



POLICY BRIEF

Health R&D as a Global Public Good

STEPPING FORWARD: A CRITICAL TIME

The 2012 report of the *WHO Consultative Expert Working Group (CEWG) on Research and Development: Financing and Coordination* represents **a milestone in long-standing international efforts** to close a critical gap in the development of drugs and other health technologies to meet the health needs of poor and neglected populations. The report recommended a global framework for research and development (R&D) including an observatory, coordination mechanisms, and financing based on the principle of de-linking the costs of R&D from the prices of end-products, created through the vehicle of an inter-governmentally negotiated convention.

Following discussions of the report at an Open Ended Meeting of WHO Member States in November 2012, the resulting draft resolution will be debated by the World Health Assembly (WHA) in May 2013.

Central to this debate will be recommendations to the Director-General of WHO concerning:

- a global health R&D observatory (Para 4.3)
- R&D demonstration projects (Para 4.4)
- coordination and financing of health R&D (Para 4.5. – 4.6)

At this critical juncture, **it is important to develop clarity on how global coordination and priority-setting arrangements could be organized and how demonstration projects could best strengthen the global R&D system.** In collaboration with the Harvard Global Health Institute, the Global Health Programme of the Graduate Institute of International and Development Studies (GIIDS), Geneva held a public seminar and expert workshop on 24 April 2013 on “**Health R&D as a Global Public Good: Cross-Sectoral Learning**” to draw lessons from global institutions delivering public goods in other sectors.

MAIN ISSUES RAISED IN THE SEMINAR AND WORKSHOP

Much of the life expectancy gains seen in the last century in high-income countries (HICs) originate in knowledge and its application and diffusion through technology, including appropriate medicines and other health products resulting from R&D. **Health disparities observed globally can be attributed in part to failures to ensure the generation of and access to knowledge beneficial for health in low- and middle- income countries (LMICs).** The 1990 Commission on Health Research for Development concluded that far too little was being spent on R&D for the health needs of LMICs and on strengthening their own health R&D capacities.

While individual health in general is a private good, the positive externalities of health mean that **population health and the norm of health as a human right may be considered public goods.** While much attention has focused on lack of development by industry of drugs for ‘neglected diseases’ (those predominantly or exclusively affecting populations in LMICs), analysis points to **three kinds of failures – in science** (lack of research to understand the disease and provide the basis for its treatment), **in the market** (lack of financial incentives or rewards for R&D) and **in public health** (lack of organization/resourcing to ensure access to and use of available treatments). In her Keynote

Address at the seminar on 24 April 2013, Inge Kaul highlighted **a fourth kind of failure: when markets are too small to drive**

innovation, there has been a state failure, she noted; markets can work – but they need to be shaped and facilitated by states to serve the public interest.



Inge Kaul, former Director UNDP Human Development Report Office, author of numerous publications on international public economics and finance, and leading scholar on the concept of global public goods.

After decades of commissions, working groups and meetings, it is now time to act to address the systems failures that have resulted in lack of R&D for the health needs of poor and neglected populations.

CROSS-SECTORAL LEARNING

PROVIDING GLOBAL PUBLIC GOODS (GPGS)

Knowledge has the potential to be a GPG, though this potential is not always achieved. It is non-rival, but can easily be made excludable by secrecy or intellectual property right protection. Incentives and policies are needed to make it nonexcludable to ensure the widest possible benefits for population health.

There are precedents for successful collective action among states to provide GPGs, including in the environmental sector (e.g. Montreal Protocol; creation of GCF, CGIAR research).

GPGs should not be tackled in silos: more intersectoral work and learning is needed – e.g. health should feature in discussions about the research needed to address climate change.

In the post-2015 development agenda, incorporating firm commitments to shared resourcing of GPGs will be important. A global health R&D framework with a good funding mechanism could be one of these.

LEARNING FROM SUCCESSES AND PROBLEMS

The **Consultative Group on International Agricultural Research (CGIAR)**, founded in the 1970s to advance the ‘green revolution’, exemplifies collective action by governments, foundations and the World Bank, which gave long-term support to 15 member research institutes, which provided a high return on investments. Over time, however, dysfunctionality developed and a new vision, mission and organizational structure were introduced in 2009. One important aspect of the governance reform is the recognition of the ‘zone of control’ where the CGIAR has accountability (e.g. conducting R&D that provides products taken up by others), and the ‘zone of influence’ where it is not directly accountable for results (e.g. poverty reduction) but has responsibility for trying to ensure impact. The CGIAR experience demonstrates the possibility of both constructing and reforming a sustainable, international collaborative research effort with strong coordination properties to generate public goods.

The **Green Climate Fund (GCF)** works with the results of R&D to galvanise action to move the world away from global warming. It will play a key role in channelling new, additional, adequate, predictable financial resources to LMICs and will catalyse public and private ‘climate finance’ for adaptation to and mitigation of global warming effects. Established in 2012, the GCF has already attracted pledges of over US\$ 34 billion, but the rates of deposit, approval of projects and disbursement of funding are proceeding with substantial time lags. With essentially the same member states as WHO, the GCF has a governing body of 40 countries with equal representation of donors and beneficiaries. Unresolved questions include how to bring in the private sector and other stakeholders.

The **Global Fund to Fight AIDS, TB and Malaria** was created as a financing rather than implementation instrument. It is results focused and based on an innovative model of governance involving equal representation of donors and beneficiaries, the private sector and civil society; and decision-making is strongly informed by independent technical review panels. It has been very successful in funding programmes and contributing to decreased mortality and morbidity. It did not have a mandate to fund or incentivise R&D, but has contributed to a stronger market pull for the development of products suitable for use in LMICs (e.g. fixed-dose combination drugs) by financing large volumes of health commodities.

However, the policy of purchasing high quality drugs at the lowest cost has sometimes adversely impacted on local drug production. Other challenges include that the Board has spent too much time on managing the fund rather than on long-term strategic vision; realities of asymmetries in power among Board members are still at play. Reasons for success include powerful activism and strong global public support; and political commitment and funding contributions from the G8 enabling a rapid start.

A review of multilateral cooperation in science and technology highlighted the importance of linking international priority setting with related government processes from the outset; developing highly flexible and adaptable structures; and combining top-down and bottom-up approaches.

Considering the broad range of determinants of health, one has to recognise that gatherings such as the WHA are not the only fora in which these R&D issues should be discussed. A strategy is needed to bring them into discussions at the WTO, WEF, European Parliament, BRICS development bank, etc. The post-2015 development agenda provides an important opportunity for cross-sectoral action and a clear, short message to those constructing the agenda regarding the vital contributions of health R&D to sustainable development has to be formulated.

GOVERNANCE OF HEALTH R&D

The development of a sustainable global framework for governance of health R&D needs to go in parallel with action on demonstration projects.

The debate on whether new governance arrangements should be binding or non-binding needs to be settled. Notably, many areas (e.g. WTO rules, including on patents) have binding agreements and transitional arrangements so that work can be initiated with a core coalition of states, with others joining later.

Financing is a key issue and needs to be committed at an early stage, in order to allow for the establishment of governance mechanisms such as priority setting machinery.

Much debate on improving the fragmented governance of health R&D focuses on whether to adopt a centralised system or a cluster of multiple pools and mechanisms. Factors include the value of competition; the opportunities to build on what already exists; and the need for economies of scale, enhancing efficiency and synergies. The plethora of actors may make a centralized system hard to achieve, but more pooling, harmonization and alignment would be beneficial.

WHO has important roles to play in coordination; convening experts in areas such as priority setting; and monitoring. While views differ regarding its capacity to manage financing for health R&D, there is a clear need for mechanisms to link priority setting, coordination and funding allocations.

The push mechanism of direct R&D financing should be complemented by pull mechanisms: e.g. the World Bank or regional development banks could provide loans to participating states, who could pool them to create a financial reward for innovation. Other ‘donor’ governments and philanthropic funders could also contribute to such a fund, or issue loan buy-downs or loan guarantees for some states. Complementing push and pull incentives could be other mechanisms to facilitate research: e.g. R&D providers could place their patents in a patent pool, and receive reasonable royalties to recoup some or all of their R&D costs.

PRIORITY SETTING FOR HEALTH R&D

Comprehensive global priority setting for R&D must consider the entire innovation cycle (involving both social and technological innovation) from basic research, through applied R&D, clinical trials, clinical use and implementation research. It also requires looking at a broad range of diseases and health conditions.

Such comprehensive global priority setting has not been conducted hitherto, but can build on the partial processes used in different arenas, including national research bodies and international initiatives for specific diseases or populations. (Some diseases are of regional rather than global interest: there is a case for some priority setting to be conducted at regional levels to address these.) Work by WHO, TDR, the GSPoA and the CEWG all provide important foundations to build on in priority setting. The information required on each disease may not all be available. Priority setting must be practical and work with what is known at the time, but in the long term will benefit from establishing a global observatory on health R&D that gathers available data and helps build country capacities to produce and use it.

A first essential step is to identify all relevant stakeholders, ensuring inclusiveness in setting priorities. A complex matrix of factors (relating to the dimensions of public health, institutional factors and social and political aspects) must be considered, with explicit attention to the context and to the values incorporated into weighting the priorities. Ultimately the choices must be made between competing diseases and competing types of research for a given disease. The biggest question is how to prioritise the priorities? These choices have a strong political component and the priority

setting framework must therefore enable a balancing of technical and political representation. The political process should be explicit and visible, not conducted through back-room dealing.

A starting point is a two-level priority-setting process. In Level 1, the composition of actors would be predominantly technical, but with some participation by political representatives. Experts and stakeholders from all sectors would be convened in a series of Working Groups to identify priority research agendas. In Level 2, the composition of actors would be predominantly political representatives, but with some participation by technical representatives. The work at this level would result in establishing a prioritised list of R&D programmes that are considered the best choices for funding. Level 2 would operate as an Oversight Group, deciding on the areas in which Working Groups are to conduct the priority setting processes; assembling the composite picture from Working Groups across the different areas; considering the competing options and establishing a prioritised list of R&D programmes for funding.

The focus should be the health needs of neglected populations, which may include product areas beyond the neglected diseases. NCDs are also ‘diseases of the poor’ affecting large and growing numbers of people in LMICs: current efforts to invent new products for treatment and prevention lack focus on ensuring affordability and utility everywhere. Also relevant are antibiotics, where, due in part to the rapid emergence of resistance, market lifetimes may be too short to incentivise R&D.

HEALTH R&D DEMONSTRATION PROJECTS

IMPETUS FOR ACTION

Operationalizing demonstration projects provides an immediate **opportunity to move rapidly from the longstanding debates into action.**

Such action should build on the many considerations emerging from the commissions, expert working groups and intergovernmental processes. The key question now is: ***What needs to be demonstrated?*** Defining expectations at the outset is crucial and the answers may include:

- **Products:** e.g. delivery, through R&D, of new drugs; other health technologies; and new knowledge.
- **Processes:** mechanisms for coordination; pooled funding; incentivising innovation; overcoming market failures; de-linking the cost of innovation from the cost of end products.
- **Participants:** Expanding the range of actors – to include the public sector (international and national), the private sector and civil society organizations.

In making the selections, it is important to keep the focus on R&D while recognizing that other areas such as improving health systems also matter tremendously; and to keep in mind that the ultimate goal is not new products per se but health impact.

SELECTION PROCESSES AND CRITERIA

The selection process for demonstration projects should not be made over-complicated, but kept speedy and simple, drawing on much work that has already been done to identify neglected diseases and their research priorities. A combination of top-down

and bottom-up processes should be employed. Some, but not all, diseases should be chosen at the regional (or even sub-regional) rather than global level, using the machinery available such as WHO regional bodies or other regional organizations and based on regional health challenges.

FINANCING

It is important to have broadly based and predictable funding with the financing level made clear early on, so that project selection takes place in a realistic context. Financing arrangements should not take years to become operational, but rather focus on those that could be set up without much delay.

TIMESCALE

If demonstration projects include products, the development of new drugs may potentially take 10-15 years - a very long timescale for ‘demonstration’. A consideration may therefore be to give some candidates already in the R&D pipeline a big push or pull, identifying projects that are already at a very advanced phase where lack of financing is an issue.

It is important to make a decisive start, monitor the programme and be prepared to make adjustments, as and if necessary.

Establishing demonstration-scale versions of a global observatory, coordination mechanism, priority-setting process, and financing mechanism would create a strong foundation to build future work.

SUMMARY OF KEY ISSUES

THE IMPERATIVE... AND THE OPPORTUNITY FOR ACTION NOW

- ***It is now time to act to address the systems failures resulting in a lack of R&D for the health needs of neglected populations.*** There is a window of opportunity to move to practical political action.
- States have succeeded in other sectors to act collectively to provide global public goods (GPGs).

WHAT NEEDS TO HAPPEN NEXT?

- Mechanisms are needed to strengthen and link the monitoring, coordination and financing of health R&D, which also needs to go in parallel with action on a set of demonstration projects.

WHAT ARE THE KEY OUTSTANDING ISSUES?

GOVERNANCE OF HEALTH R&D

- What transitional arrangements can be initiated with a core coalition of states (with others joining later)?
- How can financing be organized and committed at an early stage, in order to allow for the establishment of governance mechanisms such as priority setting machinery?
- What roles should WHO play in coordination, convening, priority setting, monitoring, managing financing, and linking these various functions?
- How to establish a global observatory on health R&D to ensure that national and international efforts will have the best available data?
- How can the push mechanism of direct R&D financing be complemented by pull mechanisms such as financial rewards for successful innovation, e.g. a prize?

PRIORITY SETTING FOR HEALTH R&D

- ***Prioritizing the priorities*** has a strong political component and the priority setting framework must therefore enable a balancing of technical and political representa-

- Health-related knowledge has the potential to be a GPG, but incentives and policies are needed to make it non-excludable to ensure the widest possible benefits for population health.

- Whether new governance arrangements should be binding or non-binding and the levels and mechanisms for financing need to be settled. Transitional arrangements have often been possible so that work can be initiated with a core coalition of states, with others joining later.

tion. How can the political process be made visible and legitimate?

- Should the focus be limited to the 'neglected diseases', or should it include other problems affecting 'neglected populations' (e.g. including NCDs and antibiotics)?
- Since some diseases are of regional rather than global interest, what kinds of priority setting should be done at regional rather than global level?

HEALTH R&D DEMONSTRATION PROJECTS

- ***What needs to be demonstrated?***
 - ***Products?***
 - ***Processes?***
 - ***Participants?***
- How should demonstration projects be selected?
- How could broadly-based and predictable funding be arranged before launching demonstration projects?
- Should long-term demonstration projects (such as new drug discovery/development) also be considered?

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More information about the seminar and workshop, including footnotes to this document, can be found on http://graduateinstitute.ch/globalhealth/Events_Global_Health_Programme/seminar24April_en.html