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Priority Setting in Biomedical Research

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The 21st century is replete with exciting discoveries in biomedical science. Even a superficial review of research conducted at or funded by the U.S. National Institutes of Health (NIH) supplies irrefutable evidence of the enormous range of opportunities that exists today. A survey of studies occurring in the private sector only adds to this evidence. And researchers in every field are enthusiastic about the knowledge and clinical benefits that their work could deliver.

The array of promising research areas presents itself in a context of limited resources, however. The NIH and private-sector funding sources must make difficult decisions about the fields and specific studies to support and must do so in a nation and world full of people vulnerable to an immense number of health problems.

Research-funding entities use broad criteria to allocate their limited resources. Under pressure to articulate the government's decision-making process, NIH officials issued a document explaining their allocation criteria in 1997. Five considerations play a role in the agency's spending choices: (1) public health needs; (2) scientific merit of specific study proposals; (3) potential for advances in a particular area; (4) distribution across diverse research areas (because it is impossible to predict exactly where advances will occur); and (5) national training and infrastructure needs.

The first NIH criterion, public health needs, is determined by the:

- Number of people with a specific disease.
- Number of deaths a specific disease causes.
- Degree of disability a specific disease produces.
- How much a specific disease shortens the average human lifespan.
- A specific disease's financial and social costs.
- Threats posed to others by contagious disease.

According to the NIH, these considerations are of equal importance in allocating research resources [1].

Resource allocation in the private sector may incorporate some of the same considerations as the NIH applies, but other factors play a role too. Pharmaceutical, biotechnology, and other companies are profit-making entities that consider the size of anticipated financial return as an essential guide to research investments. And nonprofit organizations often limit their support to research that could assist their specific disease constituencies.

Public and private choices about allocation of resources for research and public health needs raise social-justice issues. The ethical question is whether these funding sources make fair decisions about where to invest their resources. The NIH has the clearest obligation to distribute its resources fairly because it is taxpayer-supported. There is disagreement over whether private organizations have this obligation too; some believe that even businesses have a responsibility to consider the public good in their research investments [2].

The problem lies in deciding what qualifies as a fair allocation decision. The NIH lists factors that many people would use to determine fairness, but fails to rank them according to their importance. Moreover, its priority-setting criteria omit other ethical considerations that could bear on fairness, such as the relative significance of research needs of people in the United States compared to those in poor nations.

Not much attention is paid to fairness in research priority setting, but some writers have explored the topic and questioned the fairness of the NIH's current approach to resource allocation. For example, some criticize it for allowing current politics and political correctness to shape its allocation decisions [3]. A related charge is that interest-group lobbying plays too heavy a role. Others contend that the NIH should do more to show that its choices are aimed at conditions that impose the heaviest personal and social burdens. And at least one critic argues that the current criteria place too heavy an emphasis on extending the average lifespan and not enough on public health, disease prevention, and disability reduction [4].

It is not surprising that clear consensus is lacking on defensible research priorities. As the NIH criteria illustrate, there are many variables, and people differ in the value they assign to each. Is it more important to study childhood diseases than diseases affecting older individuals? Is extending life more important than ameliorating the burdensome symptoms of illness? Should life-threatening diseases that affect a small number of people take priority in the research agenda over less-serious diseases that affect many more individuals? Is it better to invest money in areas where breakthroughs appear imminent or in less-promising areas, where investments might jump-start research progress? People answer these questions differently based on their values and personal experiences with disease [5, 6].

Social justice becomes even more critical in the international context. Discussions of international research priorities often refer to the 10/90 split. Estimates are that just 10 percent of research focuses on the diseases that are responsible for 90 percent of the world's health problems. Most research occurs in wealthy countries and tends to study the diseases that affect people living in those countries [7]. Is it defensible for wealthy countries to devote so little to research on conditions like malaria, tuberculosis, diarrhea, and malnutrition, and so much to conditions that affect primarily people fortunate enough to live into their later decades [8]?

It may seem shocking to raise questions about the fairness of the current approach to biomedical research funding. But Daniel Callahan, a noted writer on bioethics and health policy, presents the following thought experiment:

> Consider—as an imaginative exercise—what we would get if there was no progress at all from this point forward, and medicine remained restricted to what is now available. The rich countries would remain rich. Most of their citizens would make it to old age in reasonably good health. There would continue to be incremental gains in mortality and morbidity, the fruits of improved social, economic, and educational conditions, and improvements in the evaluation and use of present therapies. No prosperous country would sink from the lack of medical advances [4].

Callahan's points relate to a second matter of social justice, which concerns the trade-offs between funding research and established health care. The United States has a poor record of providing basic health care to its people. Estimates are that more than 40 million individuals lack health insurance coverage and even more have inadequate coverage [9]. As a result, a large part of the community has trouble obtaining established therapies that could extend and improve their lives. This situation raises questions about the justification for investing large amounts of money in research aimed at developing health care innovations, especially those that are likely to be expensive. As health plans expand to cover the fruits of emerging biomedical research, the added costs can lead to even more disparities in health care access.

Advocates contend that research is needed to assist people with illnesses or injuries that cannot now be adequately treated. For them, social justice supports research that assists this disadvantaged group. They see a "research imperative" to conduct studies that could save lives and avoid suffering by those who cannot be helped by established medicine [10].

The case for a moral duty to undertake research must consider a second position, however. Investing resources to expand access to standard health interventions would also save lives and avoid suffering among people now deprived of this help. Most established therapies have already been evaluated in research, their benefits are well known, and they are relatively inexpensive. In poor nations, many children and adults die from easily prevented or treatable diseases because their countries cannot afford to provide them with effective medicines [11]. For example, the HIV epidemic has imposed untold suffering and devastating social burdens on people unable to obtain treatment [12].

Should limited resources be invested in research to develop health care innovations or to allow more people to benefit from already existing therapies? This question is rarely addressed in debates about U.S. biomedical priorities [13]. The social-justice inquiry raises questions about which areas of biomedical research merit the highest priority and the relative priority of biomedical research when compared to health care delivery. Delivering meaningful help to people in need requires difficult choices about where to place our nation's limited resources.

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