Drug Shortages: Ethics and Implications

By Lila Abassi — January 29, 2016

It's one thing to save someone's life in an emergency situation, but having to decide which patient is more deserving of potentially life-saving medication because of drug shortages is quite another. I don't believe that any physician would want to be placed in that kind of ethical quandary. The sad truth is that's exactly what is happening.

In the United States, there has been a rapidly increasing frequency of drug shortages that pose great challenges for doctors, healthcare facilities, patients and federal regulators. Medications, such as generic cancer drugs, are more vulnerable to shortages, but a wide variety of medications that have been around for decades are suddenly in short supply. This group includes:

- heart medications
- analgesics
- intravenous electrolytes
- leucovorin
- propofol
- morphine
- hydromorphone
- furosemide
- amino acids

Why is this happening?

Well, there are multiple factors that contribute to drug shortages, including difficulties in acquiring raw materials, manufacturing problems, regulatory issues, business decisions, and many other
disturbances within the supply chain. This all translates to negative consequences for the patient, by forcing doctors to substitute safe and effective therapies with alternative treatments; compromising or delaying medical procedures; or causing medication errors.

All of this places a tremendous burden on doctors, healthcare personnel and facilities both ethically and financially. Some institutions have policies and procedures in place to deal with the difficult decision-making process required to effectively handle drug shortages, but the majority don’t.

Generic chemotherapy agents that are routinely used for the curative treatment of common and aggressive cancers have been vulnerable to shortages in the U.S. since 2006. A retrospective analysis[3] confirmed that drug substitutions forced by shortages resulted in higher relapse rates among children with lymphoma who could have been cured.

According to an article in the *New York Times* [4], the issue with lack of a systematic approach to these shortages is particularly troubling for a group of international pediatric oncologists. They will be publishing their guidelines in the *Journal of the National Cancer Institute* shortly.

When speaking with the *Times*, Dr. Yoram Unguru, an oncologist at the Children’s Hospital at Sinai in Baltimore, and a faculty member at the Berman Institute of Bioethics at Johns Hopkins University stated, It was painful. We kept coming back to wow, we’ve got that tragic choice: two kids in front of you, you only have enough for one. How do you choose? That is not a decision anyone should have to make.

In a survey[3] of physicians who regularly prescribed chemotherapy, 82.7 percent of them reported being unable to prescribe the preferred chemotherapeutic agent at least once within the last six months because of shortages, and these shortages include medications that are an integral part of curing malignant cancers such as colon cancer, breast cancer, and leukemia, as well as palliation for patients with metastatic cancers.

More than 75 percent of these doctors were forced to prescribe an alternative regimen or a substitution to a different drug treatment. More than one third of survey participants had to delay starting treatment and decide which patients they would have to exclude from treatment. Of these doctors, 69.6 percent practiced in facilities that did not have formal guidelines on how to deal with encountering shortages.

The issue of informing patients about these critical shortages is also at the center of the ethical quagmire. While it may be tempting to take a paternalistic approach and withhold telling patients that a medication they need may not be available, the majority of patients want to be informed [5] of how drug shortages may impact their care.

Irrespective of how this happened, what is important is what do we do now. There has to be a major overhaul in how we deal with shortages of critical drugs. For a country that spends the most amount of money for healthcare, rationing life-saving medications seems more than slightly embarrassing.