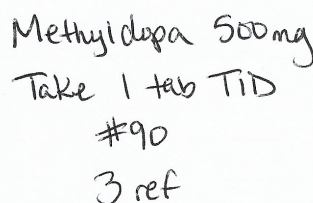


Technician Tutorial: Managing Drug Shortages

Managing drug shortages has become a common occurrence in many pharmacies. Although the number of drug shortages declined after a peak in 2011, they're starting to increase again. Drug shortages are a burden for the healthcare system and patients. They are time-consuming, frustrating, and can increase healthcare costs and the risk for medication errors. Sometimes patients can't get needed therapies when drugs are in shortage. For example, 56% of hospitals reported they had changed patient care or delayed therapy due to drug shortages, and 36% said they had rescheduled non-urgent procedures. It has become increasingly important for pharmacy teams to have tools and efficient strategies for dealing with drug shortages.



Methyldopa 500mg
Take 1 tab TID
#90
3 ref

Alice is a 32-year-old pregnant patient with high blood pressure. She is dropping off a prescription for methyldopa 500 mg, take one tablet three times a day. You do not have methyldopa in stock. 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 for the potentially medically necessary use. To pharmacies, it simply means that despite ordering adequate amounts of a drug, 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 recall of drug products because of contamination, manufacturing issues (e.g., questionable quality control), drug 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 has been damaged and cannot produce its usual supply. They can also be caused by global disease pandemics, such as COVID-19. Pandemics can lead to unexpected increases in the demand of certain drugs used to treat patients affected by the disease or manufacturing delays caused by impacts of the disease on the workforce.

An example of a drug shortage caused by a **recall** was the shortage of the stomach acid reducer, ranitidine (*Zantac*, etc). In late 2019, manufacturers began recalling their ranitidine products in the U.S. and Canada, due to an elevated amount of an unexpected impurity, N-Nitrosodimethylamine (NDMA). This is the same impurity that sparked recalls of the blood pressure-lowering meds losartan, irbesartan, and valsartan. The concern with NDMA is that it's a probable carcinogen; however, the cancer risks from most products contaminated with NDMA is very low, similar to the levels people are already exposed to from water and common foods (bacon, grilled meats, dairy, etc). In 2020, FDA took the next step and requested the removal of all ranitidine products from the market. This was due to data suggesting that NDMA in some ranitidine products increases over time and when stored at higher than room temps, and may result in an unacceptable amount of consumer exposure. Ranitidine may be available again in the U.S. in the future if a manufacturer can show that their product is stable and the NDMA levels don't increase over time to unsafe levels.

Examples of drug shortages caused by a **pandemic** are the shortages of hydroxychloroquine and chloroquine during the COVID-19 outbreak. These meds were being tried to prevent or treat COVID-19, so demand for them went up in a very short period of time. Unfortunately, this led to medication access issues for patients already taking hydroxychloroquine to treat chronic conditions, such as rheumatoid arthritis or systemic lupus erythematosus (SLE).

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

In the U.S., there's a lot of focus on shortages of hospital drugs. These have consistently included drugs like injectable epinephrine, which is used for resuscitation of patients in code situations or cardiac arrest; propofol, which is used to sedate patients when they're in surgery or intubated in critical care; and injectable furosemide, which is used to help patients get rid of fluid build-up in the body so that their hearts and lungs can work normally. There have also been shortages of some chemotherapy drugs, such as leucovorin and vincristine, which have caused treatment delays for some patients. Shortages of electrolyte solutions such as calcium salts have been troublesome for compounding parenteral nutrition. Even IV fluids such as normal saline have been in short supply at times. All of these shortages are serious, and could result in less than optimal 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 that there is a shortage of the active ingredient, which is causing the medication to be on backorder, and that there's no shortage resolution date provided at this time. You tell the pharmacist that Alice, who is pregnant, has a prescription for methyldopa. The pharmacist mentions that it's one of the preferred meds for pregnant patients who have high blood pressure, but there are other options available. He says that he will take a minute and speak with Alice.

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

Monitor drug shortage lists. These can help you anticipate shortages that might affect your pharmacy, and also help you know when a drug shortage is expected to resolve. FDA has a list of drugs that are in shortage at <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>. FDA also has a mobile app called "DrugShortages" that might be useful for keeping very close tabs on shortages. The American Society of Health-System Pharmacists (ASHP) also has a list at <https://www.ashp.org/Drug-Shortages>. Here you can find current and resolved shortages, the reason for the 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. The wholesalers and distributors you work with may also have lists of medications 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 to them. 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 shortages that are causing problems, which can be especially useful if you can't access other online resources at your workplace.

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 shortage might affect your pharmacy, and start to consider ways to help handle the shortage.

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 drug if just one strength is short because of a discontinuation. Or you might need to order an alternative drug if all strengths are short because of a manufacturing issue.

In the hospital setting, administrators could be making recommendations on how to handle shortages. However, your input is valuable, since you are able to keep your finger on the pulse of what's happening on the front lines of patient care.

Keep close tabs on your stock. It's important to know what is coming in and going out of the pharmacy. One of the big complaints about shortages is that they can happen with almost no notice at all. One day, a drug simply won't come in from the wholesaler. Just because you ordered a drug doesn't mean you'll receive it.

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

Also, when you check your stock, make sure to note expiration dates of drugs that are in shortage. Use the ones that have the shortest expiration first, to avoid wasting any valuable doses. In the hospital setting, if your practice area doesn't move a drug very quickly, contact someone in charge to see if you can trade your short-dated drug for one with a longer expiration. That way, a practice area that uses the drug more frequently can use the short-dated drug before it expires.

For drugs that are short, try to contact your supplier to get more details about product availability. Ask about limits placed on the amount you can order, and when/if the drug is expected to be available again.

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

As mentioned, certain strengths of injectable epinephrine have been short, and other strengths that have been available have been used in their place. (Although, it has been important to use strategies to help prevent dangerous mix-ups and errors with different products.) 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 for furosemide.

Know when to allocate meds in short supply. Some pharmacies may take the approach of saving shortage meds for certain patients. For example, during the COVID-19 pandemic, some community pharmacies were saving hydroxychloroquine for only their lupus or rheumatoid arthritis patients. And hospitals were saving metered-dose inhalers (MDIs), such as albuterol inhalers, for COVID-19 patients, since nebulizer use has a risk of releasing large amounts of infectious airborne particles.

Refer questions about using meds past their expiration date to the pharmacist. Patients who are taking meds that are in short supply may wonder if they could take or use expired meds that they haven't disposed of yet. Send these questions to the pharmacist. FDA has a list of specific meds that can be used past their printed expiration date if needed in an emergency situation. This list of extended use dates can be found here: <https://www.fda.gov/drugs/drug-shortages/search-list-extended-use-dates-assist-drug-shortages>. For example, some lots of the single-dose glass syringe injectable epinephrine from Pfizer have an extended use date of one year from the printed expiration date. And certain lots of the *EpiPen* epinephrine auto-injector have an extended use date of four months.

Avoid hoarding drugs. Ordering excessive amounts of a drug product for your pharmacy, or even hoarding it in your hospital pharmacy satellite, can prevent patients who need the drug from getting it by creating “artificial shortages.” Plus, hoarding can increase pharmacy costs. Instead, follow your pharmacy’s guidance on how much drug you should stock, such as by running usage reports to find out how much you will need. If you have no guidance, try to estimate how much of the drug you will actually need over a certain period of time instead of ordering all that you can get.

You are also in a position to help prevent patients from hoarding drugs. Be alert for large quantity prescriptions or unusual numbers of prescriptions for a shortage med. Some patients may be trying to get these meds for “just in case” situations, which can make drug shortages worse.

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

In some cases, you might be able to contact another pharmacy to see if they have the med a patient needs, if you don’t have it. If a drug is unavailable and a patient must be switched to another treatment, share our letter to notify prescribers, *Suggestion to Switch Medication*, with your pharmacist.

Run a report to identify patients on the shortage med. Consider contacting these patients 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 gaps in treatment. Come up with a game plan with the patient, such as by offering to check with another pharmacy or having the pharmacist contact the prescriber to switch to an alternative med.

Anticipate errors. As mentioned, your pharmacy may have to order alternate products during a shortage that are 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 that might lead to confusion. For example, the label for a product that you are using in place of a drug that is short might look too similar to a completely different product that’s usually stocked in your pharmacy. This could easily lead to mix-ups. Or stocking a different strength of a product, say a 2 mg/mL concentration, might confuse nurses who are accustomed to always seeing a 1 mg/mL concentration of a certain drug. This could lead to overdose. Consider measures such as recommending computer alerts, adding special labels, or using shelf tags to avoid these types of problems.

Another activity that could lead to errors is when prepping individual doses of injectable meds in the pharmacy to prevent wastage of meds in bulk vials. This requires drawing up individual doses of meds into syringes. Ensure the labeling of these preps include the total dose in the container, as well as the concentration of the med. This is similar to what FDA requires for labeling of injectable drugs. 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 the doses are drawn up from a single- or multidose vial.

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

You can learn more about drug shortages by reviewing our CE course, *Managing Drug Supply Chain Issues: Drug Shortages and Counterfeits*.

The pharmacist speaks with Alice. She says that methyldopa worked for her during her last pregnancy. She is open to another drug therapy, 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 get a new prescription for labetalol.

Project Leader in preparation of this technician tutorial (360580): *Flora Harp, PharmD/Associate Editor*

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“Cheat Sheet” for Managing Drug Shortages

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

- Monitor drug 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 drug if just one strength is in short supply.
- Stay on top of your pharmacy's inventory by checking how much of the shortage drug you're using and noting expiration dates of drugs 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 U.S.) 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 drugs and help prevent patients from doing this as well. Don't order excessive amounts of drugs and refer prescriptions for large quantities of a shortage med to the pharmacist. Hoarding can make drug shortages worse.
- Communicate drug 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.

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