

Facilitated Discussion and Follow-up Questions for Medication Shortage Webinar

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U.S .Food and Drug Administration (FDA)

CAPT Valerie Jensen

Question: Has anyone allowed the use of expired emergency syringes? What needs to be in place prior to implementing this?

Response: Please know that FDA is working with Pfizer on multiple issues related to this shortage. In these cases, FDA requests data from the manufacturer to support additional dating for drugs in shortage and it's up to the manufacturer to supply the data if the data is able to be generated. In this case, FDA is working with Pfizer on this and once there is information regarding additional dating, it will be posted on the FDA shortage website both under the Additional Information section as well as under each individual syringe shortage:
<https://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>.

FDA will continue to do all they can to address this shortage and you may contact the FDA Drug Shortage Staff directly at drugshortages@fda.hhs.gov.

Question: Does FDA have control over the drug cost for imported medications during a shortage (as the price for the imported version of bicarb is significantly higher)?

Response: When there are critical shortages and U.S. manufacturers are not able to meet patient needs, FDA searches for additional supply sources and evaluates the manufacturing facilities and products to ensure no risks for patients. These supplies are made available temporarily until the shortage is resolved and FDA doesn't have control over pricing of these products.

Question: What is the cause of these shortages and why are there so many different medications included (e.g., dextrose, NS, sodium bicarbonate, Atropine, D50, Labetalol)?

Response: All of the shortages mentioned above except those involving NS are caused by the delays reported by a large manufacturer, Pfizer, and additional information is contained in the recent letter from Pfizer:
<https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM559332.pdf>. The NS shortage is due to increased demand per the manufacturers and some presentations of NS remain available.

Question: What is being done to prevent shortages of critical meds from recurring?

Response: When manufacturers notify FDA in advance of pending shortages as they are required to do by law, this gives FDA time to work with the manufacturers on the problem

causing the shortage and to work with additional manufacturers on helping to address the shortage. FDA expedites review of applications or proposals to help mitigate critical shortages. When U.S. manufacturers are not able to help with shortages of medically necessary drugs, FDA turns to additional manufacturers as we did with the sodium bicarbonate injection, which is now being temporarily imported to help with meet U.S. patient needs during the shortage. In cases where an additional manufacturer is supplying the U.S. market during the shortage, such as the sodium bicarbonate injection, FDA has evaluated that manufacturing site and product to ensure no undue risk exists for U.S. patients. This link contains additional information:

[https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Sodium Bicarbonate Injection, USP&st=c](https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Sodium+Bicarbonate+Injection,+USP&st=c)

Question: Please address if FDA is looking into importing other drugs that are in shortage and what the current availability is for:

- Epinephrine 1:1,000
- Epinephrine 1:10,000
- Atropine 0.1mg
- Calcium chloride
- NaAcetate

Response: At this time there are not shortages of the epinephrine 1:1,000 vials and ampules and they are currently available in good supply from two manufacturers, BPI and Par Pharmaceuticals. The “Resolved” posting on the FDA website has more details: [https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Epinephrine Injection, 1 mg/mL&st=r](https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Epinephrine+Injection,+1+mg/mL&st=r)

For the others listed, FDA is working with Pfizer (the [Pfizer customer service letter](#) lists these drugs). FDA is also working with additional manufacturers, but at this time we do not yet have a firm able and willing to temporarily import these drugs.

Question: What is the shelf life of Epinephrine 1:10,000 if mixed by our pharmacy into a prefilled 10ml syringe?

Response: FDA receives data to support the shelf life for approved drugs, and during shortages, FDA encourages firms to submit data to extend the use date past the expiration date for commercial drugs that are nearing or past expiry. Once received and reviewed, this data is posted on the [FDA Drug Shortages](#) website.

Question: I've noticed that this particular website [FDA Drug Shortages] has not been updated frequently enough (i.e., old info and new shortages not showing in the list). Do you know how often it's updated?

Response: FDA receives updates from the manufacturers and posts those updates once received, and encourages firms to update their information as often as possible.

Question: What about the "Grey Market" distributors? [How can they] access the shortage medications and then raise the prices to extreme costs to managed care facilities (i.e., while there

is a nationwide allocation, the "grey market" always seem to get supply, specifically sodium bicarbonate vials)?

Response: When shortages occur, pharmacies receive faxed and e-mailed advertisements from unknown distributors that offer these drugs at higher prices than the pharmacy normally pays. Concerns should be reported to FDA via the Office of Criminal Investigations at this link: <https://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm>

Question: [Can you please provide clarity] in using pharmacy items that are on hand, unopened, yet have passed the expiration date (does that date instantly mean we cannot by law use the drug) in lieu of not being able to resuscitate a patient, and related legal coverage?

Response: FDA receives data to support the shelf life for approved drugs, and during shortages, FDA encourages firms to submit data to extend the use date past the expiration date for commercial drugs that are nearing or past expiry. Once received and reviewed, this data is posted on the FDA Drug Shortage website.

Question: [Can we contact anyone to ask if there] are any sodium bicarbonate syringes out there to share?

Response: Please continue to visit the FDA website where information regarding additional supplies will be updated as soon as it is received.

Question: During the 2012 HHS Drug Shortage meeting, the FDA representative (I believe) talked about the importance of establishing contracting manufactures to help step in when one manufacturer experiences or anticipates a supply interruption. What progress has been made in this area? I assume this is a different concept than allowing exportation. (If this wasn't addressed by FDA during that meeting, it may have been a concept raised by the Pfizer representative at that meeting.)

Response: FDA encourages but cannot require firms to have additional manufacturing lines and facilities as back-ups in case they have manufacturing issues on one of their manufacturing lines or in one of their facilities. FDA will expedite review of additional facilities or manufacturing changes to help prevent shortages. Many firms have developed contingency plans for shortages and have been able to work closely with FDA to prevent shortages. FDA was able to prevent 115 shortages in 2016 through working with manufacturers.

National Association of Emergency Medical Technicians

Dr. Anne Dietrich

Question: Dr. Dietrich, in your role as a pediatric emergency physician and EMS agency medical director, can you describe the issues you are facing with the current medication shortage and the decision making process you have engaged to address the shortages?

Dr. Dietrich response:

- Biggest issue EMS agencies face is we have more limited options. We try to limit the number of medications and concentrations used to limit errors and make the protocols simpler...so when a drug becomes unavailable we have problems with substitutions, we can't compound or mix medications, we don't have several alternatives.
- We are also challenged with premixed dosing shortages, which help limit errors...but when unavailable we must resort to math which can be a huge issue especially with children.
- Also shortages of critical medications, such as epinephrine and D50, which are frequently used in emergency situations and needed within minutes, there are not acceptable substitutions.
- I don't currently have a lot of solutions to offer –we discuss alternatives for example for racemic epi ...epi can be mixed and for epipen ...mix epi old fashioned way...we warn of dosing errors and cross checking concentrations...we do training sessions...I've also switched first line meds based on patterns of shortages.

National Renal Administrators Association

Dr. Joseph Lee

Question: Dr. Lee, in your role with the Board of the Renal Services Exchange and as a practicing nephrologist, you know that sodium bicarbonate is used frequently in renal medicine. What lessons did you learn from your role in the recent shortage of peritoneal dialysis solutions that you can apply to the current shortages?

Response: There was a shortage of peritoneal solution for a few months and it did affect enrollment in the peritoneal dialysis program. At that time, one company dominated the market in solution supply. But very quickly an alternative manufacturer began to fill in the gap; there was a hiccup briefly since different system used different tubing and connectors, but that was addressed with in service training.

There are other circumstances in the dialysis industry that may have mitigated the shortage crisis since the dialysis industry in U.S. is a consolidated business represented by two large dialysis companies/providers (together 76%) and NRAA (for the rest or 24%). Two large providers have their own advantage in their dealing with P.D. solution suppliers while NRAA has its own policies. That kind of infrastructure provides flexibility in the availability of supply and the operation.

During the shortage crisis, we learned these lessons:

- From business management to healthcare professionals, there is a need to update and inform on shortage status on a weekly basis and what to anticipate in what time frame; this allows planning for an operational strategy to mitigate effects.
- Share resources—one unit can share supply with other units since demand for PD solution does not occur at the same time requiring same type/concentration of solution. Therefore networking to share is critical since not every dialysis unit will encounter same shortage in the same time (fortunately large dialysis providers by its nature is a consortium/network with management).

- We also established dialogue and communication with suppliers and we were updated on the progress periodically. Suppliers were very anxious since it was not a happy moment, as they feared loss of business.

Application to current shortage:

1. Start networking especially among all Pharmacy Departments of hospitals or clinics in the region. Start to share and assist among all the clinics or hospitals in the region. Dialysis providers should use the same approach.
2. Provide weekly updates of the list of shortages and the alternative choices to the healthcare professionals using e-mail blast or flyers. For instance, when one clinic is short of “A” drug we can provide list of “B” or “C” drug as alternatives. For a particular dialysis unit, clinic, or hospital, this information and choice can be imbedded options in electronic health records.
3. Representatives of the network or healthcare system to have dialogue with drug suppliers to understand what the real situation/background of shortage is. Share this information with all local providers, and offer assistance, ideas or recommendations.

University of Pittsburgh Medical Center

Dr. Jessica Daley and Dr. Al D’Altrelli

Question: What is the clinical effect of drug shortages in a hospital setting and what role can pharmacy play in mitigating?

Response: Drug shortages can adversely affect drug therapy, compromise or delay medical procedures, and result in medication errors which means worse patient outcomes and potentially patient harm and death. In the hospital setting, we need to quickly treat patients with acute or emergent conditions, and we can use a significant number of medication treatment algorithms that rely on the provision of these drugs by pharmacy. Clinicians have these algorithms engrained into practice as tried and tested treatments. This leads to the possibility of a situation where a clinician has to scramble for an alternative medication and potentially regimen in a very time sensitive and stressful situation. So, it is critical that pharmacies proactively develop a management strategy in cooperation with physicians and other clinicians most affected by the shortage. This requires: 1) pharmacy departments to have a formal process (consistent with ASHP and ISMP recommendations including policies and procedures) for handling drug shortages, approved by medical staff, and 2) that communication is clear and comprehensive (educating others as necessary) while at the same time remaining concise.

Question: In addition to the clinical effect of drug shortages, how else is pharmacy affected?

Response: Drug shortage mitigation has become common daily practice, affects all aspects of the healthcare delivery system, and can also present administrative challenges. All of the efforts surrounding drug shortages require labor and resources, and we have found a need to dedicate pharmacy staff to these activities; though many hospitals do not have the ability to do this. Identification of a shortage is not the only personnel effort necessary, in fact, that’s just the beginning, and mitigating takes time and effort and the commitment of an entire team where

alternate availability, dosage form, other product specifications, physician acceptance, costs and many other aspects are considered. As administrators, we need to allocate personnel, negotiate between clinical groups to deliver a plan and at times serve as gatekeepers and enforce restrictions when necessary.

Question: How are you preserving supply of critical shortage medications?

Response: We have implemented a coordinated team of pharmacists, clinicians, and supply chain experts to proactively identify opportunities to preserve medications that are on shortage. Supply chain constantly monitors distribution of critical medications, regardless of whether they are on the official FDA shortage list; from this evaluation, supply chain coordinates weekly discussions around product availability, alternative purchasing channels, and expectations for return to supply with pharmacy and physician counterparts. Pharmacy routinely evaluates local utilization patterns, local supply levels, and creates estimates for ongoing utilization volumes. When the utilization estimates outpace supply, clinicians are engaged to examine protocols and make recommendations for change in practice. For example, when the supply of sodium bicarbonate became critical, supply chain and pharmacy engaged physicians who were already aware of the ongoing issue, explained the nature of the elevation to critical shortage status, and the clinicians made the final decision on the drastic cuts in utilization that were implemented across the system. We don't wait for a shortage to get critical – we constantly monitor it and engage the extended team so that there is established trust and understanding to allow for rapid response.

Question: How do you get an extended team that includes so many different stakeholders from so many different organizations to work together to impact patient care?

Response: It is a culture that you have to build around all of your drug purchasing and utilization initiatives. It is very important to create a “we” mentality instead of a “me” mentality. UPMC has a consolidated system-wide formulary. All facilities, pharmacists, clinicians, and supply chain have to work together to choose the best agent or agents to make available to the entire system, and then support ongoing governance to ensure compliance with system decisions. You have to learn to trust and work together from the very beginning. As a member of the system you know that if you need support or guidance on any issue, your counterparts across the system will make themselves available to help. When we see shortages like these, the whole system is engaged on identifying areas to alter protocols, share best practices, and, ultimately, share surplus product supply because we have already developed a culture that supports this. Many of the issues that we are facing in healthcare in the United States stem from our inability to work together across institutional boundaries. Our hope is that the UPMC culture of collegiality could be shared with other organizations across the United States, which is why we are happy to share our experiences in managing drug shortages with other systems who are struggling with the same issues.

Centers for Disease Control and Prevention, Division of Strategic National Stockpile

Question: At what point could/would we be able to access SNS stockpile for medication shortages such as sodium bicarbonate?

Response: For sodium bicarb specifically, we do not carry the drug.

Generally, using material in the SNS due to regular shortage is not feasible. Particularly in a shortage, should an event require the bulk of the SNS material for response simultaneously, had it been forwarded to cover a shortage then we would be unable to respond to an event. Also, because much of our material is held past the labeled expiry dating or may be specially labeled for specific threats, it's release must be covered by Emergency Use Authorizations which would be unlikely to apply to a regular shortage situation.

We have made provision for use of very limited material where an immediate shortage is lifesaving. For example, during a shortage of injectable anti-convulsants, we made a determination for permissive, limited use of those contacts of hospital Chempacks. Ultimately none of those drugs were used. Also where we hold material in vendor managed inventory (a very limited portion of the SNS assets), we have allowed vendors to rotate greater quantity of that material into daily use with provision for its immediate replacement.

The matter of SNS as a hedge against regular drug shortage has been considered and discussed in various fora. For those concerns noted, and with additional thinking from private supply chain partners, we have at this time determined that SNS product is generally not the best designed to cover market shortage.

ASPR National Healthcare Preparedness Program

Question: As far as coalitions are concerned, do you see their role as mainly gathering situational awareness and providing information to its members [or something else]?

Response: Coalitions may play several roles in medication shortages depending on their responsibilities and resources. At minimum, coalitions can encourage or broker information sharing about medication shortages with and between hospitals and EMS. Additionally, they can help maintain situational awareness through surveys or summaries about impact and strategies being used to address the shortages in the area. This helps encourage consistency and proportionality. Coalitions may also host strategy discussions to enhance this cooperative planning. Some coalitions may be able to assist with resource management as well, to the degree this is helpful in these shortages.