

The Multi-Regional Clinical Trials Center of Brigham and
Women's Hospital and Harvard Bioethics Collaborative

Medical Need or Market Opportunity: Setting Research Priorities

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Introduction:

Priority setting is a method used to determine how to distribute scarce resources in research, clinical care, and social policy generally. Research priority setting is driven by different types of scarcity, such as insufficient funding, scarcity of eligible and/or willing participants, inadequate or limited infrastructure, or a shortage of researchers. Due to the varying types of scarcity, different analyses are required, which often raise different ethical issues and drive different decision-making and outcomes, depending on when and what is scarce. For example, poor prioritization can result in resources being allocated to less worthy research. Similarly, with participants, poorly considered prioritization decisions can lead to incomplete studies, exposing participants to potential risks without benefit while also leaving valuable research unfinished. Given that there is no way to avoid resource scarcity at various levels, prioritization decisions are unavoidable, whether implicitly or explicitly. For instance, funding decisions involve comparisons between studies to determine which is more deserving. This is often guided by ethical principles, whether acknowledged or not.

Research priority setting is primarily conducted by funding entities, such as private companies and governments. However, other stakeholders may, and arguably should, also play a role in decision-making. Institutions, for example, contribute by providing participant pools and research infrastructure, which is critical to performing research. Given that those involved in priority-setting decisions directly determine what research gets done, it's essential to consider carefully who should be included in these processes. Engaging scientists, clinicians, medical ethicists, patient representatives, advocates, and the community in the prioritization process can allow for broader value judgments about the importance of different research areas.

Research prioritization also requires principles to guide and inform decisions. One approach is to prioritize studies based on their potential to generate valuable and useful knowledge, with studies that produce the most useful knowledge being prioritized. Another approach, sometimes called “prioritarianism,” places greater weight on research studies that benefit the worst off. On a global scale, this would mean prioritizing conditions that disproportionately impact people in low- and middle-income countries. Other principles and approaches are also possible.

Presentations and Discussion:

After the introductory presentation, a bioethics collaborative attendee emphasized that practical considerations must also be considered in research priority setting. In some communities, the needs may be vast and difficult or impossible to satisfy; however, one could argue that addressing some of the needs is still preferable to meeting none, highlighting the importance of balancing practical and other considerations when making decisions.

The group also discussed justice in global research prioritization. One member noted that prioritizing research on a global scale assumes a global theory of justice rather than considering justice in the context of nation-states. One possible challenge to global approaches to justice is the absence of a governing body capable of enforcing legal and social justice across nations. Another member, while acknowledging an important distinction between global theories of justice and those limited to nation-states, emphasized the existence of intermediate views that do not require an all-or-nothing stance. For example, , while global obligations of justice may demand consideration of everyone’s needs irrespective of their country or nationality, it is nonetheless permissible to place greater weight on the needs of one’s fellow citizens at the nation-state level.

The first speaker addressed the obligations that for-profit organizations, such as pharmaceutical companies, have in conducting socially valuable research even when it does not maximize profits. He pointed out, first, that markets are not directed to the social good; rather, they exist and are maintained through specific rules that allow entities to pursue self-interested economic activities. These activities and competitions lead to some societal good by driving innovation and economic efficiency. In an ideal and just world– where all actors act ethically, the state ensures all individuals receive goods they’re entitled to, and everyone participates on equal terms–for-profit entities would be ethically permitted to pursue their self-interests without additional restraints. However, in an actual and non-ideal world, these conditions are often not met, leading to individuals not having access to essential health

services that would allow them to live healthy and flourishing lives.

The speaker argued that everyone, including private entities, should be concerned about the unjust failure to meet health needs. Since various actors (i.e., governments, for-profit organizations, non-profits, etc.) are not fulfilling their responsibilities, no entity should be allowed to maximize profits without constraint. The speaker suggests that the ethical obligations of for-profit actors should be (1) to pick up their fair share of the slack by conducting research on conditions that disproportionately burden the worst-off rather than focusing on marketable products for higher-income populations, even when the latter would be more profitable; and (2) not to take advantage of the rules in order to secure greater profits if or when this results in reduced social benefits (e.g., using loopholes to extend the life of patented drugs to maximize profits).

A member argued that for-profit entities are accountable only to their shareholders, who fund their work, rather than the broader community. Others pointed out that if returns are not lucrative, investors will withdraw funding, leading to a decrease in drugs on the market. This led to a discussion on the obligations of justice in unjust markets. Since markets are not in fact set up fairly and just, all actors are obligated to adjust their actions in response. However, this does not imply that for-profit entities should bear a greater obligation than other stakeholders; rather, everyone should shoulder responsibility collectively.

Others argued that for-profit organization's ethical obligations should not be contingent on the actions of other actors, such as governments or nation-states, as they have limited control over them. Concerns about moral hazard were raised: If certain entities take on a greater burden, others may lose the incentive to do their part and withdraw from their responsibilities. The counter-argument was that if some actors fail to fulfill their obligations, the burden should not fall entirely on those already worse off. Instead, fairness requires distributing responsibility among all market participants, though the extent of each actor's obligation is debatable.

The group also discussed alternative ways for companies to fulfill their ethical obligations. Some emphasized that creating healthcare infrastructure is as critical as prioritizing research. Others highlighted the importance of focusing on research that yields broad outcomes and applicable interventions rather than those only suited for advanced healthcare systems.

The speaker concluded by stating that engaging with for-profit entities in healthcare prioritization often involves viewing the patient populations primarily as markets, rather than primarily as individuals with health needs and valid claims that their needs be met. While a

product can meet a health need, companies must ensure that the product is affordable and consider what other forms of support can be provided within existing infrastructures. These additional considerations are crucial to factor into the decision-making process when trying to ensure that the health needs of these populations are being considered.

The second speaker focused on the importance of community engagement in research prioritization. Most of the time, priority-setting decision-making is a top-down approach that risks overlooking participant perspectives and what they see as their most pressing health needs. The speaker shared the example of a biotechnology company using an advocacy organization to help recruit for a natural history study of epilepsy. The study required families to travel to the company's location shortly after birth for an evaluation and study intake, overlooking the fact that the participants were newborns who experienced multiple seizures daily, making travel impractical and highly burdensome for families. In this case and others, there can be major disconnects between what researchers believe would benefit patients and what the patients themselves want or feel is important. By contrast, when researchers conduct community-driven engagement (for example, a six-week interview process that identifies the priorities in a community), they can learn what health outcomes the target population values (e.g., less drooling, learning to crawl, sit up, etc.) and how to minimize the burdens of trial participation. These insights can, in turn, drive innovation, allow research to explore specific issues in depth, and improve recruitment and retention rates.

The speaker also shared a global example of a project that diagnosed individuals in LMICs despite lacking infrastructure or resources for treatment. The group deployed community-driven engagement and used a voting tool to allow the community to rank priorities based on needs and culture. The outcomes extended beyond health, including education, road infrastructure, and transportation. While not providing patient feedback on scientific outcomes per se, communities identified common challenges and provided valuable insights to guide future research.

One member asked how we can amplify the voices of invisible communities. The first step is recognizing that individuals are experts in their own lived experiences. Taking this point seriously involves actively listening to and working in overlooked communities and finding ways to amplify their knowledge and needs. It also requires a commitment to innovative ways of doing the research needed in LMIC communities that may not always have the infrastructure to support traditional research modalities. For instance, instead of conducting traditional clinical trials within a community, it may be preferable to utilize wearables or sensors to collect essential data while reducing costs and barriers to healthcare access.

Another contributor provided a high-level overview of the draft WHO guidance on the ethics of health research priority-setting. The guidance aims to spur reflection on the values that explicitly and implicitly guide research priority setting. The current guidance is intended for all stakeholders involved in health research decision-making, including for-profit entities. However, further work is needed to clarify the implications of the principles for for-profit entities. The guidance focuses on four main principles for health research priority setting. The first principle is optimizing social value, understood as the idea that research priorities should maximize benefits specifically for those who are worst off. However, measuring social value is challenging, as expected benefits may vary across studies. The second principle is respecting special obligations, which is intended to ensure that organizations align research with their mission, albeit in ways that are compatible with optimizing social value. The third principle is assessing and minimizing risk, which involves avoiding research that could lead to harm, thereby narrowing the scope of projects to consider. The final principle is following fair processes and procedures, which ensures that all ethical principles are applied through an accountable, transparent, and inclusive process. The speaker acknowledged the complexity of doing research priority while also pointing out the importance of encouraging decision-makers to recognize that the process involves not just technical aspects but also value-laden judgments and decisions.

The discussion shifted to handling fundamental disagreements about what is socially valuable and what research is beneficial. Organizations and governments each have their own priorities and are expected to serve everyone to whom they have obligations, even if some of those parties disagree with each other over what is important. At the same time, it was also acknowledged that governments tend to favor more popular positions, making investing in and funding research that benefits minority or underrepresented populations more challenging. This is where entities and organizations other than nation-states should step in to promote these goals.

The last speaker addressed challenges in research priority-setting, noting that national priority-setting efforts have been reduced to procedural components at the expense of reflection on substantive ethical issues, which can lead to skewed prioritization based on who is involved. When prioritization becomes purely procedural, existing voices become amplified; for example, specialists may prioritize research in their fields while neglecting broader population needs. This emphasizes the need to incorporate moral values into priority setting while also addressing complexities such as defining health needs and identifying the most disadvantaged populations.

The speaker also noted some challenges and limitations with the WHO priority-setting guidance, particularly in LMICs, such as continued uncertainty over how to define the scope of research obligations, social value, and equitable research in ways that allow local researchers to lead their own research that meets local needs. Certain ways of approaching these issues nationally can put a disproportionate burden on local researchers, leading to the loss of innovation and social value.

Finally, the discussion shifted to the concept of *social value*. Some members argued that the words “social value” should be replaced, as its definition varies by context and does not clearly specify the intended benefits. Others defended its use, highlighting its flexibility to encompass diverse research priorities beyond health, emphasizing that social value can be adapted and more concretely specified to align with a study’s purpose. Additionally, the term includes non-scientific outcomes, such as those valued by patient communities, allowing for a broader and more inclusive understanding of important research outcomes.

References:

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