

Duke policy provides ethical foundation for managing drug shortages

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Hospitals and health systems faced with ongoing shortages of key drugs for cancer and other diseases should develop firm rationing policies based on transparency and fairness, researchers at Duke University Medical Center report.

In a Special Article published online Monday, Sept. 24, 2012 in the [Archives of Internal Medicine](#), the Duke team outlined a policy adopted at Duke Medical Center that established clear-cut rules for apportioning scarce drugs using a hierarchy of clinical need and effectiveness.

Built on similar models that govern some organ donations, the Duke approach was written by the hospital's ethics committee and adopted by hospital leadership in 2011 as shortages of critical drugs occurred regularly.

In recent years, the U.S. [Food and Drug Administration](#) has announced hundreds of supply problems for lifesaving [chemotherapy agents](#), [pain medications](#), [antibiotics](#) and other drugs. Dozens of pharmaceuticals are on the shortage list at any given time, forcing doctors to switch patients to alternatives, delay treatments or cut dosages.

"There's no reason to believe things will get better and, in fact, they may get worse, so hospitals will have to deal with some very dicey issues," said Philip M. Rosoff, M.D., M.A., director of [clinical ethics](#) at Duke and lead author of the study. "For that reason, it's important to establish and follow an ethically defensible policy for how scarce resources are

rationed."

In their article describing the development and implementation of the Duke Medical Center policy, Rosoff and co-authors outlined five essential components:

- Rules were transparent and open to review both internally and externally;
- The policy and its rationale were relevant, clinically necessary and clearly stated;
- Patients and doctors had a path for appeal;
- Rules were followed and enforced by all and for all;
- No patient or doctor was allowed special consideration.

Rosoff said fairness was an especially important component of the policy.

"One of the issues that arises is the question of so-called 'special people,'" Rosoff said. "What if a major donor comes in, or someone who says they'd like to be a major donor? Does that person step to the front of the line? Our policy says no – all patients are treated equal."

While each shortage was unique, Rosoff said having the policy provided a uniform approach to managing different situations. When drugs were flagged as running low, hospital officials immediately responded by taking inventory of remaining stock, determining when and how additional supplies might become available, reducing waste and paring back on usage.

One tactic was to restrict scarce drugs for FDA-approved uses, or in circumstances with firm, scientific evidence of benefit. As a result, a [chemotherapy](#) agent approved solely for breast cancer could not be used

"off label" for other types of cancers unless there was strong published evidence to support it.

Hospital officials also strategically scheduled patients who needed the same drugs on the same day, pooling the small leftover amounts in single vial containers to reduce waste.

In certain critical shortage situations, Duke also had rules giving priority to existing patients, new patients from the immediate referral region, and patients who could be cured by the drug.

Rosoff said Duke's experience could be instructive to most other institutions, but noted that the hospital benefitted from having a compounding pharmacy, which enabled it to produce many scarce drugs when raw materials were available. He said that capacity created additional ethical dilemmas, requiring strong communication and cooperation with surrounding hospitals.

"We had to make some difficult decisions, most of which we foresaw in the creation of the policy," Rosoff said. "There have been several issues we thought could happen, but haven't happened yet, so in that sense, it's been very gratifying."

Provided by Duke University Medical Center

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