
Drug shortages on the ambulance: What can EMS do?

by Jeff Beeson, DO



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You've probably heard there is a national shortage for many of the commonly used medications. From an EMS perspective, these are medications that cost less than a dollar a dose, such as epinephrine...or dextrose... or a benzodiazepine — medications essential to treat some of the most common life-threatening conditions! At this writing, the most recent report from a national vendor reveals shortages in morphine, fentanyl, midazolam and magnesium with uncertain future delivery dates. There is no easy fix for this problem and the shortages will certainly continue.

The Texas Department of State Health Services and the Texas Medical Board have both released statements on use of medications past expiration. These statements assure EMS providers that they understand the national drug shortage crisis and will take that into consideration if an agency is found stocking or using expired medicines. These statements do not support their use, but they do let us know the state regulatory agencies understand the problem and are doing what they can to help.

GETAC's medical directors committee, of which I am a member, has discussed this issue at length. Still, there are more questions than there are answers. As a practicing medical director of a large, urban system, I have a few suggestions on how to cope:

- Monitor the usage of every medication deployed in your system. Historical usage data is very reliable and can give you insight on the inventory levels that you set for each medication. Consider reducing the level for the drug box on certain medications or carrying two doses of a medication rather than three. How much do you keep on hand? What is your projected time until you run out? Having answers to these questions will help you keep you prepared. A useful site for monitoring shortages can be found at www.fda.gov/Drugs/DrugSafety/DrugShortages.

- Develop a regional approach by communicating with hospital pharmacists, vendors, EMS agencies, medical directors and others to better understand the issue and its impact on patient care. Use that communication to develop local practices and guidance. The Southwest Texas RAC (STRAC) has designed a great web-based system of tracking medicines on the shortage list. This allows agencies to post needs they have and stock they are willing to share with others.
- Assign someone to make sure that your "soon to expire medications" are placed so they are used first.
- Consider extending expiration dates, though that is a decision that ultimately falls to the medical director to authorize. Companies can examine your medications for potency, but manufacturers set expiration dates.
- You may be able to find a local compounding pharmacy that can create some of the medications that we are running short on. Visit www.pcab.org to find an accredited compounding pharmacy in your area.
- Think outside the box! Look for alternatives that aren't normally utilized by our supply chains. Do you have a cache of Valium auto-injectors that could be utilized?

The American College of Emergency Physicians, National Association of EMS Physicians, National Association of EMTs, National Association of EMS Officials, and others are working to find solutions. Recent federal legislation was passed that will require manufacturers to report changes in production, but legislation cannot force manufacturers to produce medication. Most of our shortages are generics and any manufacturer can produce them if they so desire.

The following are questions I've heard or discussed:

We carry morphine and Valium. Is there a substitute?

Morphine is an opiate analgesic. You can substitute Fentanyl, but it is also on the shortage list. Some non-narcotic analgesics, like Toradol, can be used; or you can use an agonist-antagonist opiate like Nubain or Stadol. Valium is a benzodiazepine. Others in that class that can be given through IV are midazolam (Versed) and lorazepam (Ativan). One option, if you need a benzodiazepine to control seizures, is to use Valium auto-injectors found in the nerve agent (CANA) kits.

Who should be given priority for supplies of critical medications — EMS systems or hospitals?

We are all in the same business of taking care of patients. An argument could be made for either side. I do know that most hospitals purchase in large groups and are usually given preference due to the amounts purchased. This should be approached on a local level by working with your distributors and hospitals.

Is there a rule of thumb on the use of medicines that are clear and free of visible contaminants or particulate matter even if they are expired?

There is no rule of thumb. The FDA approves the shelf life based upon information the manufacturer presents to them. We know that when any medication is stored outside of the manufacturer's temperature ranges, chemical decomposition is accelerated. Some companies will test potency to assist in extending the use-by date, but they do not have the authority to extend the expiration dates.

What would you recommend prehospital providers do when they are faced with a hospital that does not replace their medications?

Look into EMS distributors. There are many who specifically sell to EMS agencies. You may also work with a local pharmacy in your area that can also help find medications you need.

Is it possible to exchange controlled substances between providers while still meeting the DEA requirements for tracking?

Any movement of a controlled substance must follow DEA regulations. If you have

DSHS Drug Shortage Statement

DSHS is aware of drug shortages cited by the U.S. Food and Drug Administration (FDA), www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm. Some of the drugs on the FDA list, such as fentanyl, magnesium sulfate and lidocaine, are being used to treat patients in the prehospital setting by emergency medical services providers. If the department receives a complaint that a provider is using expired drugs or expired drugs are found on an ambulance during an inspection, the department will require the EMS organization to provide documentation from the manufacturer and the provider's medical director regarding the shortage of the specific drug(s) before considering an enforcement action. DSHS is recommending that the documentation is on any ambulance that has expired drugs approved by the MD.

For additional information visit the Texas Medical Board at www.tmb.state.tx.us/news/press/2012/120224.php.

questions about what forms to use and policies concerning transfer, I refer you to your local DEA office. Each region may have different interpretations of the rules.

There's been discussion about accessing the Strategic National Stockpile (SNS), particularly for benzodiazepines.

If that decision were to be made, it would first be on a local level that would then advance the request up to higher authorities so

once again, begin discussions with your area hospitals and RAC.

Because of temperature variation, we pull our medications based on a 90-day period. Is that really a necessary step?

Each medication has different temperature ranges that greatly affect the potency of the medicine. Each medicine has a narrow range of temperature for storage so great care should be taken to follow those recommendations.

Is it possible to use medication besides benzodiazepines in the field to control seizures?

There are a few antiepileptic medications available for IV use. Benzodiazepines remain the first line treatment and have shown to be most effective. If those aren't available, other considerations may be IV valproic acid or levetiracetam. However, neither have been shown to be as effective as benzodiazepines and they are not routinely used for active seizures.

Any problems trying to get medications from other countries that can be used in the U.S.?

Federal regulations cover certain medications imported from other countries that follow very strict manufacturer's requirements. I do not advise importing medications with no FDA oversight, however, because we have no way of ensuring what is actually in the vial.

Have you seen any indication that drug companies have been conspiring to drive up prices through creation of artificial shortages, such as many believe occurs with the oil companies?

There have been many inquiries about this. These medicines are generic and very inexpensive at retail, but they are costly to produce. It appears the few manufacturers have chosen to discontinue these specific lines. There does not appear to be any financial gain at any level.

Would you recommend retaining expired medications in case of later need?

We do not dispose of any expired medicines on the shortage list. However, if you are going to keep expired drugs, be conscious of possible diversions and keep them safely secured.

Can you discuss the most obvious issues with giving an out-of-date medication (e.g.,

efficacy, amount to give, expectations or results to expect)?

There is limited science on this topic, but we know from military experiences that medications can be used past the expiration date. If the medicine is stored in a controlled environment, the potency is good well past that date. It is possible the dose will be less effective. It is also possible that chemical breakdown could cause an unwanted reaction. These reasons are why no regulatory agency will outright permit the administration of an expired medicine. **It will simply come down to the medical director's decision based on the circumstances he or she is currently faced with.**

We are a small service. What advice would you give for making an agreement with agencies to swap out drugs that are about to expire?

I would contact your local RAC about forming a group or task force to develop a plan of action. Some larger organizations are treating the shortages like a major incident and utilizing an ICS type of strategy. The best advice I have is a local solution.

Is there an end in sight?

Every day is new. We have a medical control team meeting every Monday to develop a plan of action for the week. Many advisory lists available with dates when a certain delivery is to occur, but I find these are often more of a hope than a reality.

We do try to avoid frequent changes to medications carried on the rigs. A strong emphasis on the basics is paramount, such as concentrating on the five "rights" of medications administration: The **right** drug, at the **right** dose, by the **right** route, at the **right** time, for the **right** patient. During these times, remind yourself to slow down, review your supplies, and take extra precautions to prevent errors, checking and the double-checking before administering any medicine.

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