Health Diplomacy Monitor

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in this issue

A Word from the Editor

The role of non-state actors is a key feature of contemporary global health diplomacy and governance. In this issue, we have excellent illustrations of the role played by universities and research institutions in different facets of global health. In an editorial comment on access to essential medicines, Rachel Kiddell-Monroe and her colleagues highlight how students have mobilized globally in order to influence their universities to adopt practices to improve access to affordable medicines in the developing world. On the other hand, Adam Kamradt-Scott reviews the recent debates around the role of scientific researchers in protecting health security; the controversy around the publication of sensitive information about the H5N1 avian flu virus also sheds light on the weakness of international cooperation when it comes to rules of conduct for the publication of results that can pose a risk to global health.

This issue of the Monitor also covers the recent meeting of the executive board of the World Health Organization (WHO), with an article on the ongoing discussions on WHO reforms, and another from Paolo de Tarso Lugon Arantes on the possible negotiations of a new WHO treaty on health innovation. In recent years, several countries have issued a strategy document to guide their actions in health on the global stage. The US Department for Health and Human Services (HHS) has just published a new strategy; Bente Molenaar Neufeld summarizes for us its key components and reactions.

Also in this issue, Bente Molenaar Neufeld provides an overview of the emerging discussions on what will

Health Diplomacy Monitor

The Health Diplomacy Monitor aims to report and inform readers about key international negotiations currently underway which have a significant impact on global health. The objective is to "level the playing field" by increasing transparency and making information about the issues and proposals being discussed more readily available.

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replace the Millennium Development Goals (MDGs) once we reach the 2015 deadline. This is still an open field; for those wishing to set the parameters of the discussions and ultimately influence the outcome, the time is now. Health objectives are central to the MDGs, but the discussions on the future of MDGs mostly take place outside health forums, including in discussions on sustainable development. This is a key element to note, as it is an increasingly important reality of global governance. Decisions made in non-health institutions or forums, such as forums focusing on trade, environment, or security, can have significant impacts of the health of populations. It is to better understand this reality and to offer recommendations as to how health can be taken better into account in multiple arenas of global governance that The Lancet-University of Oslo Commission on Global Governance for Health was launched in November 2011. I have the honour of being one of its commissioners, and I am happy to invite the readers of the Health Diplomacy Monitor to respond to the call for submissions that was recently published by the Commission.

- Chantal Blouin

Editorial

Universities and Global Access to Essential Medicines

Rachel Kiddell-Monroe
Bryan Collinsworth
Laura Musselwhite

In 2001, law students at Yale convinced their university, along with the drug company Bristol-Myers Squibb (BMS), to take steps to allow a 30-fold price reduction in Africa for a life-saving HIV/AIDS treatment discovered by Yale researchers. Yale had originally licensed this medical breakthrough—stavudine—exclusively to BMS, giving the company a patent monopoly to sell the drug at prices poor Africans simply couldn't afford. Students pushed Yale and BMS to allow low-cost generic versions in South Africa, and the results were dramatic. As Dr. Eric Goemaere of Médecins sans Frontières explains:

"Today, 12,000 patients are on ARVs [anti-retrovirals] in Khayelitsha and an estimated 800,000 nationwide... This is in great deal thanks to a few courageous and idealistic Yale students who managed to dig a first small hole in the IP [intellectual property] fortress. No one in that time could have imagined it would make the fortress collapse, change public opinion and have such consequences on survival of millions of people."

A role for universities

Stavudine was not an isolated case: 10 million people lack access to essential medicines each year, largely due to high prices created by patent monopolies. The Yale students' key insight was that universities, as major contributors to medical research, had a responsibility to become part

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of the solution rather than part of the problem. They formed the non-profit Universities Allied for Essential Medicines (UAEM) as a student-driven movement to promote equitable global access and innovation in publicly funded medical research.

Through UAEM's advocacy, universities that license medical research to industry have now begun to include requirements for generic production or "at cost" provisions for low- and middle-income countries. These "global access" provisions lower the price of the final products for poor patients, and have been adopted by leading institutions including Harvard, Yale, the University of British Columbia, and the US National Institutes for Health (NIH). Ten Nobel Laureates—among them, Desmond Tutu of South Africa and MSF—also support this strategy.

FROM WORDS TO ACTION

While over 30 research institutions worldwide have endorsed a "Statement of Principles and Strategies" supporting global access to their medical discoveries, the students of UAEM want to ensure that this translates into real-world impact. The statement itself should be strengthened, and individual universities can adopt more robust policies. Most importantly, however, universities must demonstrate that they are regularly including global access provisions in their licensing negotiations with pharmaceutical companies.

Improving the transparency of universities and their licensing practices is critical. Not only do universities need to ensure affordable access to their medical breakthroughs, but they also need to show that they are committing resources, both human and financial, to research on "neglected diseases." It is not just the pharmaceutical industry that neglects devastating illnesses like malaria and Chagas disease—which predominantly affect poor populations—to pursue more profitable research. Sadly, academic scientists and institutions also neglect them. Universities must invest in research on neglected diseases to begin to address the huge inequity in treatments available for poor patients in the Global South.

STUDENT MOVEMENT SPREADING TO GLOBAL SOUTH

Since the stavudine case, UAEM has grown into a global network that is present on over 70 campuses worldwide and includes students of law, medicine, science, and public health. This growth includes students in the Global South, who are getting fired up about the impact of health research and licensing policies in their own countries. Students in Brazil have started UAEM chapters, devising locally appropriate ways to highlight universities' role in promoting global access to essential medicines. Supporting these students is a key part of UAEM's mission: we seek to empower students worldwide to advocate for health access, thereby developing new global health leaders.

By working with universities to make sure medical discoveries reach those in need, students also ensure that these institutions respect their public mission and keep the interests of patients above those of profit. Globally, students will make sure that governments hear the same message. As students told delegates at a UN meeting in New York last September, even chronic "non-communicable" diseases now disproportionately strike youth in the Global South. Youth from around the world can and must contribute solutions to these health challenges, and those solutions must include access to life-saving medicines discovered at universities.

Rachel Kiddell-Monroe is President of UAEM (www.essentialmedicine.org). Previously, Rachel worked for over 15 years with Médecins Sans Frontières as Head of Mission in the Great Lakes Region and the Horn of Africa and throughout Latin America. She was also the Canadian Director of the MSF's Access to Medicines Campaign.

Bryan Collinsworth is Executive Director of UAEM, and Laura Musselwhite is a fourth-year medical student at Duke University.

Scientific Research vs Health Security: The Case of the H5N1 Papers

Photo: http://blogs.reuters.com

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BACKGROUND

THE ISSUE

The announcement in September 2011 that a group of Dutch scientists had created a highly virulent, airborne strain of the H5N1 avian influenza virus that may infect humans via genetic manipulation has reignited concerns over the potential "dual use" of such research if the information was to be made public. At present, regulation of scientific research has been left up to individual governments or devolved to individual universities to administer on a case-by-case basis, but this has led to inconsistent policies or no regulation at all. Leading governance institutions such as the World Health Organization (WHO) have currently been slow to respond to this issue.

GLOBAL HEALTH IMPACT

Scientific research into influenza is essential for advancing global public health and for enhancing pandemic preparedness. At the same time, genetically manipulating viruses such as the highly lethal H5N1 virus is controversial, and has raised concerns about what would happen if the information was able to be used by terrorist groups or rogue scientists to initiate a new pandemic or global health emergency. There is also the risk of an accidental release of the new H5N1 strain from those laboratories conducting the research. Government regulation to address these risks has currently been ad hoc, but the recent H5N1 studies have stimulated discussion on whether a new global agreement that may place restrictions on scientific freedom is now required.

THE ROLE OF DIPLOMACY

Diplomacy will be critical to ensuring an internationally agreed set of principles or guidelines can be developed for scientists conducting research that may be considered potential "dual-use," and how, when, or even if that information should be publicly disseminated. International forums that comprehensively engage with the scientific community will be essential to develop guidelines that all scientists will be able to comply with.

INTRODUCTION

In September 2011, it was announced that a group of Dutch scientists had successfully genetically altered the H5N1 avian influenza virus, transforming it into a highly lethal, airborne strain that could conceivably spread easily between humans. Consistent with standard academic practice, the scientists then submitted their research findings to a high-ranking journal to disseminate their research. At the same time, another team of scientists based at the University of Wisconsin (United States) and the University of Tokyo (Japan) had conducted similar research on the H5N1 virus and submitted their findings to a competing journal. Given that the US National Institute of Health (NIH) had funded both studies, the draft publications were reviewed by the National Science Advisory Board for Biosecurity (NSABB) that had been established following the September 2001 anthrax letter attacks.[1] In December 2011—in an unprecedented move for the advisory body—the NSABB recommended that certain information be removed from the publications so that, "the manuscripts not include the methodological and other details that could enable replication of the experiments by those who would seek to do harm."[2]

Although the NSABB's recommendations are not legally binding, the decision nevertheless sparked immediate controversy, with some arguing that it amounted to government censure of scientific freedom,[3] while others maintained that the research should never have been conducted in the first place.[4] In response to the concerns raised by the Board, the publishers and scientists reluctantly agreed to redact certain information on condition that the NIH develop a strategy to disseminate the full research findings to legitimate researchers. Expressing concern over a potential over-reaction, the scientists involved in both studies then agreed to a 60-day self-imposed moratorium on further H5N1 research, reportedly in an attempt to allow governments to hold discussions on how to respond to these developments.[5] The World Health Organization (WHO) weighed into the debate, noting that such research is vitally important but that it was "also deeply concerned about the potential negative consequences," particularly in relation to potentially undermining the recently negotiated 2011 Pandemic Influenza Preparedness (PIP) Framework.[6]

THE ISSUES AND THE DEBATE SO FAR

In making their recommendation, the NSABB reflected

two primary concerns: (i) that the information, if published in full, would assist terrorist organizations or rogue scientists reproduce the highly-virulent, airborne strain of H5N1 (or another pathogen), thereby granting them the ability to initiate a global pandemic or other adverse health event; and (ii) that the pathogen may be accidentally released. [2] Arguably, past events such as the 1995 Aum Shinrikyo terrorist cult attack on a Tokyo subway, the 2001 anthrax letter attacks in the United States, and the accidental release of the SARS Co-V virus (the virus that caused the 2003 SARS outbreak) in a Hong Kong laboratory in late 2003, after the disease had been contained worldwide, substantiate the NSABB's concerns to some degree. On the converse side, however, the scientists involved in the H5N1 research have questioned the need for redacting the studies' findings, arguing that "there is already enough information publicly available" to reproduce their experiments and that withholding the information only serves to disadvantage legitimate scientific research.[7]

Indeed, international public debate following the NSABB's recommendation has been intense, clearly dividing much of the scientific and policy-making community.[8, 9, 10] Within the United States, influenza researchers such as Michael T. Osterholm (who is a member of the NSABB) have been joined by prominent public health luminaries such as Donald A. Henderson (former director of the WHO Smallpox Eradication Program) arguing that the H5N1 research "will not materially increase our ability to protect the public's health from a future H5N1 pandemic" and should therefore be abandoned.[11] In response, Ron Fouchier, one of the lead scientists of the two studies, and colleagues have sought to justify their actions on the basis that the research is critical for developing new therapies and enhancing pandemic preparedness, maintaining that, "[i]f the H5N1 virus can acquire the ability of aerosol transmission with few mutations without significantly loosing virulence, the existing assumptions should no longer be used as the basis for scientific advice. Furthermore, pandemic preparedness plans would then need to be revised globally to account for much higher numbers of hospitalized cases and deaths."[12]

Certainly the case has highlighted the paucity of existing controls regarding potential "dual use" research, and scientists are concerned that policy makers may "over-react" by seeking to introduce new legislation or international agreements that will limit scientific discovery and freedom. [1, 10] David Fidler, an international legal expert on global health based at Indiana University's Maurer School of Law, concedes that existing regulatory frameworks such as the Biological Weapons Convention and the WHO's 2011 PIP Framework do not apply to the latest H5N1 research developments.[13] The WHO has also conceded that the H5N1 studies do not fall within the PIP Framework, and has expressed its concern that the findings may in fact undermine the international agreement that took over four years of intense negotiations to conclude.[6]

One of the scientists to consent to the temporary moratorium on further H5N1 research, Professor Yi Guan from Hong Kong University, stated in an interview for the Monitor that he agreed with the US government's request "to withhold some information. It is a reasonable request," he said. Professor Guan stressed though that there were wider implications to consider, namely that, "any decision must be made by a broader consensus than one national government. An international consensus on appropriate approaches is needed. National governments can only control matters in their own jurisdiction and this is an international question."[14] The WHO, which has confronted an ongoing dilemma since 1981 regarding the retention of smallpox samples, has subsequently agreed to convene a meeting of interested parties in mid-February 2012.

On February 2, 2012, the New York Academy of Sciences held a public debate to discuss the issues raised by the two H5N1 studies. Panellist Laurie Garrett, a former journalist and current member of the US Council of Foreign Relations, argued that the studies had highlighted the "inherent contradiction" that governments confronted in seeking deal with "dual-use" scientific research. Ms Garrett observed that the challenges these studies presented were more widespread, noting that, "Governance is highly contradictory at both the national and international levels regarding this issue. And no-one really knows what the appropriate measures are to take". Ms Garrett went on to say that given scientific equipment such as PCR machines (devices that are used for DNA mapping) are now sold commercially and are readily available, "At the rate that we're going, someone in their garage will be able to do genetic testing and that has to be a concern" [15].

In response, Arturo Casadevall, a professor from the

Albert Einstein College of Medicine, stressed that, "all research is dual-use. Does it need more review? Yes. That doesn't mean it shouldn't be done, but it needs more review and oversight". Professor Casadevall also went on to warn against imposing too harsh an oversight mechanism on scientists though, "If you put that system in place, you'll kill science", he said [16]. Alan Rudolph, another panellist and a representative from the US Defense Threat Reduction Agency, acknowledged that the concerns that the H5N1 studies raised, did present a challenge for the United States government, but argued "this issue extends well beyond our borders"[17].

NEXT STEPS

The WHO, which has maintained a relatively low profile regarding the controversial H5N1 studies so far, has agreed to host a technical meeting on February 16-17, 2012, to discuss the issues. While details of the meeting are being kept strictly confidential, WHO media relations officer, Mr Gregory Härtl, has stated that the meeting's participants "all have a direct relationship in one sense or another to the studies done by Kawaoka and Fouchier. This meeting will discuss these two studies concretely and will be a small gathering", he said [18].

Importantly, however, it remains to be seen what the outcome of the meeting will be, or indeed if any progress will be made given that WHO Director-General's special adviser on pandemic influenza, Dr Keiji Fukuda, recently stated that he was not in favor of a new formalized international review system that could become a "bottleneck" for scientific research [9]. Some scientists are clearly looking to the WHO for leadership on this issue though, as Professor Robert Couch from the Baylor College of Medicine in Houston stated in an interview for the Monitor, "I do think the concern is international, not country specific, and that the WHO seems an appropriate forum for discussions". But, Professor Crouch went on to say that even if a new agreement is reached on new guiding principles that "any guidelines or requirements that emerge from that body should be subject to review by individual countries before endorsing" [19].

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Do We Need A New Post-2015 Framework To Promote Health-Related Goals?

Photo: http://zyozy.org

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BACKGROUND

THE ISSUE

The deadline for meeting the Millennium Development Goals (MDGs) is quickly approaching. While progress has been made on a number of the goals, it is already clear that many targets will not be reached. Policy makers have been reluctant to start discussions of what comes after the 2015 deadline, fearing that negotiating a new framework would detract from efforts to meet the MDG goals. Efforts to reach, for example, MDG 5 on maternal health lags far behind targets, and there is a push underway to start to think about a post-2015 framework to continue the work in areas where targets will not be met by the 2015 deadline.

GLOBAL HEALTH IMPACT

While it is difficult to untangle exactly how the MDGs have helped positive change and meeting health objectives set out in the framework, it does seem clear that the MDGs, and not only the specific health MDGs (4 and 5), have brought attention to issues such as maternal and child health, and galvanized action in a range of areas that have health implications. Gains have been made in areas such as poverty reduction, access to clean water and education and reduction of under-five child mortality.[1] Despite progress, great inequity exists, and vulnerable populations and gains remain uneven, with Africa unlikely to reach any of the targets. A post-2015 framework might be a way to continue focused work in many areas, including health.

THE ROLE OF DIPLOMACY

The original Millennium Development Goals and the Millennium Declaration were the results of intergovernmental negotiations, and the Millennium Declaration was agreed by UN members in 2000. It was based in large part on a report entitled “We the Peoples,” drafted by John Ruggie at the request of Kofi Annan. The eight goals and the related targets and indicators emerged after staff from several UN agencies, the OECD, the IMF, and the World Bank met under the leadership of Michael Doyle from the UN Secretary General’s office. The MDG framework was formally endorsed at the UN Conference on International Financing for Development in Monterrey in 2002.[1] It can be expected that negotiations for a post-2015 framework will equally require intensive negotiation. In September 2010, there was a High Level Plenary Meeting of the General Assembly (GA) convened to review progress on the MDGs and chart the way forward. As a follow up, the Secretary General was asked to report annually on progress, and to recommend steps for work beyond 2015.[2]

Over the coming months, it is expected that post-2015 scenarios will be discussed at a number of international meetings, including the RIO+20 meeting (June 2012) and a special event organized by the President of the General Assembly during the 68th session of the GA (2013).[3] The question of how the discussions of post-2015 MDGs will fit the work around RIO+20 remains unanswered.

INTRODUCTION

On January 25, 2012, the Secretary -General of the UN outlined an action agenda for the next five years. In his speech, he remarked that, “[l]ooking beyond 2015, we are working to forge consensus on a new generation of sustainable development goals that build on the MDGs… I will appoint a senior advisor to coordinate these efforts on my behalf.”[4] Although this speech offered some general clues, there is very little clarity on how exactly things will play out.

So far, the official debate at the UN level has been focused on reaching the goals rather than getting wrapped up in discussions of what should happen post 2015. Although the UN has been slow off the mark, civil society groups and academics have been particularly active in identifying options and flagging important considerations.

While there is little agreement on exactly what a post-2015 framework might look like, there is broad agreement that there should be a framework to take the place of the MDGs. There is also a common recognition that the environment in which we now find ourselves is different from when the Millennium Declaration and the MDGs were agreed.[5]

CHANGED CONTEXT

Academics, civil society, and policy makers all recognize that the context in which a new post-2015 arrangement will be negotiated is different from the context in which the MDGs emerged. The Millennium

Declaration and the subsequent Millennium Goals emerged in a fiscally stable period, whereas the negotiations for a post-2015 framework might have to fit the new financial reality. The financial crisis that has gripped many countries has resulted in more uncertainty, and less support, for foreign aid among the general public.[5] The aid architecture is changed: emerging donors are becoming more important, and countries such as Brazil play a key role in global health negotiations. Recently, at the conference on aid effectiveness in Busan, Korea, "non-Development Assistance Committee (DAC)"] donors such as China, Russia, and Brazil want a greater say.[6] This shift in global diplomacy will no doubt also play out as a post-2015 arrangement is discussed. In addition to political and financial shifts, a number of observers also point to the fact that while progress has been made on some of the health-related challenges, such as infectious disease, through, among other things, HIV prevention and vaccination programs, non-communicable disease is also now emerging as a threat in developing countries, becoming a leading cause of death.[1] The changing disease burden, in all likelihood, will also help inform the health-related goals of a post-2015 framework. While environmental causes of emergency have always posed a significant risk, this risk has increased since the MDGs emerged. Erik Solheim, Norway's Minister for Development and Environment, recently noted that he is shocked to observe the division that exists between development and environment negotiations, warning that we cannot hope to achieve the MDGs without addressing urgent concerns such as climate change.[7] The Rio+20 United Nations Conference on Sustainable Development, coming up in June 2012, might go some way in bridging this gap.

WHAT OTHER OPTIONS ARE AVAILABLE?

While there seems to be broad support for a post-2015 framework, there is not yet agreement on what this could look like. As it stands, conversations are beginning to take place and it looks like there will be a number of venues for intergovernmental debate. The Rio+20 Conference that will take place in June this year might be one important venue for debate. The Colombian government put forth a proposal for the creation of sustainable development goals related to sustainable consumption and production patterns, as well as priority areas such as oceans; food security and sustainable agriculture; sustainable energy for all; water access and efficiency; sustainable cities; green jobs, decent work and social inclusion; and disaster risk reduction and resilience.[9] This first draft of the outcome document also proposes that the "Sustainable Development Goals should complement and strengthen the MDGs in the development agenda for the post-2015 period, with a view to establishing a set of goals in 2015 which are part of the post-2015 UN Development Agenda."[9]

This idea of sustainable development goals has found support by the UN High-Level Panel on Global Sustainability. The 22-member panel, established by the Secretary-General in August 2010 to formulate a new blueprint for sustainable development and low-carbon prosperity, was co-chaired by Finnish President Tarja Halonen and South African President Jacob Zuma. In its report, the panel supported the idea of creating sustainable development goals, noting that they "should be defined in a way that complements the Millennium Development Goals while allowing for a post-2015 successor framework."[10]

In another UN process, Ban Ki-moon has appointed a task force to work with stakeholders on a future agenda. The task force is led by the UN Department of Economic and Social Affairs (DESA) and the UN Development Program (UNEP). The first meeting has taken place. The mandate of the task force is to "coordinate system-wide preparations and to propose a unified vision and road map for the definition of a UN development agenda post-2015, in consultation with all stakeholders."[11] The task force is due to report back to the Secretary-General in May, in preparation for the appointment of a high-level panel to be appointed in June.[12]

Meanwhile, the MDGs, and the health-related MDGs in particular, are also under discussion at the World Health Organization (WHO). At the meeting of the Executive Board of the WHO in January, the issue of global health goals post 2015 was on the agenda. In a report by the Secretariat, it is noted that Member States must consider how to face new challenges and also meet goals. "A common voice from the health sector will powerfully influence what will inevitably be a difficult and complex debate between parties in numerous sectors."[13] The Secretariat report also emphasizes the importance of linking new targets to ongoing WHO reform in order for the next set of health-related Millennium Development Goals to match the priorities as to be defined in the next program of work for the WHO.[13]

CIVIL SOCIETY INPUT

Academics and civil society have been particularly active in examining the range of available options, hoping to rectify perceived shortcomings of the current framework. Many of them argue that the MDGs were mainly developed by the global North, with limited input from developing countries. Civil society groups also had very limited input, and are seeking to ensure that their voices are heard in negotiations of a post-2015 framework.

CAFOD and the Institute of Development Studies (IDS) collected views from 104 representatives from 27 developing countries to ensure that these voices are also heard on what should come after 2015.[14] Overwhelmingly, respondents agreed that although the MDG framework has shortcomings, it is desirable to have an internationally agreed framework in place. They also largely agreed that the process for deciding the framework is as important as the framework itself. Another important conclusion from the study is the sense of urgency felt by the civil society representatives interviewed. Health (especially HIV and AIDS, maternal health, and child mortality), as an over-arching subject area, was defined as one of the priority areas for a future framework along with poverty and hunger and the environment. Eighty percent of the respondents agreed that the post-2015 arrangement should be target based, in part because it allows monitoring of progress.[14] Amy Pollard, lead author of the 100 voices study, noted that the official process and consultations will not be focused on community-level engagement.[15]

A number of academic groups are also thinking about a post-2015 framework. For example, participants at a session in Geneva, hosted by the International Red Cross and Red Crescent Society and the Centre for International Governance Innovation (CIGI), put forth a number of ideas, emphasizing that development must be equitable. Moreover, they concluded that the goals' targets have to be "more balanced and more symmetric for all types of countries. While the group was neither in favour of maintaining the status quo, nor simply extending the timeframe with new values for the same set of targets, they concluded that the central focus has to be the eradication of poverty. Some of the principles the participants supported included that the process should reflect empowerment, transparency, and accountability. Furthermore, consultations with the poor should be undertaken, and targets must be adapted to local contexts.[16]

The Lancet Commission on a post-2015 MDG framework published its final report in September 2010. The commission focused their efforts on establishing a set of principles that would underpin the goal-setting process that inevitably has to happen when negotiating a framework.[17] The principles include adopting a holistic approach to avoid gaps; ensure a pro-poor approach; ensure equity and equality of opportunity and outcome; and should be based on "strong global obligations supported by effective international institutional frameworks.[17]

NEXT STEPS

Over the coming months, it will be important to watch the different strands of discussion come together. There is a rich mix of ideas on the table, with civil society and the academic community being particularly active in formulating options for the next period. Inter-governmental processes are also kicking off, and exactly how RIO+20, and debates at the annual General Assembly meeting on development, as well as a special event to be organized by the President of the General Assembly[3] during the 68th session of the GA (2013) will contribute to a new post-2015 framework remains to be seen. According to Amy Pollard, it might well be more difficult to broker an international agreement given the changed context, but "global leaders have it within their power to make this a priority."[15]

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Negotiation of a Treaty on Research And Development Under Consideration at the WHO Executive Board

Photo: norway-geneva.org

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BACKGROUND

THE ISSUE

In 2010, the Consultative Expert Working Group on Research and Development (CEWG) was mandated by the World Health Assembly (WHA) to assess proposals to improve coordination and increase resources devoted globally to research and development (R&D) to address treatments for diseases that principally affect developing countries.[1]

The group of 21 experts has completed its preliminary report which presents the negotiation of a new global instrument on research and development as a promising avenue. This draft report was discussed at the Executive Board (EB) of the World Health Organization (WHO) where Member States presented some initial positions vis-à-vis this proposal and other recommendations of the report.

GLOBAL HEALTH IMPACT

Ensuring that research and development responds to the health needs of populations in developing countries is crucial. However, a report of the WHO Commission on Public Health, Innovation and Intellectual Property Rights published in 2006 stressed that there is a gap in the innovation cycle.[3] In some cases, no method exists to address the health needs of the poor, and, in other cases, methods exist, but little effort is made to ensure that they are affordable for poor communities. As well as intellectual property rights, other incentives, such as financial mechanisms and coordination among stakeholders, are needed to ensure research and development lead to relevant and affordable medical innovations for poor patients.

THE ROLE OF DIPLOMACY

The CEWG is continuing the work that began early in 2009 by its predecessor, the Expert Working Group on R&D financing and coordination (EWG). Member States were not satisfied with the report produced in 2010, and requested that a new group of experts deepen the analysis

of the proposals included in the EWG's report.

CEWG has held three meetings in Geneva, an Open Forum in April 2011, and several regional consultations. [1] In its meeting last November, CEWG proposed the adoption of a convention which would incorporate a mechanism for resource distribution, pooling of funds, and global coordination.[4]

Should negotiations for a treaty be authorized by the WHA in May 2012, the WHO would move towards its second treaty making process since the adoption of the Framework Convention on Tobacco Control in 2003.

REACTIONS FROM MEMBER STATES TO THE DRAFT REPORT OF THE CEWG

During the meeting of the WHO Executive Board, Member States remained careful in their initial reactions to the draft report of the CEWG, with countries disclosing their general positions on the issue and waiting for the final report to provide detailed comments. However, the debate is already quite polarized, and a number of positions were already put on the table by delegates at the meeting. While developing countries expressed strong support for the work of the CEWG, industrial nations took a more cautious approach.

Among the regional groups, Africa, represented by Senegal, was satisfied that many of the proposals put forward during regional consultations, such as their recommendations about patent pooling and the establishment of innovation awards and a regional research fund, were endorsed by the CEWG.

The Norwegian delegation, for its part, requested that the Secretariat organize an informal meeting in order to brief the Missions in Geneva on the final report of the CEWG, after it is published. This proposal was supported by a large number of delegations, such as Canada, Brazil, Switzerland, and Bolivia. Ms. Marie-Paule Kierny, Assistant to the Director General of the WHO, confirmed that the informal debriefing session will be held, possibly in April.

India openly supported the adoption of a treaty on R&D and financing to address the lack of coordination and distribution of resources in research and development for diseases that affect mainly poor countries. India also noted the insufficiency of funds for R&D and emphasized that patents should not overrule health concerns.

Brazil submitted statistics demonstrating that over 2 billion people worldwide do not have access to medical technology to cure or treat their diseases. According to the delegate, WHO members have a moral obligation to better distribute the benefits of health technologies. Brazil expressed strong support for the CEWG, mentioning that it has fulfilled its task.

The United States' delegate welcomed the work done so far by the working group, commending its transparency and inclusiveness. He did not comment on the substance of the report, but stressed that greater efforts to better share the benefits of technological advances were needed, regardless of the existence of a binding treaty. The US delegation presented the experience of patent pooling as a positive practice which should continue. Japan, for its part, contended that more clarification is needed in some of the proposals in the report, such as the precompetitive R&D platforms.

On the issue of practical future steps, Switzerland expressed concerns regarding the impossibility of analyzing the final report of the CEWG in such a short period. The final report would be submitted in April, and Member States would have to have completed a substantive analysis before the WHA meeting in May. Therefore, they requested a suspension of the process for one year to assess feasibility and build consensus, before embarking in a negotiation process.

Brazil, opposing the Swiss proposal, contended that the EB does not have the authority to change the mandate of the CEWG given by the WHA in 2010 and therefore cannot request the suspension of the work. Still, according to Brazil, the report is to be discussed in the WHA session in May when Member States will decide on the appropriate course of action. Replying to Brazil, the Swiss delegate explained that its proposal is not an invitation to the EB, but to all Member States.

NEXT STEPS

It is probable that, at the WHA in May 2012, one of the original proponents of a R&D treaty, i.e., Bangladesh, Barbados, Bolivia, or Suriname, will table a resolution to start the formal negotiations of a convention. Such a proposition would be supported by emerging countries, such as India and Brazil.

However, a number of variables are still to be considered. A procedural resolution can be tabled to take note of the report and to request time before engaging in further negotiations, as Switzerland has suggested. The question might not be the willingness to negotiate a treaty, but rather to clarify its potential content (a matter of "what" rather than "if").

Depending on the terms proposed by a potential resolution (format of the negotiations, substantive issues, timeframe), an agreement can be reached to accommodate particular interests or to, at least, avoid thorny issues. A framework convention could be agreed in order to allow negotiation of the issues that enjoy greater consensus and to defer the most controversial ones to future protocols. Alternatively, although a treaty has been recommended, a soft-law mechanism through a resolution can be at stake, such as the Pandemic Influenza Preparedness Benefit Sharing System, which was negotiated and agreed by the EB January 2011.

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Reform of the WHO at the Centre of the Discussions at the WHO's Executive Board

Photo: http://www.norway-geneva.org

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BACKGROUND

THE ISSUE

At the 64th World Health Assembly (WHA) in May 2011, Member States endorsed the agenda for reform to the World Health Organization (WHO) in terms of programmes, management, structure, finance, and governance. After a special session of the WHO Executive Board (EB) from 1-3 November 2011,[2] the EB continued its deliberations on the reform package proposed by the Secretariat during its regular meeting on 16-23 January 2012.

GLOBAL HEALTH IMPACT

The goal of the WHO reform is to improve health outcomes, with an emphasis on refocusing its core business to address the 21st century health challenges facing countries; reforming the financing and management of the WHO to address health challenges more effectively; and transforming governance to strengthen global health.[1] These reforms will pave the way for the WHO's future role in health issues at the global, regional, and national levels. [2]

THE ROLE OF DIPLOMACY

The formal impetus for reform began in budget-related discussions within WHO's governing bodies in 2009. These discussions quickly broadened to include issues about alignment between the WHO's objectives and its funding priorities—a task that begins with clarifying the role of the WHO in the contemporary architecture for global health governance. Member states agree on the importance on having a transparent, comprehensive, and inclusive process without haste, to ensure that national voices are heard and their needs addressed.

INTRODUCTION

During the 130th session of the EB in January, Member States devoted a significant part of their meeting to discuss reforms at the WHO. Throughout the statements of Member States and the representatives of the NGO community, participants have emphasized the indispensable role and legitimacy of the WHO, as well as the need to respond to the rapidly changing environment. The deliberations on the fifth agenda item, "WHO reform," focused on three main topics: programme and priority setting, governance and managerial issues. The following section highlights key questions linked to the first two.

PRIORITY SETTING

The first issue to be discussed within the reform debate has been devoted to the current practice of priority setting. The deliberations were informed by two documents prepared by the Secretariat at the request of Member States during the special session of the EB in November 2011. They describe current practices at the three levels of the organization (headquarters, regional, and country), as well as providing suggestions "to be further considered by Member States, in which priority setting can be improved in the future."[3,6]

The key challenge is how to balance between different perspectives on priority setting. First, there is a clear demand by Member States that priority setting be driven by an analysis of country needs. "This reflects a significant change from current practice.

At present, priorities in the general programme of work inform the major categories of the programme budget (currently organized around 13 strategic objectives)."[3] Some of delegates to the EB stressed the importance of a legitimate decision-making process that includes all 194 member states, irrespective of the stage of their economic development. The second perspective focuses on what the WHO is mandated to do – in accordance with its constitution. The third perspective focuses on how the WHO is positioned in the increasingly complex global health landscape. As some delegates said during the EB, it has to be considered where the WHO has a comparative advantage in contributing towards country needs. In this context, priorities for global health could be distinguished from priorities for the WHO in accordance with its constitutional mandate as given by its Member States.

GOVERNANCE QUESTIONS: DIALOGUE WITHIN THE WHO AND BEYOND

One of the main governance issues discussed during the EB touches upon the question of how the different levels of the organization (headquarters, regional, and country offices) relate to each other. One of the key problems discussed in the report is the lack of alignment between regional offices and headquarters. To address this, the report on governance prepared by the Secretariat [4] proposes that some of the agenda items for the EB or WHA be discussed first in regional committees. The report received positive comments from the delegates during the deliberations, but some also felt the need for more time to reflect.

The second key governance issue discussed during the EB was about how the WHO "reaches out" to non-state actors, which has been discussed at previous sessions of the EB. Further discussion will be required on how to balance the need to protect the integrity of the WHO, on the one side, and on the other hand, the need to accept the reality of an increasingly complex global health landscape, where improving health de facto involves a growing number of health actors.

Statements from EB members provided arguments towards either of these perspectives, but there was one clear message: the WHO has a unique and indispensable role and must be positioned so that it continues to be the leading authority able to respond to the challenges and to deliver better health outcomes.

Member States are now invited to submit comments through a Web-based platform on the increasing linkages between regional committees and the global governing bodies and harmonization of the practices of the regional committees. The issues include how the discussions at the regional level and the EB relate to each other, the rules of procedure and operation practices followed by different regional committees, and the rules governing the interactions with other stakeholders.

NEXT STEPS

The immediate next steps include: (1) Web-based consultations where Member States are invited to comment on the proposals considered for the 130th session; and (2) the meeting on 27-28 February open to all Member States, to be held at WHO headquarters in Geneva, preceded on 26 February by a presentation and information session with the Secretariat. Moreover, NGOs in official relations with WHO are invited to provide their comments with regards to the priority setting to WHO by 26 February.[5] Meanwhile, the Secretariat is to prepare a consolidated paper covering all aspects of the WHO reform to be submitted to the WHA in May 2012.

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The First Global Health Strategy for the US Department of Health and Human Services (HHS)

Photo: http://thephilanews.com

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BACKGROUND

THE ISSUE

The US Department of Health and Human Services (HHS), the main agency for protecting the health of Americans, recently released its first strategy on Global Health. The strategy seeks to coordinate the department's ongoing global health work, while also bringing a greater recognition of the fact that what happens outside US borders has an impact on the health of Americans.

GLOBAL HEALTH IMPACT

HHS is perhaps best known for work domestically, including for programs such as Medicare and Medicaid. HHS also has an important role in global health, and the department's Office of Global Affairs (OGA) is the lead US government office in global health and international matters. [1] The OGA engages with its counterparts in other countries, as well as with multilateral partners including the World Health Organization, the Pan American Health Organization, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the GAVI Alliance. [2] HHS is also represented in the field, working alongside other US agencies and local partners on a wide range of programming, encompassing work on everything from vector-borne disease, polio, and non-communicable disease to refugee health. [3]

THE ROLE OF DIPLOMACY

With this strategy, the department explicitly recognizes that collaboration is required to tackle many ongoing health challenges. Additionally, health is perceived as a valuable entry point for cooperation with many states. Unlike other policy areas, said Secretary Sebelius, "when the discussion turns to tackling our biggest health challenges, there is a broad consensus that nations must work together." [4] Over the past decade, global health is increasingly being recognized as a key area for collaboration, and a number of countries have strategies that deal with global health. For instance, the EU White Paper "Together for Health: A Strategic Approach for the EU 2008-2013" emphasizes that while Member States have the main responsibility for health, there are areas where co-operative action is paramount, including pandemics and bioterrorism. Other countries that have a global health strategy include Japan, Switzerland, and the UK.

Global health was identified as a key area of focus in President Obama's 2010 Presidential Policy Directive on Development, closely linked to international development and security strategies. [5] The objectives identified in the HHS global health strategy "call for collaboration across US government agencies, and are consistent with the principles laid out in the President's Global Health Initiative." For instance, the global health strategy will support the President's Global Health Initiative to achieve major improvements in health outcomes for women, children, and families. [5]

INTRODUCTION

At a launch event hosted by the Kaiser Family Foundation in Washington, DC, on January 5, 2012, a panel of experts introduced the new Global Health Strategy of the US Department of Health and Human Services. [4] Secretary Kathleen Sebelius stressed that the strategy is not a radical departure from current work. Instead, it is an effort to coordinate work across the department and also with partners including the State Department, USAID, and the ongoing Global Health Initiative. The underlying motivation for the strategy is the recognition that what happens outside the United States can significantly impact the health of Americans. Secretary Sebelius said that "[i]n a world where the flow of people and goods stretches across the globe, our only chance to keep Americans safe is if the systems for preventing, detecting, and containing disease stretch across the globe also." A recent example of the importance of global collaboration was the outbreak of the H1N1 pandemic.

Kerri-Ann Jones, Assistant Secretary of State for Oceans and International Environmental and Scientific Affairs, elaborated that the strategy shows a way forward "in marrying what is happening abroad and how it links to the domestic." She said that "[g]lobal health is a foreign policy issue and is a fundamental objective of our foreign policy."

LAUNCH OF THE STRATEGY

During the launch event, Harvey Fineberg, the President of the Institute of Medicine, commented that it was striking to see the level of HHS engagement in global health. He observed that fundamental choices will have to be made in order to achieve the objectives of the new strategy. For example, decision makers will have to determine which parts of the strategy and programs should be centralized and which parts need to be decentralized in order to carry out the programs.

Helene Gayle, CEO of CARE USA, called the strategy a "huge step forward," commenting that in the past there has sometimes been "sibling rivalry" within HHS, and the strategy will help clarify roles and coordinate efforts. She elaborated that the strategy will clearly identify HHS's strengths and will help make the agency a better partner in the field.

In response to a question about the impact of financial

austerity, Kerri-Ann Jones emphasized that the tight budgets at HHS are no secret, but that the new strategy will be an excellent opportunity to coordinate efforts and to determine how limited resources can best be spent. HHS, which includes important health programs domestically, including Medicare and Medicaid is, according to Nils Daulaire, Director of the Office of Global Affairs at HHS, a "trillion dollar operation" and "[t]he vast majority of our activities and attention are domestically oriented. About 99.5 percent, but 0.5 percent of the trillion dollars is meaningful."

THE STRATEGY

According to Nils Daulaire, the challenge in drafting the strategy was to bring the work that HHS is doing into some coherence and identify a set of principles and key objectives. The overarching mandate of HHS is to keep the American population healthy and safe, and over the past decade it has become increasingly clear that, to do so, policy makers have to focus on what happens outside the country's borders too. Traditionally, the HHS has been decentralized, and the strategy will help identify the strengths of HHS agencies to better meet global health objectives. [6] Some of the important principles on which the Global Health Strategy is built include: using evidence-based knowledge to inform decisions; responding to local needs; ensuring a lasting, measurable impact; emphasizing prevention; and improving equity in health. The strategy outlines ten critical objectives that will guide ongoing global health work. These objectives include: [5]

- Enhance global surveillance to detect, control, and prevent diseases and health concerns. It is recognized that global surveillance is of critical importance to provide accurate data that informs decision making around public health threats. The priorities in this area are: to support countries, as well as multilateral organizations, in strengthening surveillance systems and addressing gaps; provide leadership and technical expertise to countries and regions where this is required; and to assist with improving workforce and laboratory capacity to support diagnosis for disease surveillance. (p. 25)

- Prevent infectious diseases and other health threats from crossing borders. The work is informed by the International Health Regulations (2005). Prevention and early actions are important in containing health threats. HHS provides assistance to partner countries in prevention work, including vector control and efforts to ensure a safe water supply. Additionally, HHS supports the development of technological infrastructure for monitoring purposes, and effective risk communication. (p. 27)

- Support the President's Global Health Initiative (GHI) to achieve major improvements in health outcomes for women, children, and families. HHS seeks to contribute to achieving the goals set out in the GHI in areas such as, for example, HIV, malaria, TB, nutrition, child health. (p. 41)

- Advance health diplomacy through scientific and technical expertise. In cases where diplomatic relationships might be difficult, collaboration around global health issues might open up an avenue for continued engagement. The priority areas of work identified to achieve this objective include assigning attachés to selected US embassies to ensure that political, security, development, and health objectives are maximized, and partnering with the Department of State to increase knowledge about global health among diplomats. (p. 43)

NEXT STEPS

Jennifer Kates noted that HHS currently does a tremendous amount of work on global health, and that "it will be interesting to know more about the specifics activities within the objectives HHS lays out in its strategies, and how they will be carried forward." She commented that it is too early to predict if having a strategy on global health will change how the department engages, but that it has prompted the department to have a look at itself and define its contributions in this new era. [7]

Nils Daulaire reminded the audience that the new strategy does not contain benchmarks as such. It is not a strategic plan. Instead, the strategy gives over-arching direction to the work of the department. The conclusion of the new global strategy acknowledges that "[i]ncorporating this strategy, and the underlying principles, into agency workplans and identifying necessary actions will be the next step."[5] (p. 45)

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