriber to recommend switching to labetalol, and to obtain a new Rx.

What are additional considerations for when a drug is recalled?

As mentioned, drug recalls are the most common cause of drug shortages. Drug recalls are usually associated with a product defect or contamination. They're often voluntary, by the manufacturer, but can be mandated by the FDA or Health Canada. Information about drug recalls is issued by FDA and Health Canada. A specific batch or lot of a product may be recalled, or all batches or lots may be affected. There are three recall classes in the US, **Class I, II, and III**. Health Canada's system is similar, where **Type I**, **II**, and **III** correspond to FDA classifications.

Class I/Type I recalls involve products likely to cause **serious adverse events or death**. For example, some lots of *EpiPen* and *EpiPen Jr* have been recalled due to concerns that the autoinjector may not release the lifesaving med during a severe allergic reaction.

Class II/Type II recalls involve products that could cause **temporary but reversible effects**. These are often due to issues with product sterility. For example, some lots of *Refresh Lacri-Lube* eye ointment were recalled because of particles that got into the ointment when unscrewing the cap.

Class III/Type III recalls involve products **unlikely to cause adverse events**. These are usually manufacturing or packaging issues. For example, one lot of amlodipine 10 mg was recently recalled due to some 2.5 mg tablets found co-mingled within the bottle.

A product is usually **withdrawn** because its risks outweigh its benefits. Withdrawals often involve a product being taken off the market completely. For example, FDA requested that *Opana ER* (oxymorphone extended-release tablets) be withdrawn due to concerns about misuse and abuse.

You'll usually get recall and market withdrawal information from suppliers and/or internal notification (e.g., email, intranet). FDA and Health Canada issue statements, at https://www.fda.gov/Safety/Recalls/default.htm (US) and http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/index-eng.php (Canada). What needs to be done will depend on the recall or withdrawal and your policies and procedures. The goal will often be removing the product from stock.

Since recalls often pertain to specific lot numbers, the first step will usually be to check stock for recalled lots. This might be simple in a community pharmacy or small hospital pharmacy with stock in one place. But it can be complex in a large hospital, with meds stored in various locations. The effort may be coordinated by one person. Check policies and procedures for what's expected of you.

In community pharmacy, also check prescriptions waiting to be picked up (will call). Look for refrigerated items, products needing to be reconstituted or mixed, etc. If possible, generate a usage report based on NDC number (or DIN in Canada) to identify prescriptions waiting to be picked up as well as prescriptions that have already been picked up.

Once recalled product has been removed from stock, it'll usually need to be sent back to the supplier. Follow directions on the recall notice and your company policies and procedures. Adjust inventory counts as recalled items are pulled and follow federal and state laws for controlled substances.

Patients who've received a recalled med may need to be notified. Manufacturers will usually issue a press release. Patients may need disposal directions, or instructions to bring unused med back to the pharmacy, get a replacement product, etc.

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"Cheat Sheet" for Managing Drug Shortages

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Why do drug shortages happen?

Drug shortages can happen for a variety of reasons, including drug recalls or withdrawals, discontinuations, unavailability of raw materials needed to produce a drug, or ripple effects from shortages of other similar products. Drug shortages can be caused by natural disasters, such as when a drug manufacturing plant is damaged and cannot produce its usual supply. Global pandemics, such as COVID-19, can also lead to increases in demand for drugs used to treat the disease or manufacturing delays caused by impacts of the disease on the workforce.

What strategies can I use to prevent problems during drug shortages?

- Monitor shortage lists from FDA (or Health Canada), ASHP, and your wholesaler/distributor to learn more about shortages impacting your pharmacy, such as when the shortage is expected to resolve, available alternatives, etc.
- Try to find out why the shortage is happening to help determine your strategy, such as ordering a different strength of a med if just one strength is in short supply.
- Stay on top of your pharmacy's inventory by checking how much of the shortage med you're using and noting expiration dates of meds in shortage.
- Order sufficient supplies of alternatives by adding the usage of the shortage med to the current usage of the alternative med.
- Manage any payer rejects for alternative meds by using appropriate DAW codes (in the US) or reaching out to the payer for an override.
- Know when to allocate meds in short supply to ensure the right patients are getting needed meds according to your pharmacy's policies.
- Refer questions from patients about using meds past their expiration date to the pharmacist.
- Avoid hoarding meds. Don't order excessive amounts of a shortage med. Refer prescriptions for large quantities of a shortage med to the pharmacist.
- Communicate shortage issues with other pharmacy staff, prescribers, nurses, and patients to help save time, avoid confusion, and prevent gaps in treatment.
- Contact other pharmacies to see if they have the med a patient needs.
- Anticipate and prevent errors with alternative meds.

What are additional considerations for when a drug is recalled?

Recalls are the most common cause of drug shortages. Recalls are usually associated with a product defect or contamination. A specific batch or lot of a product may be recalled, or all batches or lots may be affected.

The potential impact of a patient using a product that's been recalled ranges from minimal to potentially deadly. Your main goal in the pharmacy will typically be identifying recalled products and removing them from stock. Follow instructions from FDA and Health Canada, and company policies and procedures.

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