

Navigating the drug shortages

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See Commentary on page 277

In November 2010, pharmacists at Georgia Cancer Specialists, a private cancer practice with 27 offices, noticed our first instance of the latest wave of drug shortages. We had tried to place an order for doxorubicin, but our primary wholesaler was not able to fill it. We also discovered that our secondary wholesalers had little or no available doxorubicin, and that some suppliers had increased their prices for the drug to such an extent that it was out of our reach. We began to take inventory of the doxorubicin that we had in all of our offices. At that point, we realized we had a crisis on our hands.

We promptly informed our lead physicians about the situation and began running reports of patients who were actively receiving doxorubicin. A drug shortage committee comprised of 4 physicians, 2 pharmacists, and a nurse was set up and the members devised a system of prioritizing our remaining inventory and restricting the drug to designated patients. Priority was given to patients based on the intent of their treatment (see Figure). In some cases, physicians were asked to switch patients to alternative regimens whenever possible for as long as we risked running out of the drug completely. Physicians were placed in the impossible position of explaining to bewildered patients why they would be receiving a different treatment or they were given the option to try to get the medication from another facility.

The process of requesting a drug that was in short supply began with the physician or the physician's nurse completing a form that contained the following information: the clinic and prescriber name, patient's name and date of birth, the diagnosis, drug and protocol requested, treatment indication (adjuvant, induction, relapse, salvage, etc), justifications for use of drug, the date the drug would be needed, and the dosage. If the request is for 5-fluorouracil, then the prescriber

should also answer the following questions: Is Xeloda indicated? Can the patient afford Xeloda? Is the patient eligible for epidermal growth factor receptor antibody therapy?

The completed form was sent to the pharmacists on the drug shortage committee for review, and the committee would identify "high-priority" patients for treatment based on the established criteria (see Figure). Requests that fell outside of the established priority group were reviewed by the physicians on the committee. A drug that had been approved by the committee could be released when or if it was available. Such periods of waiting and uncertainty were marked by increasing anxiety for both the physician and the patient, especially as the supply dwindled.

While this was occurring, the list of drug shortages was expanding as new drugs were being added to it. These subsequent additions included paclitaxel, 5-fluorouracil, cytarabine, cisplatin, etoposide, mitomycin, and others. Among the generic supportive care drugs, which are crucial to oncology practices, those added to the list were leucovorin, diphenhydramine, mannitol, famotidine, lorazepam, levofloxacin, ondansetron, magnesium sulfate, and others. The list continued to grow. In a number of cases, there was little or no explanation for the growing shortages of generic drugs, which added to the frustration of the providers and patients.

Soon, we received word that liposomal doxorubicin would no longer be available because the manufacturing facility had been damaged in a storm. We added additional drugs to our list of drugs which required approval. The pharmacists sorted through flurries of e-mails from prescribing physicians and nurses seeking approvals for shortage drugs for established priority patients and guidance on reasonable alternatives for patients who were not designated as priority. For each drug, members of the drug shortage committee worked together to establish reasonable alternative therapies, when available. Pharmacists scoured the Food and Drug Administration and American Society of Health System Pharmacists Web sites and other

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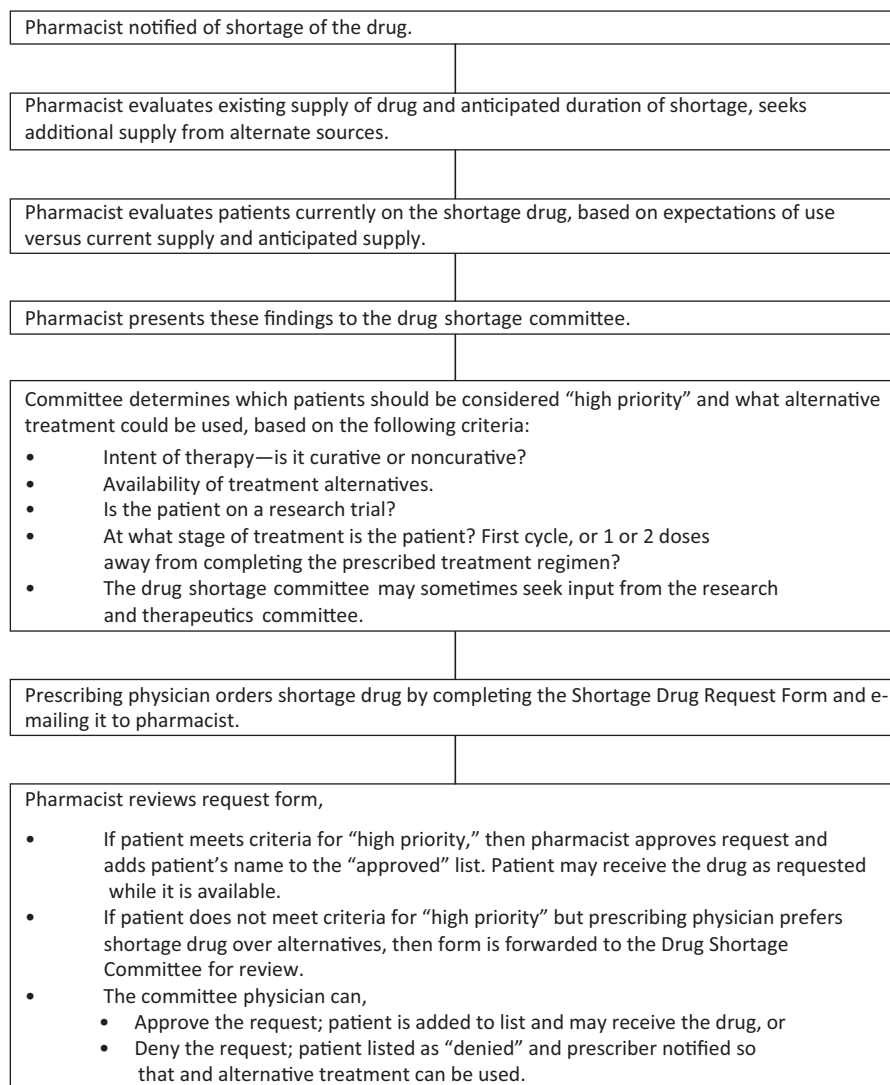


FIGURE Summary of approval process for shortage drugs.

resources to assist providers in suggesting alternatives as well as tracking down the shortage drug.

As manufacturers began to distribute the drugs that had been in short supply—sporadically, at first—shortage

began to and continues to abate. However, the problem continues as many drugs remain on the shortage list and are available in limited supply and subject only to sporadic releases, when at all.