

Connecting the Chain II: Linking research and development



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Chairman: Sir Andrew Haines, London School of Hygiene and Tropical Medicine

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1 Background

The meeting, which brought together around 70 representatives from 20 countries, was organised by the European and Developing Countries Clinical Trials Partnership (EDCTP) and hosted at the University Foundation in Brussels by the Belgian Institute of Tropical Medicine. The aim of the meeting was to stimulate discussion between national and international funders; implementers of medical research and capacity development; and development aid agencies. The goal was to identify ways to combine the expertise and resources of these organisations and to begin to develop pragmatic strategies for effective collaboration in line with the Declaration of Paris (2005), the Accra Agenda for Action (2008), the Bamako Call to Action (2008) and the Millennium Development Goals related to Global Health.

The meeting focussed on exploring how to bridge the gap between the clinical trials research agenda and development aid policy and practice. The chairman, Prof. Sir Andrew Haines stated that there needs to be greater mobility between the research and the development aid communities, and that capacity development should be done against a backdrop of excellent research. He said that in the future, policy makers will judge research much more on how effective the researchers have been in translating their results into policy and practice.

During the day, six major issues were addressed:

1. How to develop effective strategies for engagement and coordination of research and development aid partners, and how to bridge the existing gaps between them
2. How to coordinate and improve synergies between clinical research and sustainable capacity building for health systems
3. How to encourage governments to create good governance and good practices across both research and development aid activities through strengthening of research management with reinforced monitoring and evaluation
4. How to bridge the gap in translational research between generation and implementation of applied research, i.e. between products and delivery of new medicinal products to patients. And how to accelerate the uptake of new research results into health policy
5. Strategies for sustainable capacity development, utilisation and retention of expertise built within research and health care systems
6. The needs and role of centres or networks of excellence and how they can be strengthened and demonstrate local ownership.

2 Coordination of health research and healthcare delivery

In setting the scene for this meeting, Professor Hannah Akuffo, Chair of the EDCTP General Assembly and Head of Team for Research Policy and Method Development of the Swedish International Development Cooperation Agency (Sida), explained that the main goal of EDCTP is to accelerate research and development of intervention tools against HIV/AIDS, tuberculosis and malaria especially in sub-Saharan Africa. She pointed out that EDCTP was also a pioneer program for cooperation and coordination for European national programmes. Although the main focus of the Partnership is to support phase II and phase III clinical trials using best practices, sustainable capacity strengthening is an essential component of EDCTP's strategy to ensure clinical trials take place in an ethical and sustainable manner. Research results are anticipated to be used for innovation and adding value to new and existing tools in the fight against HIV/AIDS, tuberculosis and malaria, and consequently improving the livelihood of people. The European Union (EU) has committed itself in its 'Europe 2020 strategy' to make better use of existing instruments. EDCTP is a good instrument to be used in this sense. Besides this, EDCTP responds to the Paris Agenda guidelines for interaction between countries and those who provide funding in more than one way, for example: EDCTP joint programming allows several Member States to support research in

African institutions, and the EDCTP partnership with Africa allows for funding of areas of research defined by African leaders as being of strategic importance for development.

Since the path of clinical trials to the eventual use of products where they are needed is a long one, with the costs rising with every step in the chain, it is important for all funders involved to work together. Professor Akuffo called for better cooperation and stressed the importance of learning from examples where combining research funds with development agencies funding have produced good results.

Dr Ruxandra Draghia-Akli, Director for Health Research at the European Commission's Directorate-General for Research, emphasised the importance of EDCTP as an instrument that integrates both the national health research programmes of EU Member States and as a true equal and effective partnership with Africa. She pointed out some of the achievements of EDCTP, like the establishment of the first African regional Networks of Excellence for clinical trials including one for central Africa, the instalment of new national ethics committees in many African countries, and the approval of the US Food and Drug Administration (FDA) for an anti-retroviral formulation for HIV-infected children in Africa, which was tested in an EDCTP project.

She explained that the European Commission (EC) is currently carrying out an impact assessment in preparation for a possible EDCTP II. Suggestions for the new programme include whether to keep the same focus or widen the scope; extending the research area to cover the entire spectrum from phase I to phase IV clinical trials including health services research; inclusion of other neglected tropical diseases; and expansion of geographical coverage beyond sub-Saharan Africa. These questions have been opened up to public consultation and the collated feedback will result in a report in December 2010 which will help shape a possible future direction of EDCTP. EDCTP has achieved a lot particularly in terms of capacity development and networking and that in order to sustain and build on these achievements, EDCTP should be made into a long-term initiative.

Mr Luis Riera Figueras, Director for Development Policy at the European Commission's Directorate-General (DG) for Development opened his remarks with the comment that the timing of this meeting was perfect, since looking forward to a second EDCTP programme provides a good opportunity to better link research and developmental aid work. It also fits well with a number of important activities currently taking place in the European Commission's development aid agenda.

Firstly in response to the Lisbon Agenda, the EC is creating a programme of restructuring and external action to have a stronger European voice in world affairs. In the area of development this calls for renewed synergies and policy coherence between the Member States and European Commission, and for new connections with other areas like food security, trade and research.

Secondly, preparations are currently being made for the Millennium Development Goals (MDGs) conference in New York where the progress made on the Millennium Development Goals will be discussed. Thirdly, Mr Riera Figueras explained that the day before the Connecting the Chain II meeting, there was a Commission to Commission meeting between the EC and the African Union Commission in the run up to the Third Africa-EU meeting which will take place in November 2010. This is an opportunity for setting a new policy framework for Global Health, based on the European model of solidarity in order to strengthen democratic health and governance at global and local level.

At the moment, a renewed European policy framework has been made. The proposal has been discussed with the Member States and was approved in May this year. It will be part of the package the European Commission will take to the New York conference on the Millennium Development Goals. It is clear there are a number of MDGs where progress has been made, including on poverty-related diseases. However, this progress is extremely patchy and unbalanced. Many African countries are much further away from achieving particular MDGs than others and it is important to focus on these forgotten countries. Therefore there is a strong push in the development community to renewed efforts to MDG 4 and 5. There is a need to develop strong health systems. Meaningful work in these MDGs can only be done if we go for a systemic approach, not for vertical or disease specific approaches. Research is the key. Only research

carried out and implemented with the help of the final beneficiaries is useful. Research should not only propose innovative schemes or medicinal products, but should also strengthen the capacity of the countries themselves. Mr Riera Figueras proposed that research should be incorporated within the design of the health strategies of the countries and move away from a project approach towards a more systemic approach of having a research strategy within the health strategy as a whole.

Mr Figueras concluded by saying that the DG Development was ready to have input into a new EDCTP programme, so that an instrument such as EDCTP, having proved its value, can better link the areas of research and development.

Professor Charles Mgone, Executive Director of EDCTP stressed that the EDCTP is about partnership. It is committed to working with European Member States, African partners and others with similar objectives, as equal partners. He emphasised that every clinical trial that EDCTP funds is a tool for capacity development. There is therefore already a lot of overlap with the work of development agencies, for example in providing training in project management, financial administration and infrastructure development. Central Africa for example has always been very much unsupported. EDCTP proactively tries to influence the lack of capacity in this region. In 2009, EDCTP funded four Networks of Excellence across sub-Saharan Africa. One of these is located in Central Africa, and although still small, it is very active and expanding. The idea of these networks is that a group of institutions at different stages of capacity development and with different strengths enhance collaborative efforts and work together to improve the quality of the less developed institutions. Networks of excellence such as these will have an important role to play in the future in fostering closer collaborations between research and development aid agendas for health and in contributing to the MDGs.

Following the presentations, meeting participants had a number of questions and observations. Some highlighted the need for a new EDCTP programme to have even greater levels of cooperation between the national programmes of European Member States and that ways should be found in a new EDCTP programme to overcome some of the obstacles to effective joint funding encountered in the first EDCTP programme. It was acknowledged that in the end this was an issue for Member States themselves to resolve. A number of delegates emphasised the importance of research being picked up as a health issue by African governments and that health Ministers should be more aware of the importance of research results in developing health policy. Advocacy is needed to make sure research results are available for health strategies.

3 Role of clinical research in supporting health care capacity in effective delivery of clinical interventions

Dr Brigitte Jordan-Harder, of the German Gesellschaft für Technische Zusammenarbeit (GTZ), gave a development cooperation view on the importance of capacity building of the healthcare force for effective and sustainable combined healthcare delivery and research. She stressed the importance of a systemic approach to capacity development. In order to achieve sustainable results for both developmental aid and research in health issues, capacity development is not just about building personal capacity; it has to be embedded in organisational change processes. There are important advantages to cooperation both for researchers and for development aid workers. Research can provide new and evidence based approaches, guidelines and policies; methods to measure the impact of activities and new initiatives; and can identify important areas where development initiatives can be improved in the future. On the other hand, developmental organisations can link theory to practice; they can use practical experience to help identify research questions which are relevant for development and facilitate implementation of results in partner countries. Dr Jordan-Harder gave as an example the work of the ESTHER programme. This is a series of partnerships between European University Hospitals and Hospitals in developing countries to foster better health care combined with research. She concluded by stressing that effective development cooperation

needs research and research in developing countries needs development cooperation in order to achieve sustainable results. But most importantly, both need combined systemic capacity development.

Professor Bruno Gryseels, Director of the Antwerp Institute of Tropical Medicine, illustrated the gap between research and development from the researchers' point of view. Researchers are evaluated by the amount of scientific publications they produce, not that much by the impact their research has on global health. Fortunately, the field of medical research is interesting for policy makers, and for industry. There are still many unresolved health issues and major scientific questions, and there is of course a big market for new products and treatments. However, he pointed out that in terms of improving global health, the development of new drugs and treatments is not the most important issue. In order to improve the quality of life for people living with disease in developing countries, the focus should be on improvement of quality of health care. In Africa, only 30 percent of the population have access to health systems. Most patients with malaria are treated empirically on clinical suspicion without a definitive diagnosis being made. A very small percentage of the health service providers in the Democratic Republic of Congo (DRC) know the correct doses or treatment for malaria. Scientists should focus on providing new tools for health care. The implementation should be done by the governments, health care organisations and health workers. The role of development agencies should be to strengthen and help sustain capacity. Professor Gryseels called for better cooperation between all people and institutions involved in the chain from research to health care, each bringing their own strengths to bear.

4 The African perspective

Professor Jimmy Volmink, Deputy Dean of Health Sciences at Stellenbosch University, called for better evaluation and coordination of different initiatives in health care research, pointing out that health care research is meant to advance science, improve health and health care and promote economic and social development. There should be avoidance of waste and improvement of accountability in research; research should be focussed on high priority problems (not only diseases); make better use of information that is already available; urge national governments to take more responsibility and adopt a 'joined-up' approach and measure the impact of investment in research. It is important to be able to assess whether the goal of a particular funded project has been achieved. Rather than repeating work, there should be better use and implementation of results that already exist. More time should be given to evaluating different approaches. There are important questions to be asked when evaluating research:

1. Are the research questions relevant for patients and clinicians?
2. Is the research designed appropriately and is the methodology correct?
3. Is the result published and is this publication accessible?
4. Is there an unbiased report about the research?

Analysis of the research output across Africa shows that the total number of publications from the whole of the African continent is equal to that of the Netherlands alone, and the vast majority of these publications are generated in only a few countries in North Africa or the South of Africa. Furthermore, collaborations between the different countries are usually based on sharing the same language, culture or colonial history. In addition, the principal investigators (PIs) of most health research projects come from outside of Africa. Fortunately there are success stories of capacity building in Africa including the Pan-African Clinical Trials Registry (PACTR) and the work of the African Vaccine Regulatory Forum (AVAREF) in harmonisation and strengthening of regulatory activities in sub-Saharan Africa (network for capacity building in registration and regulation of clinical trials in Africa). Professor Volmink also referred to the SUPPORT Collaboration. This is a world-class, multilingual, partnership between European and low and medium income countries (LMIC) scientists in nine countries. It builds upon an existing network of scientists with a proven ability to run high quality, relevant, pragmatic randomised controlled trials in LMIC, as well as considerable experience and expertise in other research activities, in policy analysis and in research-into-policy initiatives. The aim is to improve the use of reliable research evidence in policy and management decisions on maternal and child health in low- and middle-income countries.

To avoid re-inventing the wheel and to maximise the effectiveness of investment in health research, funders should identify and refer to similar initiatives and link together the information they provide in order to better inform their funding decisions and focus.

Professor Nelson Sewankambo, Principal of the University College of Health Sciences in Makerere, Uganda, talked about the end-users perspective on optimisation of research and the link between research and health services. He pointed out that in health research not much attention is given to health services improvement. The European Union and the United States are eager to cooperate with African researchers but always appear to be in competition with one another. However, there is not only competition between Europe and the US, but also between African countries themselves. This results in inequity in the spending of funds between African countries. South Africa alone takes up almost half of all the funds the National Institute of Allergy and Infectious Diseases (NIAID) spends in African countries. However, the majority of the research such as HIV taking place in South Africa, which is world class, addresses global priorities rather than local priorities¹. Consequently very little of the research comes to the attention of national policy makers. At the same time, policy problems are also not addressed by research. This gap has to be closed. Research makes no difference to health and quality of life unless research is translated into interventions through policy; practice; products and their delivery; and health promotion.

For a researcher in developing countries, the 'publish or perish' paradigm is even more a problem than for their European and American colleagues. Local issues are often not the topics that lead to high-impact publications. Therefore evaluation of research should not only be based on publications and technological innovations, but also on how relevant the research is socially. In this discussion, the African voice is essential, but unfortunately most of the time, not listened to. There is an urgent need to promote African research leadership, share resources, encourage genuine partnerships, support indigenous initiatives and institutions and create and support centres or networks of excellence. For the EDCTP Networks of Excellence, the current funding is for three years. However, this is much too short a time to achieve research impact. Without long-term sustainability short-term investments will be wasted. For governments, research is a tool for attracting and retaining capacity and facilities, and for preventing brain drain. Smart people can be retained for the country if you provide them with a good education, infrastructure and interesting work. We must not forget that for the local people, it is unbearable that money is being spent on research in medical schools, whilst their mothers and children are still dying there. We have to ensure that research affects people's lives in a positive way.

5 Discussion

5.1 Opportunities and obstacles in linking research and development programmes

Opportunities and obstacles in linking research and development programmes were discussed by participants and a panel composed of Mrs Carol Clemenhagen of the Canadian Global Health Research Initiative (GHRI); Dr Brigitte Jordan-Harder of GTZ; Dr Sue Kinn from the UK Department for International Development (DFID); Dr Mary Ann Lansang from the Global Fund and Mr Peter Moors of the Belgian Federal Ministry for Development Cooperation.

The Global Fund has money available for both research and development and this includes scope for more implementation research. On the other hand, the Global Fund has insufficient funds to cover the enormous demands for research on the poverty-related diseases. The fight against tuberculosis for example requires an estimated 22 billion dollars, whilst only 500 million dollars is available. A further problem for developing countries is that new knowledge is not seen as a priority within ministries, and

¹ AIDS research must link to local policy: Salim Abdool Karim and Quarraisha Abdool Karim, NATURE, Volume 463, 11 February 2010

researchers are not good at communicating their results in a language that is understandable for policy makers. Furthermore, there are many successful interventions that have not been scaled up properly. EDCTP could help address these problems by also giving attention to implementation of results and health care systems research.

It was pointed out that researchers and policy makers work to very different timescales. Policy makers may want to have results almost immediately, whilst researchers look five years into the future. The measures by which the outputs of projects are valued (i.e. in terms of implementation or in terms of publications), can also be completely different for research impact and policy impact. These are issues both parties have to overcome in order to cooperate effectively. It is therefore important to identify questions and outcomes that satisfy both parties. It is essential to establish partnerships between researchers and development workers, but the challenges include identifying the type of research policy makers need and interesting researchers in working together with implementers, such as development workers.

From a development policy point of view, there are two ways of using health research for development cooperation policy. You can focus on the support of development relevant research and capacity strengthening by development cooperation departments and agencies, or you can go one step further and consider how to facilitate the uptake of research evidence into development programmes. The latter approach is much more the responsibility of the recipient countries.

The Canadian GHRI program was set up precisely to link research and development aid. GHRI is currently conducting a pilot study whereby projects are led by a team which includes an African researcher and an African policy maker. Canadian researchers act as co-researchers, but the leadership always lies in Africa. Policy makers are also included in the selection committees for the research projects. The aim of this pilot study is to see if this way of working indeed leads to better implementation of research into policy.

There is clearly a need for much broader cooperation and collaboration. Not every country should have to develop its own research agenda. It should be possible to identify problems that are common for more than one country. The EDCTP Networks of Excellence could well have a role in fostering this approach.

The importance of the role of the national government in supporting research and the need for capacity development within every LMIC was stressed several times. LMIC national governments should have a say in research policy for their country; for example, whether researchers should be looking for new vaccines or treatment regimens. They need to have access to the right knowledge to be able to prioritise and decide what research is necessary, and which issues should be addressed in their own countries. To bridge the gap between policy and research more intensive relations are necessary between both groups. Researchers and funders should consult national policy makers well in advance of providing calls and funding for new research projects.

It was pointed out that the biggest problem for health in sub-Saharan Africa is not really shortage of effective treatments but rather difficulties of effective delivery. Therefore, more effort should be put into health systems research. However, most of the current capacity and research is biomedical. Research priorities and topics for developing countries should be increasingly set by the researchers carrying out the work at local level rather than from the outside. Currently, most research is not developed in development countries, nor designed to properly address their needs. Since development agencies have on hands experience in managing and implementing projects in difficult conditions, they could make an important contribution to the research agenda. Furthermore, development agencies will only be persuaded to increase their funding for research when governments are convinced of the relevance of the research for development. Therefore, EDCTP can make an important contribution by facilitating policy makers' access to the results or outcomes of EDCTP projects.

It was pointed out that in many African countries there is limited culture of research due to a lack of skilled local people and money. As a result, most countries look for external donors to come and do research for them. Many LMICs for instance have no national research council. Consequently they work separately with each donor, on individual and usually unrelated, projects. There is a lack of coordination

between the different programmes, and each donor partner has their own policy, which often militate against effective collaboration.

Partnerships like EDCTP should be long-term investments to develop trust, capacity and use of research results. EDCTP has an important role in coordinating different programmes from different countries and organisations, which often run in parallel and sometimes on the same research question, or involving the same people. EDCTP should look into the possibility of involving policy makers in the projects, to help promote the use of the research results in health policy.

5.2 The role of clinical research in supporting health care capacity in delivery of clinical interventions

In discussing the role of clinical research in supporting health care capacity in delivery of clinical interventions, participants felt that donors and funders should take the initiative in establishing effective links between research and development aid. There were concerns about grantees sometimes having to use different reporting formats for the related projects because donors have different procedures and requirements for reporting. This can demotivate grantees from applying for collaborative funds where this is an issue. Therefore the utility of the grants should be improved and there should be more coordination between grants from research funds and development funds. Donors should do more to align their interests and objectives. If it were a mandatory requirement that in all health systems development grants, a certain percentage goes to research and research capacity building, this would help promote synergy.

Local communities should be more engaged with health research activities that concern them. It is important to raise communities' awareness of how research impacts their lives. Researchers can do this in collaboration with local health service providers and policy makers to organise open days, inform the community directly or through the media. The community can then act as an advocate for research.

It is important to strengthen research and scientific capacity. All countries should have universities and medical centres, whose researchers are independent from policy makers. Experience has shown that in countries where medical research is strong healthcare is also usually very good. Clinical research is an important element, which should be valued by the government and Minister of Health. Therefore researchers should advocate their work and its relevance to the health and well-being of the national population. Many medical doctors in Africa never hear anything about health research during their training. Communication should also be an institutional skill. Each institution should have the capacity to translate research results in a language society and policymakers understand.

EDCTP has to raise the profile of clinical research and its added value for health systems with governments, so that if a health Minister is faced with the problem of HIV, he will not just spend his entire budget on drugs, but also allocate funding to research on prevention or for new treatments. EDCTP should connect to existing groups of politicians to get the message across.

Fair contracts should be negotiated between the North and the South. In Africa, there is no capacity for advocates, patent policy and so on. The European Union has a much stronger legal position. Advocates and legal resources are needed to develop this missing capacity.

5.3 Improving the sustainability of EDCTP

Several suggestions were made as to how sustainability of the work of EDCTP could be assured.

- EDCTP should focus more on implementation of science results, and should invest in health systems research

- Networks of Excellence should be reinforced, instead of diluting funding resources across the whole continent
- All stakeholders should be involved in discussions on funding allocation strategy
- EDCTP should not reinvent the wheel, and therefore take note of systematic reviews of scientific research.

6 Actions and next steps

During the meeting, a number of issues were identified: language difference between politicians and researchers, a difference in timescales for expectation of results, different incentive schemes and poor communications between research and development agencies. To solve some of these problems, several recommendations were made:

- Better and more frequent interchange between research, policy and development. A solution could be more mobility of people between these arenas
- The incentive systems should be changed and the grant evaluation procedure should start taking more account of the potential impact of the research on local, national and regional policy and practice
- There should be a change in funding, to include communications expertise in projects to ensure researchers think about what messages they want to get across
- There is a need to identify and highlight examples of research that is integrated with health care delivery, which shows how ongoing learning improves the quality of health services
- Networks of Excellence should be encouraged to engage with development and policy partners at country level to present their research agendas. EDCTP should also engage directly in dialogue at this level
- It was pointed out that health systems research as a whole is a huge field, which is too big for EDCTP. It is also important that EDCTP does not lose its current focus. As one of the main achievements of EDCTP has been a focus on ethical and regulatory capacity building, it could perhaps fund more research on how to strengthen regulatory environments. If EDCTP begins to move into health services research, it will be important to not undermine other initiatives in that area. Therefore close coordination and collaboration with other initiatives is essential
- EDCTP should find ways of engaging policy makers more and give them buy-in to what is done. Consideration could be given to finding ways of including policy makers and communicators in the grant procedures.
- EDCTP should step up its advocacy work towards development ministries at European level, to influence their individual agendas. Development agency representatives encouraged EDCTP to intensify its contact with development cooperation, and make sure the agencies understand the importance of research. EDCTP should also look to make better use of the agencies to improve the implementation of research results.

7 Final Comments by Mr Bogdan Vandonick, DG of International Coordination of Federal Sciences

Mr Vandonick reminded the meeting that Belgium would take over the Presidency of the European Union for 6 months from 1 July 2010. During this Presidency, Belgium is willing to assist EDCTP, and put its proposals for a second EDCTP programme on the Council agenda. He also pointed out that during this period the summit between the European Union and the African union will take place and Belgium would

help ensure that the activities of EDCTP would be highlighted. Mr Vandonick also said that he would like all EU Member States to align their national programmes on HIV/AIDS, tuberculosis and malaria with the EDCTP agenda. However, as this might be a bit too ambitious at this stage he advised EDCTP to be practical and make good use of advocacy and existing instruments.