Health research systems: promoting health equity or economic competitiveness?
Bridget Pratt* & Bebe Loff*

Abstract
International collaborative health research is justifiably expected to help reduce global health inequities. Investment in health policy and systems research in developing countries is essential to this process but, currently, funding for international research is mainly channelled towards the development of new medical interventions. This imbalance is largely due to research legislation and policies used in high-income countries. These policies have increasingly led these countries to invest in health research aimed at boosting national economic competitiveness rather than reducing health inequities. In the United States of America and the United Kingdom of Great Britain and Northern Ireland, the regulation of research has encouraged a model that: leads to products that can be commercialized; targets health needs that can be met by profitable, high-technology products; has the licensing of new products as its endpoint; and does not entail significant research capacity strengthening in other countries. Accordingly, investment in international research is directed towards pharmaceutical trials and product development public–private partnerships for neglected diseases. This diverts funding away from research that is needed to implement existing interventions and to strengthen health systems, i.e. health policy and systems research. Governments must restructure their research laws and policies to increase this essential research in developing countries.

Introduction
In 1990, the Commission on Health Research for Development identified international health research partnerships as key to advancing health in developing countries and promoting global health equity. Reports from the World Health Organization (WHO) and global ministerial summits have subsequently linked health research to achieving the United Nations Millennium Development Goals. Two-thirds of child deaths and three-quarters of maternal deaths could be averted if existing interventions achieved high population coverage in developing countries. However, there is a lack of knowledge about the barriers in health systems that hinder the delivery of these interventions and the strategies required to overcome them. While further basic research is needed to develop better interventions, the Millennium Development Goals will not be achieved without greater investment in health policy and systems research. According to a report by the WHO Task Force on Health Systems Research, it is “essential to channel most resources to address the preparedness of health systems to delivering interventions”. This position has since been reiterated numerous times, with the Mexico Statement on Health Research calling for international funders of health research to establish substantial and sustainable programmes of health policy and systems research that are aligned with developing countries’ needs.

Even so, figures derived from a 2008 Global Forum for Health Research report indicate that funding for international research makes up a tiny percentage (1.6%) of the 160.3 billion United States dollars (US$) of total global health research expenditure. We define international research as research that is externally funded by organizations from high-income countries but is conducted in low- and middle-income countries.

Of the limited funding available for international research, most is channelled towards the development of new interventions rather than to health policy and systems. In 2005, US$ 2.6 billion was spent on international research in developing countries by foreign public, philanthropic and private for-profit funders, but estimates show that only US$ 134 million is spent annually on health policy and systems research in developing countries. Since this estimate was made, several new funding schemes for health policy and systems research have been created or mentioned in international funders’ strategy documents, but it is unclear whether they have led to sizeable increases in investment. There is no equivalent for health policy and systems research to the G-FINDER survey (a database of global funding of neglected disease). In the light of this neglect, the field is still in the process of defining its scope, methods and agenda.

In this paper, we show that this research imbalance is largely determined by the laws and policies governing research in high-income countries. The regulatory environment privileges the economic function of national health research systems over their health-promoting function. In the United States of America (USA) and the United Kingdom of Great Britain and Northern Ireland, international research is structured to boost national economic competitiveness, which results in a focus on the development of new health technologies. This paper argues that current policies restrict the capacity of international collaborative health research to promote global health equity by diverting funding away from research that is needed to implement existing interventions and strengthen health systems, i.e. health policy and systems research.

Economic strategies shape research
In the transition to knowledge-based economies, the United Kingdom and the USA have adopted research competitiveness strategies that support increased investment in science and technology. It is purported that, through such investment, a country can enlarge its share of the lucrative global high-technology market (through the privatization

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* Michael Kirby Centre for Public Health and Human Rights, Monash University, Alfred Centre Campus, 99 Commercial Road, Melbourne, VIC, 3004, Australia.

Correspondence to Bridget Pratt (e-mail: bridget.pratt@monash.edu).

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Box 1. Technology transfer legislation in the United States of America

- Bayh–Dole Act of 1980: created incentives for academic researchers to pursue research with outputs that could be commercialized and to then translate their discoveries into medical products that could be sold for a profit.
- Economic Recovery Tax Act of 1981: established a research tax credit for corporations, enabling them to receive a deduction on their income taxes equivalent to 20% of their research expenses above a baseline amount.
- Small Business Innovation Development Act of 1982: requires federal agencies with large extramural research and development budgets (such as the NIH) to allocate 2.5% of their funds to small research and development firms. The programme, called the Small Business Innovation Research Programme, is designed to stimulate technological innovation and make greater use of small businesses in meeting national innovation needs.
- National Research Cooperation Act of 1984: weakened national antitrust legislation to afford special antitrust status to joint research ventures and consortia, thereby allowing broad government–university–industry research partnerships.
- Federal Technology Transfer Act of 1986: set up a mechanism of cooperative research partnerships between federal agencies and private industry – the CRADA. These agreements permit corporations to select products and processes from government-owned and operated laboratories and to collaborate with them in bringing the product or process to market. In return, federal laboratories get a share of the profit either through a licence or royalty agreement.
- National Competitiveness Technology Transfer Act of 1989: extended the use of CRADAs to government and contractor-operated laboratories.
- American Technology Pre-eminence Act of 1991: further included intellectual property as a potential return under CRADAs.
- National Technology Transfer and Advancement Act of 1995: made CRADAs more attractive to private industry by providing assurances that companies will be granted sufficient intellectual property rights to motivate the prompt commercialisation of inventions. It also provides companies with the right to an exclusive or non-exclusive license to inventions arising from a CRADA.
- Technology Transfer Commercialization Act of 2000: broadened the CRADA licensing authority to include pre-existing government inventions.
- America COMPETES Act of 2007: increased research investment; strengthened educational opportunities in science, technology, engineering and mathematics; and developed an innovation infrastructure.
- America COMPETES Reauthorization Act of 2010.
- Unemployment Compensation Reauthorization Act of 2010: extended the research tax credit to December 31, 2010.

CRADA, Cooperative Research and Development Agreement; NIH, National Institutes of Health.

Technology transfer legislation has been the impetus for a new model of health research in the United Kingdom and the USA with the following features:

- Supports research leading to products that can be commercialized. The largest funders of health research in the USA – the National Institutes of Health and industry – spend 73% of their funding on basic and clinical research. There is little investment on effective approaches to deliver evidence-based public health and medical interventions. In the United Kingdom, 83.9% of public and philanthropic funding goes to basic and clinical research, and 4.8% goes to health services research.
- Targets health needs that can be met by profitable, high-technology products.
- Has licensing of a new product as its endpoint.
- Evaluates research activities and outputs according to their contribution to the national economy. There are measures to promote the development of regional science clusters.

Impact of laws

Successful commitment to technology transfer legislation has resulted in significant changes to research in the United Kingdom and the USA, leading to the introduction of new organizational forms and altered roles for research funders and sponsors. Industry participation in research has shown tremendous (re)growth since the 1980s. By 2000, industry supported 62% of biomedical research in the USA, almost double the proportion of 1980. In the United Kingdom, industry supports nearly 50% of research. There has been a gradual privatization of clinical research. An increasing number of privatized biomedical research actors have emerged, including private physician-investigators, contract research organizations, and commodification of science-based intellectual property and generate high-salary jobs in its domestic economy.

Research competitiveness strategies in the United Kingdom and the USA have been embodied in a series of laws that have fundamentally changed the shape of health research. This legislation has an overarching emphasis on technology transfer, i.e. translating research results from the science laboratory to products on the market.

In the USA, research tax credits were established for corporations and research institutions were permitted to patent their research outputs and license those patents to industry. In the United Kingdom, technology transfer laws created incentives to encourage private sector research investment, programmes to promote knowledge transfer between universities and industry, such as the Higher Education Innovation Fund, and site management organizations and for-profit institutional review boards. Until 1990, 80% of clinical trials in the USA were performed through academic medical centres. By 2005, that percentage had fallen to 25%, with industry outsourcing clinical trials to private doctors and contract research organizations.

National research bodies and universities’ traditional mandates have expanded to include “contributing to national economic development”. Accordingly, the United States’ National Institutes of Health and the United Kingdom Medical Research Council have prioritized translational research and public–private partnerships and strongly support both in an effort to improve commercialization of their research outputs. Both institutions have established their own technology transfer offices to further support this process.

Universities in the United Kingdom and the USA have also created technology transfer infrastructures and implemented new policies to advance their entrepreneurial function. New courses combine business with science training, e.g. Masters of Business and Science at Rutgers University, New Jersey, USA, and grants by the Science & Technology Facilities Council for PhD students in the United Kingdom to learn how to promote technology transfer.

A new model
an increasing number of government reports that evaluate national research outputs according to science and technology indicators (e.g. National Science Foundation’s Science and Engineering Indicators 2010 and United Kingdom Department for Business, Innovation and Skills’ Annual Innovation Report).

- Emphasizes science education and combined science/business education.
- Focuses on increasing share of the global research market for economic prosperity. This militates against supporting other countries to build research capacity.
- Characterized by partnerships between government agencies, academia and industry. In the USA, federal laboratories participated in 7327 cooperative research and development agreements with businesses in 2007.30

Global health strategies

The United States’ global health strategy has been described in two key reports by the Institute of Medicine. Its 1997 report, America’s vital interest in global health: protecting our people, enhancing our economy and advancing our international interests advocates for America to tackle global health problems from its strongest base – its pre-eminence in science and technology. The report recommends expansion of public and private sector investment in biomedical research addressing major global health problems and the continued training of scientists and health professionals from other countries.31 Fulfilling the latter recommendation is identified as particularly important because it provides opportunities for American medical products and technologies to enter overseas markets.32 The 2009 report also calls for the American research community to develop novel health technologies for developing countries, primarily through product development public–private partnerships.33 Increased investment in health systems research is discussed as a means of improving delivery of existing health technologies.34

For the past 5 years, the United Kingdom government has echoed calls to use science and technology to tackle global health disparities and meet the Millennium Development Goals.35,36 A major component of Britain’s international research strategy consists of investing in research that creates science and technology solutions to global health problems and building this capacity in other countries.37 The 2008 Health is global: a United Kingdom Government Strategy 2008–2013 affirms the government’s intention to increase its investment in product development public–private partnerships and to support research on vaccines, microbicides and drugs for HIV/AIDS, tuberculosis and malaria.38

Public–private partnerships

Product development public–private partnerships have become the preferred way to fund health research in developing countries. They are supported by the Bill & Melinda Gates Foundation and public aid agencies including the United States Agency for International Development and the United Kingdom’s Department for International Development.39 Of the more than 60 existing drug projects for neglected diseases, three-quarters are being performed under public–private partnerships.40 In 2007, 23% (US$ 469 million) of funding for neglected disease research granted to external research organizations was done under this model. If funding from the National Institutes of Health is excluded from the analysis, they account for 42% of global research funding for neglected diseases.35

In 2009, the Department for International Development nearly tripled its funding of product development public–private partnerships in accordance with its five-year Health is Global strategy.37 Key features of this model are: a public health objective combined with a private sector approach, single disease targets, development of technical interventions (vaccines, drugs or diagnostics), and a scope that includes a large-scale clinical trial (usually in developing countries) and regulatory approval of successful products. Large-scale manufacturing, distribution and adoption of these products in developing countries is not a necessary feature, nor is building research capacity in developing countries.35

The financial benefits associated with this form of product development go almost exclusively to businesses and universities in the countries that provide the funding. In 2007, 87.8% of public–private partnership expenditure was re-invested in high-income countries. Only 12.3% of this kind of external funding was allocated to research institutions in developing countries.35

Both the USA and United Kingdom governments advocate for a model of international research that not only advances health using science and technology solutions but also recycles money within their economies. The public–private partnership model fits neatly within these countries’ national economic strategies. Not surprisingly then, and as is clearly shown in Table 1, these funding partnerships share most features with American and British research models based on technology transfer legislation.

International pharmaceutical trials

Industry investment in international research is primarily channelled to clinical trials that are outsourced to contract research organizations and are often conducted on large patient pools in developing countries. In 2005, 40% of all pharmaceutical trials were carried out in developing countries, up from 10% in 1991.36 Countries with a high annual growth rate of industry-sponsored clinical trials include China (47%), the Russian Federation (33%), the Czech Republic (24.6%), India (19.6%), Argentina (19%) and South Africa (5.5%).40 Industry-sponsored clinical trials in developing countries are organized as an economic activity.40 Predictably, these trials are entirely consistent with the model of research encouraged by American and British research policies (Table 1).

Implications for global health

Current research models are unlikely to support research that improves global health equity. They do not provide strong incentives for:

- non-biomedical forms of health research (within high-income countries and internationally);
- biomedical research on rare diseases within high-income countries (although in the USA, the lack of incentives to conduct research on rare diseases is addressed by the Orphan Drug Act);
- international biomedical research to develop interventions that target health conditions mainly found in developing countries;
- creating real access (availability, af-
Research capacity strengthening in clinical trials. The G-FINDER survey national research principally supports Of the limited investment in international research, the majority is channelled to high-income countries, ensuring their products are available at low-cost. Industry investment in international research, though not necessarily in developing countries where trials were conducted. Host governments of trials are considered responsible for product availability and adoption. Evaluates research activities and outputs according to their contribution to the national economy. The new model of health research and its alignment with product development public–private partnerships and international public–private partnerships plan to create licensing agreements with manufacturers in developing countries, ensuring their products are available at low-cost. Evaluate research activities and outputs according to their profitability. Aim to create a sizeable differential between product development costs and the revenue generated by product sales. Rely upon educational structures that emphasize science and combine science and business training. Do not support research capacity strengthening for innovation in other countries. Trials emphasize profitability, hypermobility and speed. They do not generate by product sales. They do not typically allocate funds for capacity-building or generate long-term relationships with research institutions in developing countries. Rely upon the findings of publicly-funded basic research. Trials may be outsourced to academic medical centres. Clinical trials are usually performed in high-income countries today. Drug development has contributed to some of the dramatic health gains of the 20th century and has the potential to improve health in developing countries. Nonetheless, development of new medical products is slow, expensive and there is a high failure rate. Importantly, the full benefits of new and existing technologies cannot be put into practice (in high-income countries or developing countries) without investment in health policy and systems research. Rudan et al. said in relation to child illness: “…this experience ... where highly cost-effective interventions to fight childhood pneumonia and diarrhoea were developed decades ago but then failed to be implemented, is a good predictor of what can be expected to occur in the future if the current research investment model is to persist.” - Bull World Health Organ 2012;90:55–62

Table 1. The new model of health research and its alignment with product development public–private partnerships and international pharmaceutical trials

<table>
<thead>
<tr>
<th>Features of research influenced by high-income government policies</th>
<th>Features of product development public–private partnerships</th>
<th>Features of international pharmaceutical trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leads to products that can be commercialized – basic, clinical and translational research</td>
<td>Support basic and clinical research that leads to products that can be commercialized. Clinical trials are usually performed in developing countries.</td>
<td>Support clinical research that leads to products that can be commercialized. Trials are increasingly performed in developing countries.</td>
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<tr>
<td>Targets health needs that can be met by profitable, high-technology products</td>
<td>Target health needs that can be met by high-technology products</td>
<td>Target health needs that can be met by profitable, high-technology products. Target chronic and lifestyle diseases with large markets</td>
</tr>
<tr>
<td>Endpoint is the licensing of a new product</td>
<td>Endpoint is the commercialization of products. Several product development public–private partnerships plan to create licensing agreements with manufacturers in developing countries, ensuring their products are available at low-cost.</td>
<td>Endpoint is the licensing of new products, though not necessarily in developing countries where trials were conducted.</td>
</tr>
<tr>
<td>Evaluates research activities and outputs according to their contribution to the national economy</td>
<td>Research activities and outputs not evaluated according to their profitability. Contribute to the economies of high-income countries through the re-investment of funding.</td>
<td>Evaluate research activities and outputs according to their profitability. Aim to create a sizeable differential between product development costs and the revenue generated by product sales.</td>
</tr>
<tr>
<td>Demands educational structures that emphasize science and combine science and business training.</td>
<td>Rely upon educational structures that emphasize science and combine science and business training.</td>
<td>Rely upon educational structures that emphasize science and combine science and business training.</td>
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<tr>
<td>Does not strongly support research capacity strengthening for innovation in other countries</td>
<td>May support clinical research capacity strengthening in other countries.</td>
<td>Do not support research capacity strengthening for innovation in other countries. Trials emphasize profitability, hypermobility and speed. They do not typically allocate funds for capacity-building or generate long-term relationships with research institutions in developing countries.</td>
</tr>
<tr>
<td>Characterized by partnerships between government agencies, academia and industry.</td>
<td>Characterized by partnerships between public agencies, academia, private foundations and industry.</td>
<td>Rely upon the findings of publicly-funded basic research. Trials may be outsourced to academic medical centres.</td>
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</table>
In this example, there was a lack of research to identify and address barriers to high-volume delivery of interventions and so widespread coverage of existing interventions was not achieved. Had high coverage been attained, child mortality could have been reduced by two-thirds. Similarly, while investment in product development public–private partnerships has resulted in the development of new drugs for malaria and leishmaniasis, failure to invest in health policy and systems research means that challenges in delivery continue and the potential health benefits will not reach the people who need them.

Investment in health policy and systems research may have a greater impact on population health than product development research. Recent analysis has shown that, while new technologies could reduce child mortality by 22%, achieving full utilization of existing technologies would result in a 66% reduction in mortality.10

Health gains are already being made through health policy and systems research conducted in developing countries. For example, operational research has resulted in improvements in diagnosis, reporting and management of tuberculosis in Malawi and has enhanced onchocerciasis control in Africa.13,44 Implementation research has improved HIV care and treatment in Africa by identifying local constraints to delivery to inform programme design and policy.13 Recent findings also indicate that results from local operational research on cotrimoxazole preventive therapy for HIV were put into national policy in Malawi and Uganda faster than the results of randomized-controlled trials testing the same therapy in Zambia.46

Thus, health policy and systems research improves health care by, first, generating evidence informed by local constraints on the best delivery methods for interventions and then linking this evidence to changes in treatment practice and policy.13

Ultimately, research on product development and on health policy and systems are complementary. The latter is essential if interventions targeting diseases are to be integrated into health systems. It is also needed to design and evaluate interventions that target health system components.45 Over-investment in biomedical research to the detriment of health policy and systems research will continue to hamper progress on reducing disease in developing countries.

Conclusion

Laws and policies in high-income countries ensure that most international research funding is not directed to much-needed health policy and systems research. International collaborative health research, thus, makes a limited contribution to improving global health equity. Although there will always be a role for new product development where no effective interventions exist or resistance to treatment emerges, research funding must be more evenly allocated.

To redress the investment imbalance, its structural causes must be clearly identified. Achieving sustained growth in health policy and systems research in developing countries will require significant reform to existing research law and policy in high-income countries. No doubt this will be politically challenging. To begin, high-income country governments should design and enact policies that: (i) create strong incentives for health policy and systems research; (ii) support higher education and university departments in such research; and (iii) foster health policy and systems research partnerships between public research bodies, academia, health providers and private foundations. To encourage this kind of research, governments could, for example, create a fund source by applying a tax to the profits from products derived from trial data collected in developing countries. Governments could then distribute the funds in response to open competitive tenders. Research tax credits could be extended to health providers and research institutions that conduct health policy and systems research.

To support infrastructure for such research, governments could amend laws such as the America COMPETES Act (Box 1) to apply to global health, public health and the social sciences as well as science and technology. The creation of public–private partnerships for health policy and systems research might also be considered, with governments providing an incentive through a partial rebate for funds contributed by private entities.

These findings and recommendations are also relevant to developing countries, many of which are considering research competitiveness strategies similar to those enacted by the United Kingdom and USA. The New Partnership for Africa’s Development’s Consolidated Science and Technology Plan of Action states Africa’s “commitment to collective actions to develop and use science and technology for the socioeconomic transformation of the continent and its integration into the world economy”.48 Implementation of this plan includes initiatives by the United Nations Educational, Scientific and Cultural Organization to develop national science, technology and innovation policies for African countries without them, and to build university and industry science and technology research partnerships in Africa.49 To date, more than 25 African countries are in the process of drafting revised science, technology and innovation policies or are designing action plans for the revision process.50

The danger for African countries is twofold. First, the full health benefits of new interventions developed by international partnerships will not be achieved. Second, national health research systems will be structured without the promotion of health being their primary focus. Like high-income countries, African countries must incorporate incentives for health policy and systems research into their research policies.

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ملخص

نظام البحث الصحي: تعزيز الإنصاف في مجال الصحة أم القدرة التنافسية الاقتصادية؟

من المتوقع أن نمو مبادرات تساعد البحث الصحي التعاوني في البلدان النامية أمرًا ضروريًا في نقطة هذا العمل، غير أنه يتم في الوقت الراهن توجيه التمويل الخاص بالبحث الدولي بشكل رئيسي للاستثمار في إنفاذ المعايير العالمية. ويفضل هذا الاختلاف في التوزيع الإقتصادي للبحث الصحي في المجال الصحي على المستوى العالمي. ويمثل الاستثمار في البحث الصحي والسياسة الصحية في البلدان النامية أمرًا ضروريًا لهذه العملية، غير أنه يتم في الوقت الراهن توجيه التمويل الخاص بالبحث الدولي بشكل رئيسي للاستثمار في إنتاج الممارسات الطبية. ويتعين القيام بذلك في إطار استراتيجيات جديدة للبحث الصحي والسياسة الصحية في البلدان النامية. هذا العمل يهدف إلى تعزيز الإنصاف في مجال الصحة والقدرة التنافسية الاقتصادية في البلدان النامية، من خلال تحسين الاستثمار في البحث الصحي والسياسة الصحية في البلدان النامية.
باعتبارها نقطة النهاية له؛ ولا يستلزم قدرًا كبيرًا من تعزيز القدرات الحكومية إعادة صياغة سياساتها وقوانينها البحثية لزيادة هذه النظم الصحية، أي بحوث النظم والسياسة الصحية. ويتعين على التمويل عن البحوث اللازمة لتنفيذ التدخلات القائمة وتعزيز العام والخاص لتطوير المنتجات للأمراض المهملة. وهذا يصرف البحوث الدولية إلى التجارب الصيدلانية والشراكات بين القطاعات البحثية في البلدان الأخرى. ووفقًا لذلك، يتم توجيه الاستثمار في النبذه والمواد العلاجية

لا يوجد نص يمكن قراءته بشكل طبيعي.
препаратов и на организацию государственного и частного партнерства в вопросах разработки продуктов для оставшихся без надзора заболеваний. Такой подход уводит финансирование в сторону от исследований, которые необходимы для внедрения уже разработанных методов медицинского вмешательства и для усиления систем здравоохранения, например, политики в области здравоохранения и системных научных исследований. Правительства должны произвести реструктуризацию законов и политики, регулирующих проведение исследований в своих странах, чтобы увеличить долю этих важных исследований в развивающихся странах.

Resumen
Sistemas de investigación sanitaria: ¿promoción de la igualdad sanitaria o competitividad económica?

Es lógico esperar que la investigación sanitaria internacional ayude a reducir las injusticias en materia sanitaria en el mundo. Para este proceso resulta fundamental la inversión en investigación acerca de estrategias y sistemas sanitarios en países en vías de desarrollo. No obstante, la financiación para la investigación internacional está canalizada en la actualidad hacia el desarrollo de intervenciones médicas nuevas. Este desequilibrio se debe en gran parte a la legislación y a las estrategias de investigación empleadas en los países de ingresos elevados. Esas estrategias han llevado a dichos países a invertir cada vez más en una investigación en salud dirigida a aumentar la competitividad económica nacional más que a reducir las injusticias sanitarias. En los Estados Unidos de América y el Reino Unido de Gran Bretaña e Irlanda del Norte, la regulación de la investigación ha fomentado un modelo que: se dirige a productos que pueden comercializarse; se centra en necesidades sanitarias que puedan cumplirse a través de productos rentables y de alta tecnología; tiene como objetivo final la autorización de productos nuevos; y no implica un fortalecimiento considerable de la capacidad de investigación en otros países. Por consiguiente, las inversiones en investigación internacional están dirigidas a ensayos farmacéuticos y colaboraciones público-privadas de desarrollo de productos para enfermedades desatendidas. Esto desvía fondos de investigaciones necesarias para aplicar las intervenciones existentes y para reforzar los sistemas de salud, por ejemplo, las políticas de salud y los sistemas de investigación. Los gobiernos deben reestructurar las leyes y políticas de investigación para aumentar esta investigación que resulta esencial en los países en vías de desarrollo.

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