Ethical Process Principles and Implementation Strategies	
The following principles & strategies expand on the ASCO recommendation: "Institutions should establish a working multidisciplinary utilization committee to monitor drug shortages, provide and communicate internal policies on utilization, and act as an independent arbiter to promote equitable use of drugs in short supply". ASCO offers this information for voluntary use to highlight key process principles. It does not illustrate all issues that an institution could consider in the development of its allocation policies and procedures.	
Ethical Process Principle	**Implementation Strategies**
Stakeholder Participation	• Multidisciplinary committees should include clinical staff, patients, pharmacists, infusion nurses, clinical ethicists or ethics committee members, and other stakeholders • Committees should consult with affected individuals and groups who are not part of committees • Oncologists without practice or institutional support can consider joining with other practices in their state or region to develop a strategy
Relevance	• Articulate relevant values and principles to guide allocation decisions • Develop clearly stated goals for an allocation plan that can be tracked and measured during planned reviews • Primary: Incorporate evidence based clinical guidance; consider factors such as likelihood of benefit and certainty of benefit, existence of effective alternatives, relative toxicity, phase of treatment • Secondary: Fair and unbiased process for deciding between patients with the same position after primary clinical analysis

	• Create or follow a model framework grounded in organizational values and responsive to patient population • Strive to create mitigation and allocation strategies as explicitly as possible so that individual physicians are not forced to make allocation choices and to limit heterogeneity in decisions
Consistency & Review	• Apply allocation policies consistently • Include a timely and consistent appeals process • Collect data on the effectiveness of the policy at achieving the stated allocation goals and, if possible, patient outcomes • Perform data reviews at regular intervals, ideally aligned with key timepoints (e.g., new supply estimates), to assess concordance with goals and for unanticipated issues (i.e., inequities) • Revise policies, as needed, based on findings from the above • Maintain the committee to monitor for shortages and plan for future events
Equity	• Include patients from disadvantaged groups fairly in allocation decisions, and explicitly consider whether allocation frameworks might unintentionally continue or worsen existing inequities • Consider whether patients from disadvantaged groups should receive priority in allocation decisions (e.g., if a given minoritized group is known to have worse outcomes from the disease treated by the drug in short supply; or are more likely to present with more advanced disease) • Develop decision procedures that avoid awareness of the specific patient in need to prevent bias and/or preferential treatment for powerful patients and clinicians • Facilitate access to care (e.g., transportation, childcare, disability accommodations) so that access issues are not a factor in allocation of drugs in shortage • Share drugs, if possible, and exchange information about shortages between institutions and networks of institutions; avoid hoarding and stockpiling; ASCO opposes “brown-bagging" chemotherapy medications

	• Promote access for patients in remote and underserved geographic locations, and mitigate impact on economically disadvantaged patients • Ensure patients and their families who cannot receive the scarce medication receive the best available treatment. This includes palliation and psychosocial support
Transparency, Trust, and Communication	• Communicate clearly with patients, families, and members of the care team • Include language translation and interpretation in communications plans • Inform patients if shortages could impact care • Whenever possible, clearly and publicly describe any mitigation and allocation plans that will be implemented • Consider targeted guidance to not unnecessarily worry patients and families who will not be affected

Allocation Principles and Their Respective Benefits and Limitations

Below are a series of allocation principles that are commonly used when developing plans for allocation of drugs or other resources in short supply. Of note, most allocation plans use several of these principles together, either in a tiered or combined approach. Recognition of these principles (and their benefits and limitations) can help institutions to develop a rational, practical policy for allocation of scarce drugs.

Allocation Principle	Practical Method of Application	Practical Benefits/Justification	Practical Issues/Limitations
Lives-Saved **Live-Years Saved**	Prioritize by curative intent	• Promotes a utilitarian concept, aligns with evidence-base • Easy to apply in complex situations when shortage effects multiple diseases and regimens	- Does not equal likelihood of long-term survival, can have non-curative intent patients with one disease living longer than curative intent with another disease - Does not account for additive value of one drug in a multidrug regimen - Non-curative deprioritization may exacerbate disparities as persons with less access to healthcare more often present in later stages - Requires consideration of whether age should be a consideration in allocation decisions

***Notably, the difference between lives-saved and life-YEARS saved depends on whether age of patient (and how many years they are expected to live) is deemed ethically relevant**	Prioritize by expectation of long-term survival	• Promotes a utilitarian concept, aligns with evidence-base • Can be useful when deciding between a small group of patients with high levels of evidence for regimens	- Requires cross trial and cross disease comparison with differing levels of evidence - Can be difficult to enact as a strategy if there are many patients and regimens across many disease types
	Prioritize by either of the above but accounting for lowest usage per patient	• Useful to maximize drug across a heterogeneous group • Aligns with youngest first in most cases • The research consideration of "double denial" discussed under reciprocity also applies here	- Practically difficult to align with the above in a timely manner
Worst off	Prioritize those with inferior or medically contraindicated alternatives	• Useful for determining need based on lack of effective alternatives • Reasonable metrics include differences in overall survival (or established surrogate outcomes)	- Worst off defined as "those closest to death" would prioritize those least likely to benefit and is not an appropriate definition in the context of chemotherapy shortages - With many diseases and alternatives, difficult to stratify by individual regimens/alternatives; a binary or simplified metric may be practically acceptable (i.e., is the

			alternative statistically inferior? [Yes/No]; or is the alternative statistically inferior and decreases the HR for long term survival by xx% ? [Yes/No])
Youngest First	Prioritize children and younger adults	• Directs treatment to a group that is generally recognized as worth prioritizing • Often aligns with expectation of long-term survival and lowest usage per patient	- If enacted alone, can prioritize younger patients with low likelihood of long-term survival over older patients with higher likelihood of long-term survival - If applied in groupings (e.g., <18, 18-30, etc.), it is difficult to justify different priority between individuals who are near cutoffs - Prioritization with a diminishing multiplier (i.e., a continuous score for priority that decreases by age) may be difficult to enact in a multiple criteria system; may be based used as a tie breaker
Lottery	Random choice	• Useful when prioritizing within a homogenous group	- If applied by itself does not account for known differences in efficacy, toxicity, alternatives. Best use may be as a tie breaker within groups.

First-come, first-served	Waitlist based on time from known need for scarce medication	• Useful when prioritizing within a homogenous group	- Favors the well-connected, affluent, etc. - Can compound disparities
Reciprocity	Prioritize a select group of individuals who have previously provided some sort of usefulness, good, or sacrifice (e.g., those patients who are participating on a clinical trial where the scarce drug is given as a standard of care)	• Recognizes altruism of patients and importance of advancing research • Allows patients to not be denied scarce drugs via standard treatment allocation and study allocation • If study completion/fidelity would be compromised, this also recognizes the participation of prior patients who have completed treatment	- Can be coercive if patients are prioritized only because of trial participation - Can exacerbate inequities by giving preference to patients who are offered clinical trials and can participate
Instrumental Value	Prioritize based on future usefulness	• Allows for care to those who are needed for ongoing care delivery in a crisis, such as first responders	- Little relevance for cancer drug scarcity as this is value laden
Duty to Care for Existing Patients within Home Institution	Prioritize patients who are currently being treated (not synonymous with first come- first serve as it does not differentiate based on start date)	• Allows for evidence-based completion of regimens that have already been started	- Unless used in conjunction with utilitarian goal, can prioritize patients with little benefit

	Limit transfers of care specifically for scarce chemotherapy (not new diagnoses/progressions)	• Allows for understanding of supply and demand in a consistent manner such that patients who are prioritized can receive the scarce drug • Dissuades advantaged patients who can travel from accessing other supplies • Promotes consistency across institutions	- Limits the effectiveness of sharing across institutions or regions - Can prioritize advantaged institutions (those with more drug) - Can exacerbate inequities

*Principles adapted from Persad G, Wertheimer A, Emanuel EJ. Principles for allocation of scarce medical interventions. Lancet. 2009 Jan 31;373(9661):423-31. doi: 10.1016/S0140-6736(09)60137-9. PMID: 19186274.

Additional Resources

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Allocation Frameworks Grounded in Ethical Principles

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