

Drug Shortages in EMS

Coping Strategies and Best Practices

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An Overview of Strategies Identified at the EMS Drug Shortages Summit

National Association of State EMS Officials (NASEMSO)



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The National Association of State EMS Officials (NASEMSO) Medical Directors Council hosted the **EMS Drug Shortages Summit** on March 5, 2014, in Orlando, Florida. The purpose of the gathering was to bring together EMS medical directors, EMS managers and practitioners, as well as other subject matter experts to identify best practices for coping with this ongoing problem facing the nation. While the outcry over the crisis has faded, the fact remains that the total number of existing drug shortages has increased. The Government Accountability Office (GAO) found:

The number of drug shortages remains high. Although reports of new drug shortages declined in 2012, the total number of shortages active during a given year—including both new shortages reported and ongoing shortages that began in a prior year—has increased since 2007.¹ (Figure 1)

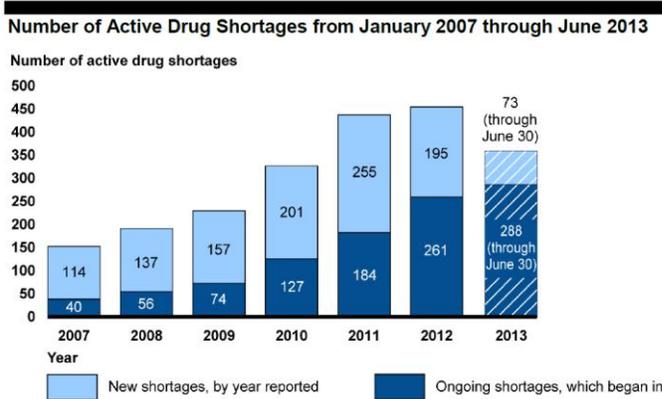
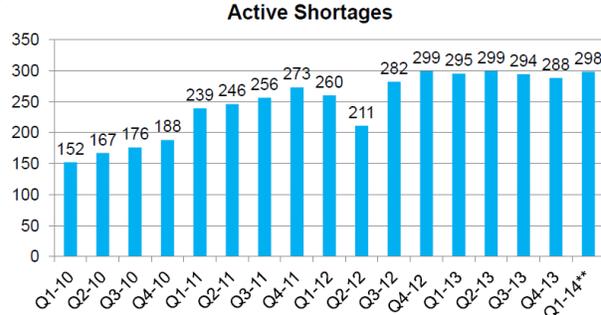


Figure 1 Source: GAO analysis of University of Utah Drug Info Service

More recent data presented at the NASEMSO Summit by Erin Fox, PharmD, Director of the University of Utah Drug Information Service, showed the total number of active shortages during the past two years rising to and hovering at just under 300 -- the highest sustained number since the crisis began. (Figure 2) This alarming data is in spite of the fact that the number of *new* drug shortages has been decreasing since 2012. (Figure 3)

Government intervention, including the President’s Executive Order issued on October 31, 2011, the Food and Drug Administration (FDA) Interim Final Rule published in December 2011, and the Food and Drug Safety and Innovation Act (FDASIA) enacted in July 2012, appear to have kept the problem from being much worse.² The new requirements for pharmaceutical manufacturers to provide advance notice of impending shortages, along with the FDA’s increasing responsiveness to prevent or ease predicted shortages, have contributed to the falling rate of *new* shortages. However, the root causes of the

National Drug Shortages – Active Shortages by Quarter



Note: Each column represents the number of active shortages at the end of each quarter. Q1-14 are data through 2/28/14.

University of Utah Drug Information Service
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Figure 2 Source: Erin Fox, PharmD, Univ of Utah Drug Infor Service

¹ GAO-14-194: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability, Feb 10, 2014

² Public Law No. 112-144, 126 Stat. 993 (2012)

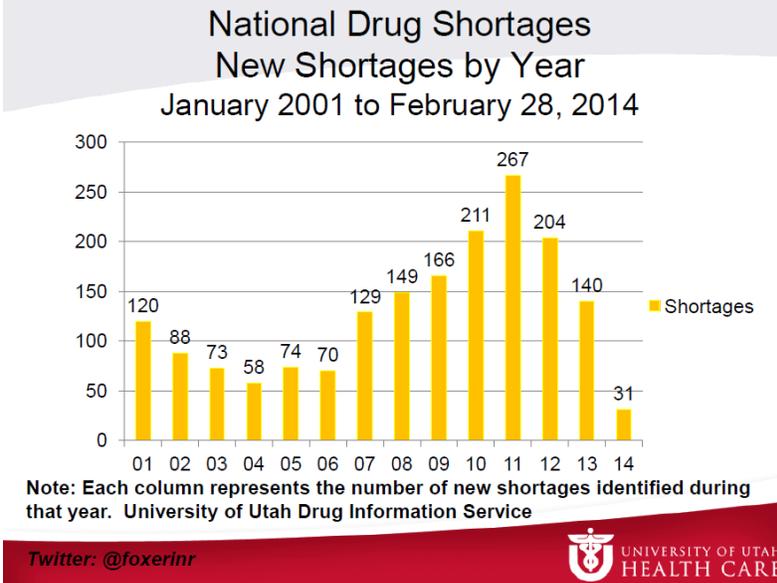


Figure 3 Source: Erin Fox, PharmD, University of Utah Drug Information Service

produced by a single manufacturer, which often produces multiple products on an ultra lean, just-in-time production schedule. The lack of redundancy in manufacturing, combined with the length of time required for remediating a production facility quality issue or bringing a new manufacturing facility on line (if production is not discontinued altogether) all exacerbate the problem. The economic disincentives for correcting a quality problem at an existing manufacturer or building a new production operation for a medication that is no longer profitable go hand in hand with the quality issue to add to the dire situation. Further, the FDA has no authority to require a drug to be manufactured, regardless of necessity or demand for it.

problem are multi-faceted and remain more difficult to address. As such, all indicators point to the conclusion that the shortages will be with us for the foreseeable future.

The FDA reports that in most cases a shortage is preceded by a disruption in manufacturing. While the disruption can be caused by a natural disaster or a decision to discontinue the product due to low profitability, more often it is due to production quality issues.³ Many drugs on the shortage list are

Shortages of EMS Basics

- Frequent fliers
- 10 medications short > 50 times between 2001 and 2013
 - Dextrose, diazepam, epinephrine, fentanyl, lorazepam, morphine, ondansetron, nalbuphine, naloxone, promethazine



Figure 4 Source: Erin Fox, PharmD, University of Utah Drug Information Service

Coping Strategies for EMS: *Best Practices in a Bad Situation*

Emergency Medical Services has not been spared by the unavailability of medications, some of which can be life-saving. Many of the first line pre-hospital drugs have been on the shortage list more than 50 times between 2001 and 2013.⁴ (Figure 4) One fortunate outcome of the ongoing dilemma is that coping mechanisms have been developed, including state level responses and a multitude of strategies by EMS agencies.

³ Strategic Plan for Preventing Drug Shortages, FDA, Oct. 2013

⁴ [Drug Shortages-Causes, Progress and Strategies](#) Presentation by Erin Fox, PharmD

States Respond

At the state level, there are a number of EMS regulatory authorities that have taken steps to alleviate the drug shortage problem for EMS agencies and the patients they serve. Dr. Peter Taillac, Medical Director for the Utah Bureau of EMS and Preparedness, presented an overview of the range of actions taken by some states. Dr. Taillac identified two states of which he is aware -- Utah and Pennsylvania -- where the state EMS office issued statements allowing EMS providers to administer medications up to 6 months beyond their expiration date when unexpired drugs are not available and other conditions are met. These policies were enacted due to the ongoing shortage situation and acknowledging the general consensus that the most medications remain effective beyond their expiration dates under recommended storage conditions. When faced with the choice of no drug or one that has recently passed its expiration date with a patient who has a fractured femur or who is seizing, for example, the choice is not difficult. It was not necessary to enact legislative or administrative rule changes in either state to implement the policies. Pennsylvania requires pre-approval and reporting when using expired meds while Utah pre-approves the use of a specified list of shortage meds and requires agencies to maintain records of their use. More information can be obtained at the Pennsylvania Department of Health, EMS website under [PA EMS Information Bulletin 2013-008 Expired Medications](#). Utah's policy is available at health.utah.gov/ems. Another state EMS office, the EMS and Trauma Systems Program of the Oregon Health Authority, enacted an emergency rule in 2012 which essentially authorized EMS agencies to retain expired medications when shortages were documented and use of the expired drug was authorized by the medical director. Because it was an emergency rule, it was temporary and has since expired. For more information, see oregon.gov/EMSRulesChange/333-250-0051.

Not all states have been able to adopt such a policy without a legislative or rule change, as noted by Cory Richter, Chair of the Florida EMS Advisory Council and the Florida Drug Shortage Task Force. Florida Statutes, Section 499.006 defines an expired drug as an adulterated drug, thus criminalizing the administration of expired drugs by providers. Richter reported the Florida Drug Shortage Task Force is preparing to launch a research study with a university to examine the potency of expired medications at different intervals. The goal is to determine the efficacy of first line medications utilized by EMS at different points past expiration. Assuming the research concludes the drugs remain potent beyond the expiration date, they would have the data to support a change in statute with the State Legislature.

State EMS offices have taken other steps in acknowledgment of the dilemma faced by EMS providers as a result of the ongoing unavailability of multiple medications. The Arizona Bureau of EMS and the Tennessee Division of EMS are among states that have issued written notices indicating the allowance they would make at the time of inspection should the ambulance service not meet the minimum drug supply requirements due to the shortage situation. The Arizona notice is posted at www.azdhs.gov/bems/drugs. Tennessee's statement can be viewed at [Tennessee-Drug-Shortage-Ambulance-Inspections](#). The Texas Department of State Health Services also issued a written statement that it would consider the shortage situation before taking any enforcement action in a complaint

related to the administration or stocking of expired medications by EMS providers. See www.dshs.state.tx.us/ems_trauma_systems. These are examples and not meant to be an exhaustive list of what states have done in an attempt to alleviate some of the problems faced by EMS agencies due to the shortages.

A new issue has arisen with the current trend in many state legislatures to enact provisions to allow naloxone to be more accessible to lay persons, including law enforcement and families of persons with opioid addictions. A life saving antidote for those who suffer respiratory arrest from opioid overdose, the drug is critically important. Given its shortage status, EMS providers are understandably concerned that the increased demand for the drug will result in its unavailability to EMS.

EMS Agencies

In addition to the attempts by state EMS offices to ameliorate the problem, there are many steps at the local level that ambulance services have taken in response to this dilemma that shows no sign of ending. Dr. James Augustine shared strategies he has found successful at EMS agencies where he serves as medical director. These include:

1. Active inventory management
2. Protocol changes
3. Point of care support and education
4. Packaging (using color coding)
5. Incident management team and action plan

Active Inventory Management: It has never been more important to focus on inventory management. The individual responsible for the medication supply must not only track, but also know the use of each drug in the agency protocols. By focusing on the shortage list, it is easier to be prepared and respond quickly with alternatives. The medical director should identify therapeutic alternatives before the problem is immediate. If in a state where protocols are mandated by the state EMS authority, the ambulance service will need to ensure substitutions are acceptable (although state EMS offices have generally made provisions for substitutions in view of the drug shortages). Consideration of different purchasing options when drugs are unavailable is another option. Compounding pharmacies may be able to meet certain needs, although they can be an expensive alternative and quality is important. Reducing the amount of drugs in the drug box, while keeping more centrally located can help. And, of course, keeping the medicines closer to expiration date at the site they are likely to be used is another effective approach. Active inventory management is time consuming, but when done correctly promotes efficiencies not previously realized. Cost savings can be achieved with fewer products wasted.

Protocol Changes: Changes in protocols must be ready to implement when drugs are unavailable. “Just in time” protocols should be developed and ready to use when first line drugs are not available. Keeping in mind the aforementioned warnings about ensuring compliance with state requirements, the EMS agency must also be nimble in training and

otherwise preparing providers to implement those changes. Providers are understandably more prone to making errors when confronted with a change in the standard medication. This requires training, but there are mechanisms to reduce the risk of medication errors.

Point of Care Education and Support: Educating providers about protocol changes, including varying dosages for new therapeutic alternatives is critically important. Educational brochures, email blasts and even text messages explaining changes should help to reinforce previous instructions. The new information should be posted and available in multiple accessible locations (at site of acquisition, drug box, laptops). No amount of repetition and reinforcement is excessive when ensuring crew members are well-prepared for the changes they must make when first line pharmacological interventions are not available. The goal is to make the system as error-resistant as possible. However, there will always be human error, even in the best systems. Error-reporting should be encouraged, as that is the entryway to system improvement. Without being aware of the problem, it is difficult to make the changes that will eliminate it.

Packaging: An effective strategy to reduce the risk of medication errors is to repackage the drugs for use on the truck in color coded packages based on drug type. Select distinctive colors that crews will easily recognize. (Figure 5) The obvious color differences will help distinguish the medicine purpose lessening the chance of error, especially when substituting alternatives with which providers are not familiar.

Referred to by Dr. Augustine as the **3 P's** -- **p**rotocol changes, **p**oint of care education and support, and **p**ackaging-- these strategies go hand in hand when coping with drug shortages.

Pain Medications	Morphine, Fentanyl, Hydromorphone
Seizure Meds	Midazolam, Diazepam, Lorazepam
Nausea Meds	Ondansetron, Promethazine, Prochlorperazine, Droperidol
Sedatives	Ketamine, Etomidate, Propofol

Figure 5 Source: [Managing Emergency Drug Shortages in EMS, by James Augustine](#), Presented at the NASEMSO EMS Drug Shortages Summit 2014

Incident Management Team and Action Plan: Applying models and skills acquired from emergency preparedness training can be constructive when faced with drug shortages, especially when they become potentially life-threatening. An incident management team can be assembled beginning with in-house resources. Cooperation should be initiated with any regulatory authority (state EMS office or pharmacy or medical board, if applicable) and with other area EMS agencies and hospitals. The goal is to develop plans for varying levels of medication shortage conditions. The example illustrated below includes different actions based on the situation and includes: Level 1- Advisory (Preparatory, when shortages are imminent), Level 2- Moderate Shortages, and Level 3- Severe Shortages. (Figure 6)

Figure 6 Source: [Managing Emergency Drug Shortages in EMS, by James Augustine](#)
Presented at the NASEMSO EMS Drug Shortages Summit 2014

LEVEL 1 - ADVISORY	LEVEL 2 - MODERATE SHORTAGES	LEVEL 3 - SEVERE SHORTAGES
<p>Advisory and Preparatory Activities</p> <p>Hospitals Intel and Feedback on shortages Design and approve agreements for sharing meds with each other and EMS.</p> <p>County EMS and Fire Agencies Develop therapeutic equivalent list. Make appropriate protocol changes to allow substitutions. Using paramedic input, design: - Packaging solutions for safety - Safety program - Needed just in time educational programs</p> <p>DOH Assist in study of tracking program for typical and atypical meds. Study sources for atypical meds.</p> <p>Planning Team Study legal and regulatory challenges and develop recommendations. Design medication tracking program and what elements of DOH program that can be applied. Create the process for declaring shortage and allowing compounding. Design a “no risk” safety reporting program. Study the central sourcing program. Publish “Drug Shortage Status Bulletin” for Command Team, state, local hospitals and providers. Develop LEVEL 3 elements and props.</p> <p>Finance Create budget projections on impact of this program. Develop purchase order (PO) process for timely and emergency acquisition, and designate a compounding pharmacy. Study reliable sourcing and pricing programs.</p>	<p>Medication shortages affect availability and patient care in emergency operations, with Life Threatening Risk</p> <p><i>Trigger: When multiple therapeutic substitutions are being used, and multiple medicines are in shortage status at hospital and EMS sources</i></p> <p>Hospitals approve agreements for sharing meds with each other and EMS.</p> <p>County EMS and Fire Agencies Implement protocol changes to allow substitutions using paramedic input design initiate: -Packaging solutions for safety -Safety program -Just in time educational programs</p> <p>First stage of “Medication Command” utilization: DOH implements elements of tracking program for typical and atypical meds. Initiate sourcing for atypical meds.</p> <p>Planning Team Implement needed legal and regulatory changes. Finalize state “releases.” Implement process for declaring shortage and start needed compounding program. Implement medication tracking program and elements of DOH program. Implement “no risk” safety reporting program. First stage implement central sourcing program. First stage of drug quality management program Final design LEVEL 3 elements and props</p> <p>Finance Purchase Order process for timely and emergency acquisition.</p>	<p>Many medication shortages affect patient care, with Life Threatening Risks</p> <p><i>Trigger: When many medicines are in therapeutic substitutions at hospital and EMS</i></p> <p>Hospitals actively sharing meds with each other and EMS.</p> <p>County EMS and Fire Agencies Implement protocol changes to allow substitutions. Implement the following: -Full complement of packaging solutions for safety Safety program -Just in time educational programs -Uniform use of “Medication Command” program, with core group of designated personnel and distribution program</p> <p>Make full use of DOH tracking program for typical and atypical meds. Implement program for use of atypical meds.</p> <p>Planning Team Implement needed legal and regulatory changes. Declare shortage and fully utilize compounding program. Implement central medication sourcing program and elements of DOH program. Convert to drug quality management program doing active analysis of the “no risk” safety reporting program. Design the “all clear” criteria. Integrate Finance and timely emergency acquisition.</p> <p><i>Aftermath</i> <i>Active medicine inventory management with overall less budget impact</i> <i>Safer medicine packaging and “No Risk” reporting</i> <i>Expanded protocols and JIT education program.</i></p>

Clearly, there have been many creative approaches utilized by various EMS agencies in responding to the limited and variable availability of medications. Providers have learned how to adapt to the ever-changing landscape of available medicines. They have learned new methods of conserving what previously seemed to be an inexhaustible supply. Nonetheless, there is justifiable concern that the quality of patient care is impacted negatively when pharmacological interventions are unavailable. Is the shortage drug being rationed at the expense of the patient? Does substituting with alternative medications, when available, lead to medication errors? These concerns must continually be considered given there seems to be no end in sight of this ongoing dilemma.

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Presentations from the NASEMSO EMS Drug Shortages Summit 2014 are available at [NASEMSO.org Meetings MidYear](http://NASEMSO.org/Meetings/MidYear)

Further information on drug shortages can be found at:

- University of Utah Drug Information Service
<http://www.ashp.org/shortage>
- U.S. Food and Drug Administration
<http://www.fda.gov/drugs/drugsafety/DrugShortages/default.htm>

This document was prepared by Mary Hedges, NASEMSO Program Manager, from information provided by the speakers, as well as public reports from the Government Accountability Office and the Food and Drug Administration.