Innovation and Technology Transfer for Global Health

Oxford
9 -13 September 2007

‘Bridging the Gap in Global Health Innovation – From Needs to Access’

A conference supported by
The Bill and Melinda Gates Foundation

CONFERENCE EXECUTIVE SUMMARY

OVERVIEW

This document summarises the proceedings of the 2007 conference ‘Oxford Conference on Innovation and Technology Transfer for Global Health - Bridging the Gap in Global Health Innovation – From Needs to Access’.\(^1\) Bringing together 100 participants from all over the world and from backgrounds ranging from commercial companies to community-based initiatives and product development partnerships, the conference provided a valuable forum to explore many of the key issues in global health. The conference commemorated the contributions of the late Professor Sanjaya Lall whose work, writings and presentations were instrumental in developing the field of technology transfer, foreign direct investment and corporate development in the developing world.

Within the context of identifying gaps in global health innovation and delivery, particular emphasis was placed on the role of institutions and a range of public-private, private sector, non-profit and government initiatives aiming to enhance capacity building and ensure innovations in health. The conference’s objectives were to explore the current and prospective structures and incentives for managing innovation for health needs, which mechanisms deliver effective and affordable interventions and what innovations are needed to address critical gaps in financing and infrastructure. Sessions were structured so that over a third of the participants were able to give short presentations on their experiences relating to these objectives, giving substantial opportunity for a rich debate.

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DIMENSIONS OF THE CHALLENGES

Carlos Morel gave a plenary lecture which introduced and discussed the disconnect between science, technology and production. There is a need for strong and active intellectual property (IP) management and sustainable and well-sourced funding for health interventions, as well as public policies and effective markets that foster interaction between these factors and support delivery of health interventions.

The first session looked at these issues in more detail, with Stephen Mallinga of the Ugandan Ministry of Health describing the challenges faced by the health system in Uganda, work with public-private partnerships and attempts to learn from modern medicine in a society still very much defined by traditional hierarchies and solutions; Patricia Atkinson of the BMGF discussing new solutions supported by the Bill and Melinda Gates Foundation; Harold Jaffe of Oxford University describing the extent of the challenges faced particularly in relation to the HIV epidemic; Rebecca Affolder of GAVI discussing the successes the Global Alliance for Vaccines and Immunization (GAVI) has achieved through partnerships and its work in creating innovative financing mechanisms; Howard Zucker of WHO introducing the Intergovernmental Working Group on intellectual property rights, innovation and public health and the key areas which IGWIG is focussing on; and Peter Ndumbe of the University of Buea finishing the session with a presentation discussing the importance of listening to those in need and the role of governments in taking responsibility for supporting research and innovation as a centrepiece for developments in health care.

In discussion, the challenges that policy makers faced and the extent to which their responsibilities could be realized in the context of limited finances and many demands were brought up. There is a need for driving the creation of a sustainable funding mechanism externally, as the need for bridging the gap on access to health can be defined as a "global public good", but it is difficult to take responsibility at a global level and a risk of misalignment between an ideological method and important views at the ground level. Governments of developing nations need to develop a ‘systems’ approach which actively integrates health systems, communities and infrastructure with product development. A question was raised as to whether it was necessary to have a “champion” for a new intervention to be successful.

It was also recognized that all countries are heterogeneous and made up of different communities. At the national policy level, lessons could be learnt from those developing countries which have closed the gap on OECD; and at a local policy level, success stories from different communities should be used to assist policy makers through communicating local understanding. It is important to share and develop best practise. There is a need to step back from the many different initiatives which do exist to improve global health and to incentivise innovation and to ensure that all groups avoid duplication of efforts and expertise but rather utilise collective resources and realise any potential synergies that exist.

STRATEGIES FOR SECURING PRODUCT AVAILABILITY AND ACCESS

The second session heard case studies from the pharmaceutical industry and representatives of a range of initiatives working to develop products and improve access to treatments through partnerships. Katherine Woo of the Institute for One World Health, described the development of Paromomycin through working with many different partners and using behavioural research to implement suitable and sustainable delivery; Dianna Derhak of DNA International Consultancy introduced the Bio Ventures for Global Health (BVGH) partnering meeting, a means to build networks and develop the marketplace for drug development; Richard Barker of the ABPI presented on the broad role of the pharmaceutical industry and its ability to contribute in partnerships in the discovery and development process, the development of manufacturing capacity, technical skills, pharmaceutical supply chains, as well as contributions to the development of appropriate finance mechanisms; Arun Purohit of Ranbaxy presented on
the challenges currently faced by the generic drugs industry in delivering increased quantities of high-quality ARVs in new fixed-dosed and child-friendly combinations which need to be registered in multiple countries; Gill Samuels presented on behalf of Dr Gail Cassell of Eli Lilly on its initiatives to address multi-drug resistant TB and the Lilly partnership enabling technology transfer; and Robert Mallett of Pfizer focused on building capacity in health research and healthcare systems, especially in addressing challenges in running clinical trials in developing countries and with funding shortages.

There was much discussion about the importance of partnerships. Government support for neglected diseases may often be uncertain in the long term so industry involvement and ongoing support for product development partnerships (PDPs) is essential. Whilst partnerships are key, managing the incentives that stem from different stakeholders requires a nuanced and informed approach. PDPs can help to make risk more manageable across partners.

Further work is needed to shed light on what other competencies industry might be able to share with the non-profit sector, particularly around embedding new medicines. Although firms have found challenges relating to a dearth in developing-country technical capabilities and resources, there is evidence to suggest that perceptions around the extent of these challenges are negatively biased. Rather than develop new initiatives, investment needs to be targeted at existing centres of excellence to strengthen capacity. Further research and policy adjustments are needed to support industry and other partnerships to invest appropriately, addressing challenges posed by issues such as fragmented product demand and regulatory systems and broken and insecure supply chains.

Difficulties in pharmacovigilance were discussed, particularly in reference to counterfeits which undermine technological solutions producing high-quality products. Behavioural research is also needed to support a greater emphasis on disease prevention and integration of modern medicines into traditional practice. A distrust of industry still exists in many developing country contexts and it is important for firms to work more closely both at local level and with international organizations to mitigate this reputation. Intensive knowledge transfer is needed to support contract high standard contract manufacturing.

THE INTERFACE OF SCIENCE, TECHNOLOGY TRANSFER AND ACCESS

The second day of the conference began with a session focussing on the role of different industry and governance structures, before looking at specific examples where technology and knowledge transfer have been developed into successful programmes. James Geraghty of Genzyme presented on the value that the biotechnology industry can contribute to product development and delivery for impoverished populations, and on strategies for increasing engagement in the future through partnerships and networks; Devi Sridhar of the Global Economic Governance programme based in Oxford discussed the need to enable developing countries to engage in global governance and priority setting, strengthen accountability in policy-making, and undertake behavioural and social research to deliver effectively at the community level; Prabuddha Ganguli and Praful Naik of Bilcare described the challenges presented by counterfeiters of medicines and presented a technology-driven solution, which is an integrated device that can be part of a comprehensive healthcare knowledge management system; Rafael Rangel-Aldao from Simon Bolivar University discussed the importance of networks for innovation and in enabling knowledge and technology transfer; Katsuya Tamai of the University of Tokyo presented on the successes and challenges faced by universities in Japan aiming to develop IP rights and technology transfer through collaborative partnerships with universities; Barbara Timmerman of the University of Kansas and the International Cooperative Biodiversity Group (ICBG) presented on the impact of the 1992 Biodiversity Convention on research and development programmes and collaborative partnerships, which have been engaged in knowledge and technology transfer and the development of local research skills; and Eva Harris of the University of California and the Sustainable Sciences Institute (SSI) described the SSI's
grassroots approach to capacity building for biomedical research, based on small-scale, bottom-up projects which become self-sustaining.

The participants agreed that it is essential to enable communities to develop and become sustainable. Power should be transferred more evenly in the policy-making process - developing-country governments must assume responsibility and commitment to fully realising the potential of research and development R&D and delivery initiatives, as well as trying to control the problems of counterfeit medicines. They must listen to communities who must voice their needs. The private sector must take responsibility in developing integrated support systems and supply programmes. In partnerships between industry and developing countries, or between governments and universities, there is a strong need for managing expectations. This can be dealt with through applying the principals of ‘principled negotiation’, in which parties are open and there is no reason for any distrust.

With regards to counterfeiting, the issue was raised as to whether IP protection could actually attract counterfeiting activity by creating higher profits. A similar dilemma might face companies with respect to maintaining high prices to preserve their reputation for quality, when these could attract counterfeitors. The division of responsibility in addressing counterfeiting, between manufacturers on the one hand and government and international agencies on the other, was discussed.

The orphan drugs model could be beneficial in the area of neglected diseases, providing appropriate incentives for research, perhaps simplifying legislative processes, enabling price differentiation and stimulating innovation by developing countries in disease areas which are particularly important at a local level.

PARTNERSHIPS IN PROMOTING INNOVATION AND MANAGING RISK

This part of the conference was broken down into two sessions so that the topic could be fully explored both through presentations on overall strategies and suggestions for best practice, and also through case studies on different initiatives and partnerships.

Mary Moran of the George Institute discussed the need for different strategies for product innovation and the role that PDPs could play in presenting smart and flexible ways of dealing with the different costs and risks which appear through the development process, defining interim markets and different incentives that exist for stakeholders; Jerald Sadoff of the Aeras Global TB Foundation presented the role of Aeras as a PDP and its work in shaping the TB vaccine market as a developer, manufacturer and distributor through various partnership arrangements with industry, academic groups, philanthropic groups and governments; Labeeb M Abboud of IAVI discussed IAVI’s activities to support the R&D process to create an HIV/AIDS vaccine, generate political and scientific support, strengthen community capacity building, create appropriate performance indicators and strengthen industry involvement through IP management; Harold Margolis of PDVI presented PDVI's work as a PDP building a network of developing-country manufacturers, a public health network engaged in surveillance and diagnostics and in trial sites for dengue vaccines; Michael Free of PATH presented the role of PATH in accelerating new technologies for health intervention across the overlapping areas of innovation, introduction and integration, through engaging with many commercial partners, and targeting country decision-makers and international agencies; Jane Morris of SAMI, presented on this nascent PDP located in the developing world, revealing its basis on a local and global research network, its experience developing IP policies appropriate for a consortium and the challenges which it faces in evolving its partnership processes.

During the second session, Chris Hentschel of MMV, one of the first PDPs to work across all areas of the product development process, described its new focus on access, “commercialisation” and delivery; Zeda Rosenberg of IPM highlighted its work as a “bridge”
between companies selecting and developing anti-HIV prevention products in the form of microbicides, the innovative agreements it has developed, and its delivery and capacity building work; Adrian Towse of the OHE discussed the rewards for donors for investing in PDPs as managers of a diverse portfolio and the difficulties in understanding best practise given current metrics, referring to the FSG report on performance indicators for PDPs; Siti Sundari of the Indonesian Ministry of Health presented Desa Siaga, an initiative from the Ministry focussing on health systems and health development activities at a community level; Jose Miguel of Universidad de Concepción presented on the Chilean experience in technology transfer and challenges in innovation with respect to collaborative relationships between universities and the private sector, as well as the critical role of governments in supporting these processes; and Paulette Baukol of the Mayo Clinic presented an initiative which uses community-based participatory research to combine knowledge with action in achieving social change to improve health outcomes, focussing on improving access to cancer treatment for under-served North American Indian communities.

The importance of partnerships for promoting innovation and managing risk; and the difficulties faced by PDPs were discussed in detail. Partnerships work best when the partners are diverse; when they represent a range of disciplines; when they operate on mutual trust; when they work towards a common goal and when they include innovators, producers and end users in the partnerships. PDPs face tension between rapid development and delivery of products to improve health of the poorest populations and strengthening and building capacity in developing countries to engage in the product development process. PDP’s engagement in different activities along the R&D, delivery, advocacy and capacity building spectrums need to be measured differently.

There is a need to start thinking about access as early as possible and to consider it as a process in the same way that R&D is. Access can improve if demand and supply gaps are reduced through community led surveillance, planning and financing and cultural integration tools. It is necessary to consider the different parts of this process, from conceptualising a suitable product profile to managing IP arrangements that enable flexible pricing and manufacturing strategies and through building on technical and policy experiences and lessons learnt from all partnerships.

Patents can be a misleading measure of innovation as they rarely translate into products and are costly to file and maintain, so caution should be exercised when deciding whether or not to patent. PDPs often use IP to ensure they are not blocked out of a technological field and to strengthen their negotiating power with firms.

MANAGING INTELLECTUAL PROPERTY FOR HEALTH AND AGRICULTURAL INNOVATION

This session investigated the relationships of global IP policy and foreign direct investment to health and agricultural innovation. Jayashree Watal of the WTO addressed uncertainty about the scope and nature of the flexibility of the TRIPS agreement, by outlining its terms and its implications for public health in detail; Keith Maskus of the University of Colorado discussed early findings on the impact of TRIPS, suggesting that overall prospects had improved for collaborative IP management and effective contracts, although unrestricted IP protection could cause problems; Magdy Madkour of Ain Shams University presented the Egyptian Ministry of Agriculture’s Agricultural Genetic Engineering Research Institute (AGERI), which has commercialised its research into biotechnology products with the support of its newly established technology transfer office; Douglas Lippoldt of OECD discussed research which suggests a positive relationship between the ability of pharmaceutical firms to protect and capitalise on their innovation using IP and their willingness to trade, invest or to transfer technology in to new markets. TRIPS-plus may increase the attractiveness of a country to investors; K. Satyanarayana of ICMR presented the Indian Council for Medical Research and the development of its approach to technology transfer and public-private partnerships, citing the successful example of collaboration with IAVI, and highlighting the need for best-practice IP management, policy and financial support for product innovation and introduction, and
government engagement; **Anatole Krattiger of Arizona State University** presented the MIHR/PIPRA IP Handbook in Health and Agricultural Innovation which offers strategies for managing innovation and IP in order to achieve access and impact.

With regard to drug pricing models and tiered pricing in particular, participants suggested that there is a need for “middle markets” between low-volume/high-price and high-volume/low-price market segments. The role of IP protection and TRIPS was discussed further in relation to their impacts on access to medicines. There might be scope for harmonising IP enforcement beyond the current agreement. IP protection plays a significant role in enabling technology transfer and attracting investment but there is a trade-off with the possible increase in cost of access to technology. Singapore and India are examples of good practice in encouraging FDI and innovation and conference participants suggested the establishment of a working group to explore and share good practice in national policy making. Plant-derived vaccines as a technology are an alternative to the main commercial paradigm for innovation but present a number of technical and political challenges.

**FINANCING FOR INNOVATION AND TECHNOLOGY TRANSFER**

Strategies for financing and initiatives for promoting innovation, entrepreneurship and technology transfer were presented. **Adrian Towse of the OHE** discussed the role of PDPs in managing risk and access to markets and presented different finance mechanisms which can incentivise R&D and address market access issues, including AMCs; **Anne Reeler of Axios** presented its approach which emphasises creation of local ownership to facilitate sustainable initiatives and discussed some of the challenges in integrating local priorities to developing appropriate policy in government; **Marcos Kulka of Fondacion Chile** presented the principles and structure of the privately owned not-for profit alliance which has led to the formation of many new innovative companies, through an extensive network connecting developers with suppliers and supporting entrepreneurship with different models of technology transfer and capacity building; **Andrew Farlow of the University of Oxford** discussed the intersection of economics and access with reference to a range of global health problems including the limitations of current mechanisms designed to incentivise funding for health, and human resource and infrastructure difficulties faced by developing countries; and **Diran Makinde of NEPAD** presented NEPAD’s role in promoting innovation in African countries through local capacity building programmes which support technology transfer, developing biosafety and monitoring frameworks and encouraging public commitment to investing in R+D in biotechnology.

Financing mechanisms and their relative strengths and weaknesses were discussed, particularly around the appropriateness of the selection of pneumococcal disease as the pilot AMC. Optimal models of innovation and technology transfer between public sector, research institutes and the market place were debated, especially in the context of encouraging entrepreneurship and appropriate ownership.

Tensions exist between top-down and bottom-up capacity building approaches. Axios’ focus on local ownership, delivery and influencing policy is highly beneficial, for example, however it is difficult to scale-up such initiatives due factors such as lacking government capacity to focus on the delivery agenda, IP structures and market mechanisms which already exist.

**KEY CONCLUSIONS**

Effective linkage between policy-makers, scientists, donors and communities is essential and dependant on sustainability of funding, of political will, of human resource, and of infrastructure. Success will require commitment, learning and participation from developed and developing country governments, NGOs, pharmaceutical companies, university technology transfer offices and the product development public-private partnerships.