



**Critical Conversations: Navigating Drug Shortages
 and Empowering Oncology Pharmacists**
 Audience Q&A | Published: July 7, 2023

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Webinar Recording Available

In case you missed the roundtable online seminar, Critical Conversations: Navigating Drug Shortages and Empowering Oncology Pharmacists, you can watch it here: <https://youtu.be/tPHFiJlooDQ>

FDA Rapid Approval of Imported Drugs

How comfortable are you with the FDA rapidly approving drugs from other countries?

Natalie Osagie: Somewhat confident. This is because if it is already being used in those countries and it has been proven safe and effective for them, then in the absence of non-availability of the United States usual brands, and especially if there are no other options, then it may be worth the trial.

Jeff Pilz: The FDA staff assess potential import products for safety issues and would not support import of a product that was identified as unsafe. This is usually a means of last resort when other mitigation factors for US-approved formulations are not successful. The agency may request the import manufacturer to follow enhanced quality oversight for products. Transparency is lacking in the pharmaceutical industry with regards to quality oversight in manufacturing sites for all commercial products, so there is no specific information available to further guide end users beyond what the FDA determines.

Critical Conversations Q&A

Navigating Drug Shortages and Empowering Oncology Pharmacists

In the current shortages of cisplatin and carboplatin, for example, employees at a foreign plant were found to have altered recorded data for particulate content for items that were US approved, leading to the import ban.

The imported products may have very different labeling or packaging, which may present a safety risk from the pharmacy operations perspective even though it may not be a clinical concern. Before using an import item, a best practice would be to examine the FDA materials (usually supplied as a Dear Healthcare Provider letter) and physical product carefully and, if possible, perform a safety analysis on potential failure modes.

Peter Stuessy: I agree with Jeff, but our organization is only purchasing if it is the only product available.

Drug Shortages in Other Countries

What are other countries doing with this cancer drug shortage supply? Do any of you believe that other countries, such as Canada or Europe, will follow suit with the USA ban of foreign cancer drug supply?

Peter Stuessy: I have not researched other countries, but the FDA does allow for drugs made outside the US to be part of the US supply as long as the FDA approves the manufacturing at that facility. The current platinum drug shortage is due to Intas Pharmaceuticals plan in India (US distributor Accord) being shut down by the FDA due to violations.

Buying Groups and “Always the lowest cost”

Please speak to the buying groups HPS, Vizient, and Premier and always the ‘lowest cost’ as the reason behind the shortage.

Jeff Pilz: To be clear, the current oncology drug shortages are directly due to production issues at the manufacturing level. The contribution of group purchasing organizations (GPOs) on drug shortages *in general* is not well defined relative to other supply chain entities (e.g., wholesalers, industry, etc.)

The FDA has a Drug Shortages: Root Causes and Potential Solutions report that provides detailed insight to why shortages occur. Access it here: <https://www.fda.gov/drugs/drug-shortages/report-drug-shortages-root-causes-and-potential-solutions>

GPOs exert influence on manufacturers through the presence of preferred award contracts, consolidation of buying power, and sole-source purchasing requirements as furthering unfavorable pricing in supply chain. Critics cite GPOs as furthering consolidation in the pharmaceutical market for older, generic medications. There are also statements suggesting additional fees from GPOs may take away from opportunities to reinvest in new manufacturing capacity or sourcing, although transparency is again lacking in this area to quantify the impact precisely. If the award to participate in a GPO contract as the preferred NDC does not consider reliability of supply and quality of the finished dosage form, the negotiation bids drive a price competition among the available generic manufacturers available to find a lowest bidder.

When considering old, low-priced generics have lower margins for manufacturers, a company who does not gain a GPO network may be excluded from large groups of hospital purchasers. This could further lead to some manufacturers with minority market shares to discontinue product or leave the US market altogether due to the

lack of a return on the continued production investment. Fewer manufacturers increase the risk of shortages, especially if a product is sole-source (one manufacturer only).

The counter to this viewpoint is that drug shortages are not solely driven by these supply contacting issues. Shortages have increased in recent years despite GPO practices remaining consistent in the same period. There is no excuse for manufacturers to falsify data records and release product to consumers knowing it may be outside specification, as seen with the current oncology shortages. It is important to note the benefits GPOs provide to health-systems, as they may offer emergency supply programs or advocate in failure to supply situations on the member systems' behalf.

An emergency supply program may provide an allocation for GPO members to weather some of the shortage further than not having any impact. Some GPOs are also involved in private label manufacturing, reinvesting membership income into subsidizing alternative supply for critical medications.

This is a complex dynamic that is influenced by relationships at every step of the supply chain, so it is not simply one actor or entity that is worsening the situation.

Peter Stuessy: Jeff summarized this very well. GPOs play a key role in many ways, but I would say that the price pressure for contracts with GPOs is one component of a complex situation causing these oncology generic drug shortages.

Ethical Guidelines for Prioritizing Patients

Have organizations established "ethical guidelines" to make decisions on how to prioritize patients?

Natalie Osagie: Yes, my organization did create priority guidelines depending on our PAR if we are unable to replenish.

Jeff Pilz: There is an Ethical Framework for Resource Allocation During the Drug Supply Shortage available from the Ontario Ministry of Health and Long-Term Care (MOHLTC). Each shortage is unique, so the few times we have used this process it was a new discussion. There are general recommendations available for ethical decision-making in healthcare, if you are looking for a starting place to develop ethics guidelines for the shortage allocation process.

Our organization maintains an Ethics Consult process to use for individual patients or small populations as needed, with availability 24/7. This consists of routine, urgent, and anonymous consult options built into the EHR but with option to page for time-sensitive items. For shortages, the large impact on many patients required creation of a Scarce Resource Committee that meets ad hoc to determine how limited products will be allocated. The latter involved the C-suite of the business units, supporting the enforcement of the final decision. Our Drug Shortage Committee has leeway to also set clinical restrictions on use of products during a shortage, exempting P&T as well as other governing committees.

Ethical Framework for Resource Allocation

Panelists have mentioned an ethical framework to help with patient prioritization – where can that be found?

Peter Stuessy: For prioritizing patients, my organization based our decision making on the “Ethical Framework for Resource Allocation During Drug Supply Shortage,” which was created by the Ontario Ministry of Health and Long-Term Care (MOHLTC). On March 20, 2012, their Drug Shortage Technical Advisory Group published this paper: https://www.health.gov.on.ca/en/pro/programs/drugs/supply/docs/ethical_framework.pdf.

We had a group that met during COVID pandemic and used this framework, so we resurrected the group but added oncology folks (Risk, Ethics, Public Affairs, Pharmacy, Medical Staff, etc.)

Platinum Drug Restrictions

What restriction criteria have institutions implemented for the platinum drugs?

Natalie Osagie: We have not implemented a restriction criteria per se, but priority goes to those with curative intent in the absence of an alternative therapeutic viable regimen.

Peter Stuessy: The general criteria I have been seeing elsewhere and the criteria our institution used based restrictions on curative potential or if there is far decreased effectiveness of alternatives. We let any curative therapy receive drug unless there was an alternative (for example, instead of carbo/paclitaxel for upper GI + radiation treatment, we recommended modified FOLFOX). We also let SCLC first line and at least some doses of platinum sensitive ovarian first line be allowed even though not curative due to far inferior alternatives.

Sarah Hayward: Restriction criteria include:

1. Determine the patients who are curative intent and prioritize them to receive standard of care platinum.
2. Dosing carboplatin by one AUC level but not going below 4 (i.e., if dosing at AUC 6 then dropping to AUC 5).
3. Dosing reduce by 10% across the board.
4. Our institution is having more difficulty obtaining carboplatin currently so we are prioritizing those with curative intent and those who CANNOT receive cisplatin for assorted reasons to receive carboplatin.
5. Substitution of oxaliplatin if reasonable based on available data.
6. Substitution of topotecan in metastatic/recurrent cervical cancer instead of a platinum.
7. Consider fewer cycles of chemotherapy if clinically appropriate.
8. Extend cycles from Q3 weeks to Q4 weeks if clinically appropriate.

Drug Supply for Curative vs Palliative Care

At what drug supply level are you 'rationing' drugs to curative vs. palliative patients?

Natalie Osagie: 50-75% of normal supply.

Jeff Pilz: There is no specific level for rationing at my institution, as this is always discussed in the context of each shortage uniquely.

Peter Stuessy: Around 3 weeks of supply with normal usage.

Guidelines for Evidence-Based Replacement Drugs

The clinical impact of drug shortages can only be minimized by replacing the agent with other ones if evidence is available. Are there any quick reference guides available to help pharmacists and the primary care team?

Natalie Osagie: My organization has algorithms for some cancers but otherwise NCCN, ASCO, ESMO, are some that I usually would reference. I also would source for primary literature but bear in mind that any solid data out there would already be included as a standard of care in one of these guidelines in most cases. There may be some regimens out there that are effective but not included in treatment algorithms because they were looked at in a small population of patients and confirmatory larger trials are still needed.

Peter Stuessy: There is no quick reference that I am aware of. Our organization does check the same guidelines as Natalie's as well as primary literature to come up with alternatives. For example, we found literature (though not strong) to support the use of oxaliplatin as a substitute for metastatic NSCLC in some patients.

Sarah Hayward: For the gynecologic oncology setting, Society for Gynecologic Oncology (SGO) has printed communiques that are available without a membership through their website. It is a great resource: <https://www.sgo.org/news/drugshortage/>.

ASCO has endorsed these guidelines for chemo shortages. ASCO has also produced general guidelines and a few disease-site specific recommendations: <https://old-prod.asco.org/practice-patients/practice-support/drug-shortages>

Prior Authorization of Alternative Therapy

Can you comment on how best to navigate the prior authorizations with alternative therapy especially when failure of prior therapy is required?

Natalie Osagie: My organization does not deal with third party payers. Prior authorizations are internal and when there is a drug shortage, the criteria for use of alternative medications are usually relaxed.

Peter Stuessy: Our Prior Auth team adds literature or guideline comments, when possible, in these situations. For example, they included phase II studies of oxaliplatin for metastatic NSCLC when submitting.

Sarah Hayward: We have had very open communication with our chemo authorization and financial navigation departments about the changes. As we do not get much reimbursement on cisplatin/carboplatin to begin with, even prior to the shortage, it has not been too significant. We are also a larger institution that is able to absorb the loss.

For those that need to work through prior authorization:

- Appeal if they are denied.
- Provide your reasoning in the appeals and provide the temporary guidelines put forth by SGO/ASCO.
- Create a form letter for your clinic/institution so you do not have to reinvent the wheel with a new letter for each insurance company.

Sarah Hudson-DiSalle: Addressing shortages with insurance companies starts with a transparent approach to the insurance when a long-term drug shortage is identified. Our facility will reach out to the pharmacy directors at the insurance companies to help educate on the drug shortage and any recommended alternative that might be identified by national guidelines such as NCCN, or ASCO.

We provide our team of Clinical Financial Managers who work with the insurance companies with drug shortage information, alternative therapies, and any available literature if needed. For extreme shortages, we have proactively made changes to patient therapies and identified patients who need immediate changes. We then work to update plans and resubmit requests for authorizations.

Some insurance companies use third party companies to complete their insurance authorizations. These companies may require FDA notification to prove the drug shortage, identify an alternative therapy with peer-reviewed literature, or request a peer-to-peer conversation with the prescriber to discuss the alternative being requested.. This provides an opportunity to discuss any evidence-based literature that may have been provided and emphasize, plus educate, the physician reviewer on the drug shortage.

Carboplatin MDV Expiration

Has anyone looked at extending the expiration date for Carboplatin MDV (currently 14 days)?

Jeff Pilz: The presence of the shortage does not supersede regulatory, legal, and accreditation requirements. Expiration dates of commercial products must receive FDA authorization to be extended, which is contingent on manufacturers supplying evidence for stability and sterility for the extension period. USP <797> will govern BUD assignment for compounded preparations. The package insert must be followed to use the BUD dating outlined in that document.

There are mechanisms to safely support extending beyond-use dating (BUD) on products, but they require the individual compounder to perform specific testing on samples. This is time consuming and costly, so it is not likely an option for most organizations and must be done in advance of a shortage occurring. USP <797> outlines the requirements for multiple-dose compounded sterile preparations. Peer-reviewed primary literature can only be applied in specific circumstances to extend a BUD.

To avoid waste, there are other strategies that can be used. Consider the ability to adjust appointment dates or times to cluster infusion appointments within the expiration or BUD window, and if needed consider repackaging bulk packaging into smaller aliquots. Non-formulary packages may also be available in a smaller size, if available.

Use of closed-system transfer devices (CSTDs) to extend BUDs is not currently recognized by the FDA as an approved indication. Thus, accreditation bodies like The Joint Commission do not consider this practice within compliance. Double check local regulations and accreditation to inform on available options.

Use of Imported Qilu

Has anyone reviewed/approved use of the imported Qilu product that was approved for import by the FDA? Are you following the mixing instructions in the packaging for the Qilu product including "rinsing" the vials and mixing in 1-liter bags?

Natalie Osagie: Our organization has not used it, but if we need to use it, the plan is to follow the mixing instructions.

Jeff Pilz: Our institution is awaiting an initial order of the import product to further assess.

Use of AI in Supply Chain Process

Is anyone using AI (artificial intelligence) as part of their supply chain process to predict a coming shortage?

Jeff Pilz: No, our system does not utilize AI (or a third-party application) for drug shortage proactive identification. Our purchasing staff are very diligent and often identify the shortages first, if not reported in advance by the manufacturer.

There are several organizations including HOPA, FDA, and ASHP that maintain shortage alert databases, allowing healthcare providers or members to sign up for email alerts and RSS feeds. List serves within professional organizations may also have dedicated drug shortage communities, although any major shortage quickly gains attention across all relevant forums.

Ability for EMR to Project Future Usage

Is your EMR set up to be able to project future usage?

Jeff Pilz: As Epic EHR users, our sites can perform estimates on day supply by looking at historical use reports and conservatively estimating reduction in use. A separate analytics platform may be necessary to run more advanced statistics and predict trends.

Peter Stuessy: We use reports and lots of EHR data to assess usage and distribute what product we do have. But at this time, we are not set up to project future usage.

Short-Dated Product/Purchasing Portal

How do you get access to a short-dated product/purchasing portal or find out about this type of portal?

Jeff Pilz: I am not familiar with all the offerings that may be available, but there are third-party sites that act as a marketplace for you to obtain items that may be excess (unsold) stock or short-dated stock.

The specific company my institution uses requires a set fee to set up an account and view products, and manufacturers supply the products that are up for sale. It may not always be the largest selection, but there may be an option for shortage product if your sites have sufficient need to use down the short-dated product.

A good strategy is to use the short-dated supply first and save your longer-dated product for later, hopefully bridging the shortage period if it is a temporary issue. Outside of third parties, you can always ask your wholesaler(s) if they have short-dated product that may not be reflected in an ordering portal – this may require additional approvals on their end before you can purchase.

Role of FDA in Drug Shortages

What role, if any, does the FDA have in the drug shortage issue? Have they looked at extending expiration dates based on clinical evidence?

Natalie Osagie: I am not aware of extending expiration dates. Perhaps a task force could be created to analyze the root causes for shortages. This may require manufacturers to provide notifications for impending drug shortages, and fix problems causing the drug shortage. Manufacturers could be asked to increase production or allow temporary importation from unapproved sources.

Jeff Pilz: The FDA maintains a database of extended use dates to assist specifically with drug shortages. Stability data is provided by manufacturers and reviewed by FDA staff. This is applied to specific lots as data allows. Current regulatory authority granted to the FDA limits the actions they can take; for example, they cannot mandate a manufacturer produces a product or how much they produce. Access the FDA database of extended use dates: <https://www.fda.gov/drugs/drug-shortages/search-list-extended-use-dates-assist-drug-shortages>

Sarah Hudson-DiSalle: The FDA has the potential to expand its regulatory authority but only if granted by the federal government. ASCO, ISMP, AHSP and other leading medical groups have proposed options that may assist the FDA in their ability to make regulatory impact. These include:

1. Develop a list of critical drugs. Use the WHO Model Lists of Essential Medicines and other existing resources, as a starting point to define what a shortage is and develop a list of critical drugs needed for emergency response and for saving and preserving life. Using historical data and manufacturing input, address why these drugs have been on the shortage list. The critical list can be used to:
 - a. Stabilize the availability of critical drugs by working with manufacturers and the Food and Drug Administration (FDA) to create redundant product in multiple locations in anticipation of natural disasters and other supply chain threats.
 - b. Assess the quality of pharmaceutical manufacturers measured against the importance of drugs on the critical list.
 - c. Work with the private sector for greater transparency surrounding the source of raw materials and manufacturing locations so providers can more easily assess pharmaceutical product quality. The FDA has proposed a star rating system for pharmaceutical manufacturers, which could increase transparency.
2. Create a multi-stakeholder advisory panel with the FDA to address key issues, such as the possibility of creating a stockpile of critical drugs, the logistics of warehousing such excess pharmaceutical inventory and where the excess inventory should be stored.

3. Enhance communication with the entire drug supply chain, including healthcare providers during, or in advance of, a public health emergency or other event that may create a drug shortage. FDA should provide the health care community with information simultaneously on the type of products that may be impacted and the expected duration of the impact. To prevent hoarding of inventory that could result from such communication, manufacturers could put product on allocation to ensure that remaining supply is distributed equitably.
4. Streamline regulations to incentivize increased manufacturing production.
5. Encourage FDA to consider how reducing the number of unapproved (pre-1938 FD & C) drugs on the market might impact shortages

Tracking Changes to Chemo Regimens

What tracking are you implementing for patients who had their chemo regimens changed due to the drug shortage? Are you noting what changes are being made?

Natalie Osagie: Thankfully my facility has not had to change patient regimens, but I do keep a spreadsheet of all patients who may be potentially affected by the drug shortage. The spreadsheet does include the number of cycles they are supposed to get, the numbers they have gotten, the number spent, and the approximate dose per cycle. This way I am able to keep tab on what is potentially needed in relation to the PAR level.

We also have a rule that all new starts with curative intent must have enough medication to complete the number of cycles needed before the patient can be started on the platinum-based treatment.

Peter Stuessy: Yes. We are tracking all patients we are aware of to quickly contact providers when we have enough drug and no longer need to use alternatives. We are tracking what they have changed to as well, but not outcomes. We are not aware of some patients if the provider chose an alternative therapy from the start because we are only running reports on protocols that contain carboplatin or cisplatin.

Sarah Hayward: Presently we have two tracking systems created in Excel spreadsheets. One is a continued update of supply, anticipated shipments, and current weekly usage of the meds. The other is specific to patients, to keep track of who is on a platinum, who has switched and been consented, etc.

Insurance Companies and Alternative Therapy

How are insurance companies responding when the alternative therapy options are much more expensive?

Natalie Osagie: My facility does not deal with the insurance companies but there has been no pushback on using alternative therapy options.

Peter Stuessy: So far, we have not received pushback. One example I know of is instead of cisplatin/gemcitabine for metastatic bladder, providers are using pembrolizumab/enfortumab.

Sarah Hudson-DiSalle: Addressing shortages with insurance companies starts with a transparent approach to the insurance when a long-term drug shortage is identified. Our facility will reach out to the pharmacy directors at

the insurance companies to help educate on the drug shortage and any recommended alternative that might be identified by national guidelines such as NCCN, or ASCO.

Some insurance companies use third party companies to complete their insurance authorizations. These companies may require FDA notification to prove the drug shortage, alternative therapy support with peer-reviewed literature or request a peer-to-peer conversation with the prescriber to discuss the alternative being requested based on the drug shortage. The provides an opportunity to discuss any evidence-based literature that may have been provided and emphasize plus educate the physician reviewer on the drug shortage.

First-Line Metastatic NSCLC Treatment

What are you using for metastatic NSCLC first line?

Natalie Osagie: We have considered using immunotherapy base regimen such as ipi/nivo, gem/taxane or gem/vinorelbine for combination regimen. Consideration for single agent such as Abraxane, docetaxel, paclitaxel, gemcitabine, or pemetrexed (only if non squamous).

Peter Stuessy: Oxaliplatin substituted based on phase II data. If considered too toxic, then no platinum agent.

US Generic Drug Production and Supply

Pfizer and Teva both shut down US generic production facilities due to repeated FDA 483s in recent years. How do we have a sustainable generics supply?

Natalie Osagie: Maybe allow other manufacturers not in default to increase their production level and support the manufacturers who are in default by providing assistance for early resolution of the problem(s).

Jeff Pilz: Increased transparency in the pharmaceutical supply chain would be an immediate and short-term change that could allow a tailored healthcare provider response to shortages. Shortages may be exacerbated by organizations hoarding or panic-buying products, not to mention the gray market suppliers. If the information was available for what quantities were produced, locations where they are produced, and known vulnerabilities of the supply chain (e.g., is there an API that is notoriously hard to obtain?), end users can make a more specific shortage plan and may not need to take as drastic steps. Likewise, for long-term supply interruptions, sites can take a proactive approach to reduce utilization early in the shortage before the intensity worsens or reaches a stock out period.

Some of our BMT or CAR-T treatments require an immense amount of coordination and preparation that spans several weeks before the procedure date, so knowing as soon as possible the specific outlook for a shortage is critical to even consider some alternatives. More information on the FDA 483 finding specifics and the transparency from the manufacturer on remediation actions will also help in planning for a resolution to the shortage.

The long-term solutions include rewarding companies for quality manufacturing, rewarding for production prioritization of critical drugs impacting public health, and invest in better production or supply chain links. Critical drugs such as oncology agents used in first-line regimens could be prioritized. A star-rating system has

long been proposed to highlight manufacturer quality, allowing a higher price to be paid for an item that is of higher quality or is more reliable in supply.

I personally would not suggest reducing any sort of regulatory requirements, as that can negatively impact patient safety. The FD&C Act and other FDA requirements are often a result of historical events that caused significant harm to patients or consumers, and I would not want to see preventable harm occur in the future. There may be ways to reform the way contracting and supply chain sourcing occurs that could better support multiple manufacturers and the less expensive generics, particularly for sterile products.

Peter Stuessy: I agree with Jeff. I think changes are needed within the government, health systems, manufacturers, GPOs and wholesalers to break us out of our current situation.

The Grey Market

What is considered the grey market?

Natalie Osagie: Grey market is a supplier who sells outside of the distribution networks and can charge exorbitant prices for drugs that are in short supply.

Documenting Dose Reductions and Alternative Therapies

Any suggestions on how to protect ourselves from legal ramifications that may come when making direct patient care recommendations on dose reductions and alternative therapies? How best to document on the EMR?

Natalie Osagie: This can be done through a committee that consists of all stakeholders. Recommendations can be made into an allocation plan that is then approved by the facility. This way it is in writing and there is protection. You can document this in the EMR by referencing the approved allocation plan.

Jeff Pilz: An ethics committee or consultation process will be important to have in place when making the hard decisions around allocation of product. This group should include risk management and legal representation. Using primary literature and national guidelines to shape your decision is also very important to support the alternatives selected.

For oncology agent shortages, my institution engaged the division physician leaders for each affected disease state to help make recommendations for their patients.

Communicating with patients up front is also important. Make sure to include the reasons why they need to make changes to the clinical treatment plan with specifics, as necessary, regarding the shortage situation. Document the criteria selected and have a mechanism available to audit whether these are being followed consistently throughout your organization.