

## Ch. II-5 Duty of Restraint

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### ISSUE: Cyclophosphamide is on shortage with no known re-supply date. How do you represent the Neuro-ICU to ensure rationale and ethical use across the institution?

#### DUTY OF RESTRAINT

Duty of restraint refers to the ethical and/or legal obligation of a provider to limit, restrict, or withhold therapy. Arriving at a decision that might include a duty of restraint as it relates to the care of an individual patient could result from numerous scenarios. Generally speaking, all health systems struggle with meeting population health needs under resource constraints. As such, resource allocation decisions are necessary. Some examples include:

- Withholding or withdrawing of care in the setting of medical futility
- The allocation of scarce resources, which could include medications or equipment in limited supply, financial resources, and human resources
- Decision making that pits the collective good of all patients vs. the interests of an individual patient

#### INDIVIDUAL PATIENT VS. PUBLIC HEALTH

Providers are increasingly faced with the moral and ethical dilemmas, wherein choices need to be made that directly place a provider's fiduciary obligation to an individual patient in opposition to their professional obligation to steward medical resources responsibly. In the scenario above, an individual may feel compelled to advocate for and secure access to cyclophosphamide for their patient population (e.g., for indications such as central nervous system vasculitis, acute demyelinating encephalomyelitis, or acute autoimmune encephalitis). By acting solely on the principle of beneficence (doing what is right for the individual patients in their ICU), they are simultaneously violating the principle of non-maleficence by limiting the amount of cyclophosphamide available for other indications in the hospital (e.g., as part of a curative chemotherapy regimen in some oncology indications). If the ultimate goal is to obtain the maximum cumulative benefit in terms of patient outcome from the remaining supply of cyclophosphamide, a duty of

restraint on the part of providers and/or the institution itself may be required.

Another example encountered frequently is in the setting of antimicrobial stewardship. While using antibiotics to broadly cover for multiple pathogens may be beneficial for the individual patient with an infection, intensivists are forced to balance this with an increasing prevalence of antimicrobial resistance and have to make choices based on the most probable source even when diagnostic information is limited. In making patient-specific determinations that balance a provider's duty to treat vs. their duty of restraint, an ethical framework for decision making should be employed.

#### ETHICAL FRAMEWORK

It is generally recognized that in order to successfully make decisions that maximize the amount of good from a limited resource, one must expand their ethical analysis beyond the principles which focus on the individual (i.e., autonomy, beneficence, and non-maleficence). Values focused on the common good must also be considered, such as utility, communal beneficence, distributive justice, and stewardship.

In the setting of a known shortage or limited resource, one could argue that distributing that resource in a first-come, first-serve fashion is unethical. Ad hoc decision making under these conditions can result in scenarios where some patients (intentional or otherwise) are judged to be more deserving than others based on who they are, who is treating them, or other factors like their financial means. Decisions that ultimately result in a duty of restraint on providers should be rooted in a multi-disciplinary framework that is ethically defensible. This framework should factor in the available scientific evidence, provide for deliberation around the moral implications of the decision, and be rooted in norms of distributive justice. Importantly, it is advisable that this process be developed and decided on outside of any particular resource allocation decision itself in order to achieve

legitimacy and fairness. Rosoff and colleagues have proposed such a framework for the allocation of scarce resources that is rooted in the “accountability for reasonableness” processes described by Daniels and Sabin. The five principal components to this process that seek to establish an ethically defensible framework are as follows:

- **Transparency/publicity:** The rationale and allocation scheme should be made public and available for comment. How the decisions are made and the implementation plans should be available to all. Decision should not be made in secret.
- **Relevance:** The rationale for the decision should be clinically relevant, grounded in evidence when available. It should be explained such that unbiased, neutral observers would be able to view the allocation scheme as relevant to the situations for which it has been devised and applied.
- **Appeals:** There should be a timely appeal process such that those who feel the allocation scheme is flawed may appeal the decision. Given the clinical complexity of some of these allocation decisions critical issues may be missed. An appeal process presents an opportunity for learning and adjustment of decisions as more information and other situations present themselves.
- **Enforcement:** The institution must have means and ability to guarantee the implementation of the strategy such that it is followed by all.
- **Fairness:** The rules must be applied such that clinically similar patients are treated similarly. No individual patient should receive exceptional consideration because of who they are.

This should likewise apply to providers who could use their prominence in the institution to serve as an advocate for a particular patient.

Whether it is related to issues such as medical futility, avoidance of harmful or unnecessary medications, allocation of scarce resources, or decisions for the public good, clinicians and institutions frequently encounter situations where a duty of restraint is an appropriate result of an ethical decision making process. When possible, institutions should work to establish and engrain an ethical framework for decision making into these decisions in advance.

### **SUGGESTED READING/REFERENCES**

- Daniels M. Accountability for reasonableness: Establishing a fair process for priority setting is easier than agreeing on principles. *BMJ* 2000;321:1300-1.
- Parsonage B, et al. Control of Antimicrobial Resistance Requires an Ethical Approach. *Frontiers in Microbiology* 2017;8:2124
- Rosoff PM et al. Coping With Critical Drug Shortages: An Ethical Approach for Allocating Scarce Resources in Hospitals. *Arch Intern Med* 2012;172(19):1494-99.
- Rosoff PM. Unpredictable Drug Shortages: An Ethical Framework for Short-Term Rationing in Hospitals. *Am J Bioethcis* 2012;12(1):1-9.