HNP DISCUSSION PAPER

Purchasing of Knowledge for Health Gains

Dean T. Jamison

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HEALTH, NUTRITION, AND POPULATION
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Health, Nutrition and Population (HNP) Discussion Paper

Purchasing of Knowledge for Health Gains

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Paper prepared for the World Bank's Resource Allocation and Purchasing Project

Abstract: The 20th century witnessed a global transformation in human health. Chile's experience illustrates the magnitude of this transformation. By the mid-1990s Chile's per capita income had reached about US$4,000 (adjusted for purchasing power), and Chilean women had achieved a life expectancy of 79 years. A century ago, in 1900, today's high-income countries also had income levels around $4,000—and, therefore, had resources sufficient to provide their populations with adequate food, water, shelter, and sanitation. Yet, for them, female life expectancy at the time was perhaps 30 years less than it is in Chile today. An important factor has been advance in scientific knowledge and its application both in creating powerful interventions and in guiding behavior. Acquisition and utilization of health research and development or its products becomes, then, an essential function of a country's health system. Much knowledge is embodied in global public goods: once a vaccine for hepatitis B has been developed anywhere it becomes, in some sense, available everywhere. Although monopoly pricing made possible by patents may slow the diffusion of some innovations, the temporary nature of patent-induced monopoly pricing limits this effect. But an innovation's being cheap, powerful, and globally available in no way entails its global use. There indeed appears to be enormous variation in the rate at which different countries make use of knowledge and products that are globally available. This discussion paper presents knowledge as an important function of national health systems. The paper uses the term "acquisition" rather than "purchasing" for the most part because of its more general connotation. That said, most of the issues such as agency roles and organization that are important for resource allocation and purchasing in general are likewise important with respect to research and development.

Keywords: Resource allocation, strategic purchasing, health policy, research, knowledge

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FOREWORD

Great progress has been made in recent years in securing better access and financial protection against the cost of illness through collective financing of health care. This publication – *Purchasing of Knowledge for Health Gains* **by Dean T. Jamison** – is part of a series of Discussions Papers that review ways to make public spending on health care more efficient and equitable in developing countries through strategic purchasing and contracting services from nongovernmental providers.

Promoting health and confronting disease challenges requires action across a range of activities in the health system. This includes improvements in the policymaking and stewardship role of governments, better access to human resources, drugs, medical equipment, and consumables, and a greater engagement of both public and private providers of services.

Managing scarce resources and health care effectively and efficiently is an important part of this story. Experience has shown that, without strategic policies and focused spending mechanisms, the poor and other ordinary people are likely to get left out. The use of purchasing as a tool to enhance public sector performance is well documented in other sectors of the economy. Extension of this experience to the health sector is more recent and lessons learned are now being successfully applied to developing countries.

The shift from hiring staff in the public sector and producing services "in house" from non governmental providers has been at the center of a lively debate on collective financing of health care during recent years. Its underlying premise is that it is necessary to separate the functions of financing health services from the production process of service delivery to improve public sector accountability and performance.

In this Discussion Paper, Jamison highlights that the acquisition of knowledge is an important aspect of a functioning health system. The contribution of the private sector to health research, in the traditional pharmaceuticals (drugs, vaccines, diagnostics, devices) industries, and in a growing list of other health products such as health education materials, has been highly significant in recent decades. Public sector requirements for new product development are dependent on industry for many reasons, including the industry's expertise in development, its efficiency as a manufacturer and distributor, its knowledge and skills in market research and, not least, its financial power. Unfortunately, current incentive structures to produce health products for the lowest income groups is often lacking in the private sector. And because knowledge is a public good, it is often ignored as one of the critical inputs during the purchasing process in the public sector. The author concludes that the public sector must either harness the skills, energy, and capacity of the private sector to develop and bring promptly to market products for the lowest income groups, or it must take responsibility for doing so itself. In most cases, a combination of the two is likely to lead to the best outcomes.

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Lead Economist
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INTRODUCTION

The 20th century witnessed a global transformation in human health (Jamison 1999). Chile's experience illustrates the magnitude of this transformation. By the mid-1990s Chile's per capita income had reached about US$4,000 (adjusted for purchasing power), and Chilean women had achieved a life expectancy of 79 years. A century ago, in 1900, today's high-income countries also had income levels around $4,000—and, therefore, had resources sufficient to provide their populations with adequate food, water, shelter, and sanitation. Yet, for them, female life expectancy at the time was perhaps 30 years less than it is in Chile today. Why has health improved so dramatically *after controlling for income and, hence, availability of commodities that, like food, are essential for health*? Although there can be no unambiguous answer to this question, an important factor has been advance in scientific knowledge and its application both in creating powerful interventions and in guiding behavior. Acquisition and utilization of health research and development (R&D) or its products becomes, then, an essential function of a country's health system.

Much knowledge is embodied in global public goods: once a vaccine for hepatitis B has been developed anywhere it becomes, in some sense, available everywhere. Although monopoly pricing made possible by patents may slow the diffusion of some innovations, the temporary nature of patent-induced monopoly pricing limits this effect. But an innovation's being cheap, powerful, and globally available in no way entails its global use. There indeed appears to be enormous variation in the rate at which different countries make use of knowledge and products that are globally available. A recent assessment (Jamison, Sandbu, and Wang 2004) found, for example, that the rate of "technical progress" in reducing infant mortality in 1960–90 ranged from 5 percent a year in some countries down to none at all in others.[1] While infant mortality could certainly decline somewhat from income improvements in the absence of technical progress, a 5 percent rate of technical progress would lead to a halving of the infant mortality rate in 15 years beyond whatever improvements may have resulted from gains in income and education levels. The implication is clear: globally available knowledge and products offer enormous opportunities to countries, but national policies and national health systems determine whether this knowledge is put to local use. Additionally, and importantly, some information for improving outcomes is local and must be locally produced.

This chapter discusses acquisition of knowledge as an important function of national health systems.[2] Hence, in the nomenclature of this volume, resource allocation and purchasing (RAP) for R&D are important policy issues. The chapter will use the term "acquisition" rather than "purchasing" for the most part because of its more general connotation. That said, most of the

[1] Technical progress was defined in this study, as in the literature on economic growth, as an unexplained residual. In the cited study, technical progress was the rate of infant mortality decline after controlling for improvements in levels of education and income and increases in physician availability. Hence, technical progress encompasses increased utilization of better drugs and vaccines, diffusion of knowledge to guide individual behavior, and, potentially, better ways of organizing health systems.

[2] Most discussions of health system development neglect the role of R&D; the World Health Organization (1999) is an exception.

issues discussed in chapter 1 concerning agency and organization that are important for RAP in general are likewise important with respect to R&D.

This chapter is organized into two main sections. The first discusses main topics that R&D needs to address. The second has sections on the role of the government that deal with areas of knowledge that governments should both pay for and produce; areas that governments should pay for but purchase externally; and, finally, areas that governments should neither pay for nor produce but should encourage, for example, by creating intellectual property or by investing in R&D capacity. The perspective throughout is that RAP policies need to be informed by the particular character of knowledge as a commodity: major fixed production costs leading to a need to focus effort. Nevertheless, although published knowledge can be considered freely available, there are genuine barriers to the diffusion and use of knowledge that RAP policies—institutional designs—need to address.

PRIORITY AREAS FOR R&D

In 1996, the World Health Organization's Ad Hoc Committee on Health Research Relating to Future Intervention Options published the report of its deliberations.[3] The committee proposed creation of a mechanism, now institutionalized as the Global Forum for Health Research, which provides annual updates of the status and directions of health R&D for developing countries. The priority areas identified by the committee (Ad Hoc Committee 1996) have been broadly followed by the forum and may be summarized as observing that four challenges to health systems will remain important for decades to come and, hence, that specific R&D initiatives would contribute significantly to meeting these challenges. These challenges are the unfinished agenda, the continually changing nature of microbial threats, epidemics of noncommunicable diseases and injury, and the efficiency and fairness of health systems themselves.

- *The unfinished agenda.* Despite progress, there remains a huge and unnecessary burden of infectious disease among the poor that can be addressed with available cost-effective interventions. Addressing this unfinished agenda is mostly a matter of political will and (modest) commitment of resources. This unfinished agenda relates closely to the Millennium Development Goals (MDGs) for health and emphasizes the priority needs of those in poverty. R&D can help through operational and behavioral research to facilitate implementation (often by developing and evaluating linked packages of care, such as integrated management of childhood illnesses) and by selective development of new tools, including improvements in vaccines.

- *Continually changing microbial threats.* A more global class of challenges results from the continually changing nature of microbial threats. New pathogens—such as human immunodeficiency virus—and evolution of drug-resistant variants of familiar ones (for example,, ones causing tuberculosis and malaria) create needs for biomedical understanding, for understanding systemic determinants of the spread of drug resistance, and for new drugs and vaccines.

[3] Much of the material in this and the following section was drawn, with only minor modification and updating, from the report of the Ad Hoc Committee (which was chaired by the author of this chapter.)

- *Noncommunicable diseases and injury.* Low- and middle-income countries increasingly face major (and hitherto neglected) epidemics of noncommunicable diseases and injury. Selected psychiatric conditions, heart disease, stroke, and road-traffic accidents dominate the disease profile projected for these countries for the year 2020. R&D is required to ascertain ways of preventing and managing these conditions under budgetary constraints far more stringent than in the high-income countries, which have dealt with the problems far longer.

- *Efficiency and fairness of health systems.* Finally, health systems themselves vary greatly in how efficiently and equitably they provide services. Research can assist decisionmakers in solving specific problems, learning from the experience of others, and placing the performance and characteristics of their systems into international and historical context. Such research should pay careful attention to measurement of performance and should include investigation into health systems and their finance, the determinants of the behavior of health care providers and the behavior of individuals and households.

RAP FOR R&D

In some cases, additional resources (probably from lower priority areas within national health budgets or health aid budgets) will be required to meet these R&D needs adequately. In many cases, institutional change will be necessary to create the information and incentives required for efficient RAP. At the international level, resource allocation has often lacked focus (resulting in failure to bring results to the point of application) and has neglected important conditions and issues while providing (relatively) generously for less important ones. Reform is needed. Successful models of competitively driven international funding (and experience-sharing) networks should be applied to currently neglected clusters of conditions.

The conduct of research and development in low- and middle-income countries is commonly hampered by brain drain to the richer nations. For those who remain, there are considerable problems at the operational level that RAP policies must address. We summarize them here.

Just as the quality and productivity of research efforts vary dramatically from one institution to another within the established market economies, it varies in the low- and middle-income countries. Exemplary work is done in a number of institutions and countries; but, in general, the obstacles to high quality are greater when countries' incomes are lower. Inadequate training, insufficient staff motivation, and lack of competition prevent many institutions from attaining their potential. The instability of short-term funding, isolation from peers, and poor access to the research literature all compound the problem and prevent researchers from responding rapidly to ever-changing demands. Salaries are generally poor; rewards to productivity are hampered by nonmerit considerations in the appointment and promotion of senior staff and by restrictive personnel policies. Core support for the maintenance of libraries, databases, equipment, and buildings is inadequate, and communication between scientists at the regional and international levels is difficult. Recent communications improvements resulting from electronic mail and

distance learning programs have so far benefited mainly those who are already internationally networked, not those who are most isolated.

The basic cell of research is a laboratory or unit headed by a senior scientist, with each research institute or university employing a number of senior scientists. A department or institute's interests will tend to be multidisciplinary, while each basic cell will focus on one discipline or a small set of closely related ones. Crucial to the success of research is the ability to respond quickly to change—both at the level of the cell and the institute as a whole. The basic cell must respond by acquiring new technologies and skills; the institute must respond by acquiring new or more developed disciplines. In the public sector at least, this ability to respond is continually compromised by the very nature of the mechanisms that fund R&D. Governments usually provide basic core funding for R&D institutes, and their civil service personnel policies tend to push research institutions too heavily toward management structures that lack accountability, thereby creating institutions that become unproductive and unable to respond to new challenges. Over time, salaries often devour core budgets, reducing maneuverability still further. To overcome the structural weaknesses in institutions, network centers of the type described above have evolved in some countries.

LESSONS LEARNED FOR INSTITUTIONAL DEVELOPMENT

Individual teams, institutions, and programs have demonstrated that it is possible to do first-rate research in low- and middle-income countries. Their experience and advice have been well documented elsewhere (see, for example, the interviews with individual leading researchers in TDR 1995). Specific RAP policies seem likely to facilitate the success of institutions and programs, including the following:

- Autonomous management
- Appropriate compensation policies that will attract young and talented scientists
- The capacity to train a large number of individuals from whom subsequent leaders can emerge a large enough number to allow for transfer to other sectors and other losses
- Stable core funding
- A significant element of competitive funding that might be allocated to research projects, or to individual development, or to institutional development
- Internationalization and collaboration not only with institutions in the north but also with other institutions in the south
- Increased use of electronic media for peer review and publication as a first step toward reducing the regional bias in established publishing formats.

Investors and institutions could take a number of steps to make these factors more widespread. More institutions in low- and middle-income countries should be freed from civil service management procedures, as is happening already in other government-funded institutions worldwide. This step would enable institutions to offer salary scales that will give them a competitive advantage and begin to combat the brain drain. To secure good staff, institutions should be enabled to recruit by active search and on the basis of peer-reviewed competition. Some—and possibly many—national governments will conclude that the financial, administrative, and even political costs of these steps exceed their benefits. This may be a

reasonable choice, but it creates an environment where science is unlikely to flourish and where competition for international support is unlikely to be effective.

Institutions are more likely to succeed if they receive stable core funding, but also if a proportion of their work is funded competitively. They may decide to support some extramural work, set up collaborative networks with an element of competition, or develop internal competition mechanisms. Some institutions such as the Oswaldo Cruz Foundation in Brazil have already moved in these directions with great success, for example, by freeing up intramural resources for competitive allocation between groups and within the institution, with assessments being made by an external review group. There have also been notable successes with the formation of networks such as the International Clinical Epidemiology Network and, more recently, the Global Forum for Health Research.

High-quality research increasingly depends on international collaboration, and almost no institution can now perform effectively without an international element. Institutions should therefore expect that some of their staff will be foreign nationals, although restrictive policies in some countries may, at present, prevent this. Where foreigners may not be employed, it is at least preferable for the scientific advisory board of the institution to contain some international representation. Staff should be enabled to participate in international fellowship schemes, exchanges, and other mechanisms that foster long-term links and enhance the capacity of reciprocating institutions.

PRIVATE SECTOR INVOLVEMENT

The contribution of the private sector to health research, in the traditional pharmaceuticals (drugs, vaccines, diagnostics, devices) industries, and in a growing list of other health products such as health education materials, has been highly significant in recent decades. Public sector requirements for new product development are dependent on industry for many reasons, including the industry's expertise in development, its efficiency as a manufacturer and distributor, its knowledge and skills in market research and, not least, its financial power. Officials in a number of countries are exploring the ethics and potential of new collaborative ventures between the private and public sectors, and their efforts may bring significant new funding sources to address unmet health needs.4 For the present, however, both private and public sectors recognize that the health problems of the world's poorest are neglected by industry. The problem is more acute in relation to pharmaceutical products, and we shall focus on them here.

As a result of these limitations on what can be expected from the private sector, national and international research programs in the public sector (with support from the private foundations) have increasingly accepted that they must take some responsibility for researching and developing products themselves, through new mechanisms of collaboration with industry. At the same time, the pharmaceutical industry is itself adapting to recession and other factors to turn itself more into an integrated organizational framework that is comparable to some of the international R&D programs financed by the public sector. This is partly because of the growing

[4] Two good examples of public–private partnerships (the "PPPs") are the International AIDS Vaccine Initiative and the Medicines for Malaria Venture.

interdependence of different types of skill and capacity in the industry, as, for example, in the relationships between the small biotechnology companies and the larger, more stably resourced, pharmaceutical companies. The industry increasingly contracts out its research and manufacturing components, locating each component in the most economically and technically suitable place rather like an assembly industry. The increasing integration has been described as a move toward an "extended family" network and offers major opportunities for developing country participation in private sector R&D.

The failure of current incentive structures to produce health products for the lowest income groups demands remedial action. In essence, the public sector must either harness the skills, energy, and capacity of the private sector to develop *and bring promptly to market* products for the lowest income groups, or it must take responsibility for doing so itself. In reality, a combination of the two is likely. Public sector RAP policies may engage the private sector in each of the following ways:

- By supporting the costs of the early stages of product development, from compound screening through to phase II trials, if necessary, and offering to support postmarketing surveillance.
- By providing the industry with detailed analyses of the potential market and of the risks and benefits of introducing a product.
- By providing the industry with guaranteed markets for new products such as vaccines. In such schemes, national governments agree to purchase a known quantity of a specified product, raising the financing either from their national budget or through special loans. The up-front investments needed for successful collaborations of this type must be large.
- By streamlining the regulatory controls imposed by the public sector on the industry to the minimum necessary for good standards, in order to cut the industry's costs.
- By carefully designed tax-relief schemes.
- By financial incentives within the patent system. A number of attempts to modify the patent system have been attempted, such as the Orphan Drug Act of 1983 in the United States. This gives companies tax breaks and lengthened exclusivity rights for drugs with small markets, creating strong incentives where there are third-party reimbursement mechanisms that are relatively insensitive to cost. However, the act has not reversed the downward trend in R&D on drugs for diseases that are prevalent in demographically developing countries, and further extension of the period of patent protection—beyond the 20 years recently internationally agreed in the Uruguay Round—is unlikely to substantially affect incentives, pointing to the need for additional mechanisms.
- By making the best use of the extraordinary commitment of individuals and particular companies within the private sector. Some have already demonstrated themselves willing to undertake research and development, production, and supply of drugs on a break-even or defined-profit basis; more may be encouraged to do so. The example of some individuals is clear. For example, Jonas Salk, when asked who owned the patent on his polio vaccine, answered: "Well, the people, I guess. There is no patent. Could you patent the sun?" Salk believed that public goods should be common property for all time. There is certainly a major role for patents among the RAP instruments designed to stimulate innovation. Yet the spirit that Salk conveys—of personal or corporate commitment—

represents an important additional resource to draw upon. Likewise, innovation at public expense, even if in the private sector, requires an important reduction in unrestricted patent rights, as, for example, through guaranteeing relatively low prices to public sector buyers.

Developing countries that participate in private sector innovation—typically with their own institutions as subcontractors, but not entirely so—will be positioned to more quickly learn about and have access to the technical progress that is critically important to driving improvements in health.

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