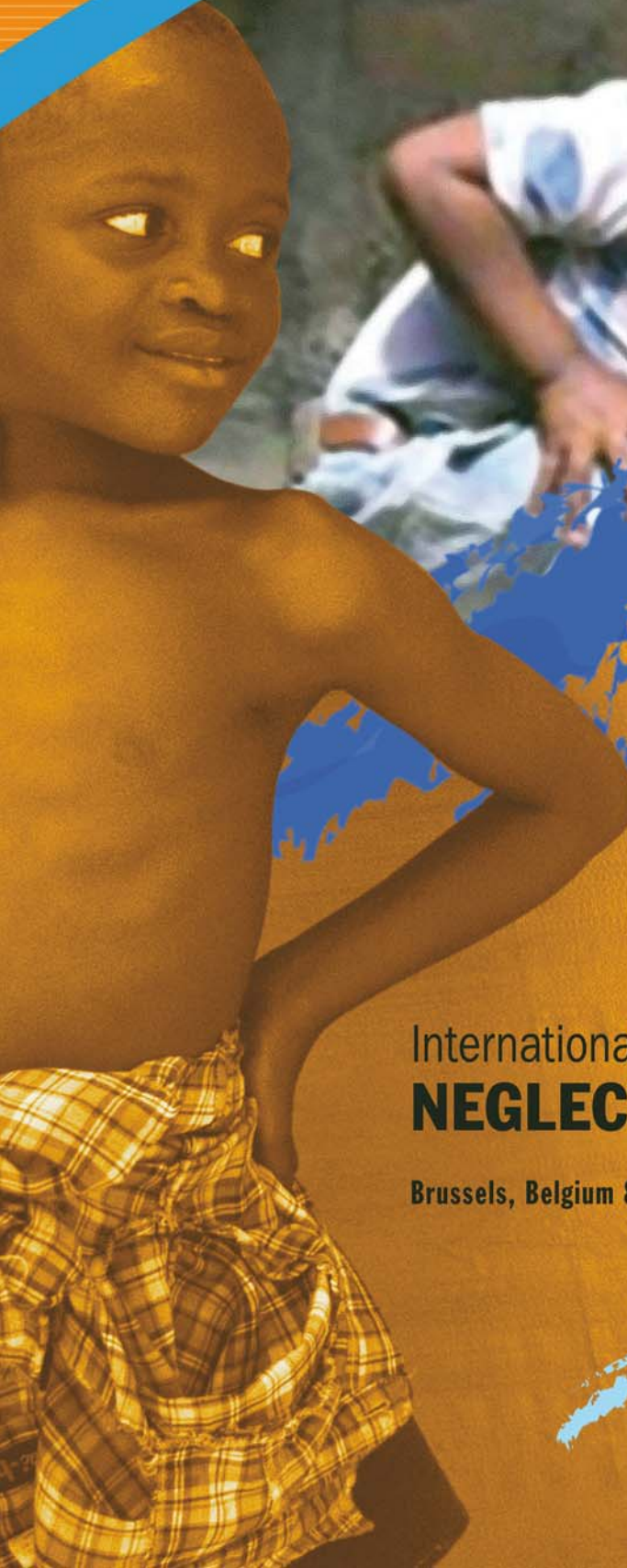




Community Research



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International Conference on
NEGLECTED INFECTIOUS DISEASES

Brussels, Belgium 8-9 November 2006



Neglected Infectious Diseases



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International Conference on **NEGLECTED INFECTIOUS DISEASES**

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▶ PROGRAMME

▶ Wednesday 8 November 2006

Day 1 of the conference will focus on research policy issues (such as raising awareness and accessibility of funding), on funding models such as public-private partnership, and on the accessibility of research findings and their translation into policy.

Morning session

chaired by R. Burmanjer, DG RTD, Head of Unit "Specific international cooperation activities"
Charlemagne Room S3

10.30	Welcome DG RTD
10.40	Opening of conference J.M. Silvia Rodriguez , Research Director-General
10.50	Introduction Directorate International Cooperation H. Spoor, Acting Director
11.00	Introduction Directorate Health O. Quintana Trias, Director
11.10	The parliament's report and resolution on neglected diseases J. Bowis, MEP
11.35	Background of EC funded International collaborative health research and infectious disease control A. Karaoglou, DG RTD International Cooperation
11.45	Overview of current INCO projects on NID control A. Jahn, DG RTD International Cooperation
11.55	An example of INCO-funded research: WOLBACHFIL (Oncocerciasis-control) A. Hoerauf, Institute of Medical Microbiology, Immunology and Parasitology University Clinic Bonn
12.20	The Kenyan Brazilian proposal for essential health research and intellectual property rights A. E. O. Ogwel, Ministry of Health, Kenya
12.40-14.00	Lunch

Afternoon session

chaired by B. Mulligan, Acting Head of Unit "Infectious diseases"
Charlemagne Room S3

14.00	The urgent need to change the rules in essential health R&D Mr Unni Karunakara, Médecins Sans Frontières
14.15	Research needs, Research capacities and recent achievements in NID research in Asia S. Sundar, Institute of Medical Sciences, Banaras Hindu University
14.30	What type of research is needed: The TDR/WHO matrix R.G. Ridley, WHO/TDR
14.45	Current funding of NID research public/private E. Torreele, DNDI
15.00	Strategies for NID research funding in the US M. Hollingdale, National Institute of Health
15.15	NIDs in the FP7 draft D. Zanon, DG RTD Directorate Health
15.30	Drugs for NIDs: Is there an ethical imperative for the pharmaceutical industry? R. Sebbag, Sanofi-Aventis
15.30-16.00	Coffee break
16.00	How to put on NIDs on the political agenda? How to continue private-public partnership? How to balance investment in NID research vs. the "big three diseases" Moderator: S. Luka DG RTD Panel: A. Karaoglou, McCarthy (DG RTD), J. Bowis (MEP) B. Gryssels, S. Sundar, R.G. Ridley, K. R. Sebbag
17.20	Closing Moderator /Chair

▶ Thursday 9 November 2006

Day 2 will focus on scientific issues in two parallel sessions, outlining the state of the art and providing a forum for discussing diseases-specific (Session A) as well as health systems specific (Session B) research priorities.

Session A 1 -Disease-specific research needs

Chaired by T. Junghans, University Hospital Heidelberg
Charlemagne Room S3

9.00	Childhood infections Diarrhoeal diseases overview W. C. Pinto, PRISMA Research Unit	
9.15	Rota Virus infections J.P.Gagliardi Leite, Ministry of Health, Brazil	
9.25	Meningitis G. Pluschke, Swiss Tropical Institute Basel	
9.30	9.35	Other NIDs Leptospirosis R. Hartskeerl, KIT (Royal Tropical Institute) Amsterdam
9.45	Plague N.C. Stenseth, University of Oslo	
10.00	Buruli ulcer B. Fleischer, Bernhard Nocht Institute for Tropical Medicine Hamburg	
10.15	Selected viral infections Dengue: diagnosis and management T. Jänisch, University Hospital Heidelberg	
10.25	Dengue: perspectives for future research L.Baril, Institut Pasteur, Paris	
10.35	Dengue: Global research efforts A. Kroeger, TDR-WHO	
10.45-11.15	Coffee break	

Session A2 - Disease-specific research needs continued

chaired by J. P. Gagliardi Leite, Ministry of Health, Brazil
Charlemagne S3

11.15	Viral Hemorrhagic fevers J. Ter Meulen, Crucell Holland B. V.
11.30	Helminths Schistosomiasis R. Stothard, Natural History Museum, London
11.45	Onchocercosis D.W. Taylor, University of Edinburgh
12.00	Echinococcosis M. Kachani, Institut Agronomique et Vétérinaire Hassan II, Maroc and T. Junghans, University Hospital Heidelberg
12.15	Leishmaniasis Leishmaniasis in India S. Sundar, Institute of Medical Sciences Banaras Hindu University
12.30	Trypanosomiasis Sleeping sickness S. Torr, Natural Resources Institute, University of Greenwich
12.45	Chagas disease F. Guhl, Universidad de los Andes
13.00 - 14.00	Lunch

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Session B1 - Health systems and health policy research needs
Chaired by D. Sanchez, Pan American Health Organisation
Charlemagne Room S4

- 9.00** **Control of NIDs from a public health perspective**
H.J. Diesfeld, University of Heidelberg
- 9.30** **Burden of disease of NIDs and integration of NID control with HIV/TB/Malaria control**
D. de Savigny, Swiss Tropical Institute
- 9.50** **NIDs and environmental health**
M. Traore, Ministry of Health, Mali
- 10.10** **Transdisciplinary approaches to NID control**
S. Mas Coma, University of Valencia
- 10.30** **Accessibility and integration control programmes in general health services**
B. Criel, Institute of Tropical Medicine Antwerp
- 10.50-11.20** **Coffee Break**

12.50 - 14.00 **Lunch**

14.00 -14.30 **Session B2 continued: Rapporteur panel 2**
wrap-up discussions and identification of key issues

Afternoon plenary

session chaired by M. Traore, Direction Nationale de la Santé Mali
Charlemagne Room S3

- 14.30-15.30** **Meeting in the plenary:**
Summary of rapporteurs from both panels and plenary discussion
- 15.30-16.00** **Coffee break**
- 16.00** **NID Research priorities Suggestions for FP7:**
Which priorities?
Which type of research?
Moderator: F. Van Cauwenberghe, DG RTD
Panel: B. Mulligan, A. Jahn (DG RTD) M. Traore, S. Mas Coma, J. H. Ouma, F. Guhl, A. Kroeger, B. Fleischer, A. Jones
- 17.00-17.30** **Closing**
Janez POTOČNIK,
Commissioner for Science and Research

Session B2 - Health systems and health policy research needs, continued
Chaired by H. J. Diesfeld, University of Heidelberg
Charlemagne Room S4

- 11.20** **Novel approaches to financing NID control**
Ms. Bifani, Gavi, Switzerland
- 11.35** **What can Europe contribute towards research on NIDs**
B. Gryssels, Institute of Tropical Medicine Antwerp
- 11.50** **North-South Partnership in research on NIDs**
J. H. Ouma, Biomedical Sciences and Technology Programme, Maseno University, Kenya
- 12.05** **NID control strategies in Latin America**
D. Sanchez, Pan American Health Organisation, Uruguay
- 12.20** **NID control from a country perspective: The case of Burkina Faso**
B. Kouyate, Centre de recherche en Santé de Nouna, Burkina Faso
- 12.35** **NID control from a country perspective: The case of Tanzania**
R. B. M. Kalinga, Ministry of Health, Tanzania





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JANEZ POTOČNIK

Neglected infectious diseases – a common challenge

“We take some things for granted in Europe. For example, we consider diarrhoea a temporary inconvenience. But in some parts of the world, it is a major cause of illness and death, particularly in children. Around 90% of neglected infectious diseases are found in low-income countries. Neglected diseases mean neglected victims. And these victims are in the millions. These diseases impact on more than just health.

For most of these infectious diseases, the sooner you find them, the easier the cure. So early, specific diagnostic tools are essential. These tools also need to be affordable, reliable and usable in the field. Research is seeking new drugs and treatments for neglected diseases. But more research is also needed on epidemiology and development of new surveillance and control strategies. Prevention is key.

The European Union supports research dedicated to Neglected Infectious Diseases (NIDs), and has done so for many years. The EU's Seventh Research Framework Programme, or FP7, will build on the advances of previous programmes that, from 1997 to 2006, provided 70 million euro to 55 excellent NIDs research projects. FP7 is where Europe can play its part in researching these diseases. It will promote further scientific excellence and cooperation in these fields, at European and international level.

Working in partnerships for health research in developing countries is essential. The EU has been involved in research co-operation with other parts of the world since 1983, covering areas from health, to food security, to sustainable development. We have not stopped adding to our international partners, working with them towards the United Nations' wider aims, and notably the Millennium Development Goals. We need partnerships in health research because diseases cover so many areas - the EU cannot, and does not, act alone.

For FP7 to be truly successful, international scientific cooperation will have to play an increased role. This will strengthen EU research through better links - both scientific and political - helping us face common challenges.

This conference is a unique event, where all the main players on neglected diseases gather and discuss the way forward. These discussions on future funding strategies for NID research will help us reflect on what the EU should do in the future to confront these diseases.»

Janez Potocnik, European Commissioner for Science and Research





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Executive summary

The international high-level conference on Neglected Infectious Diseases (NIDs) – “How to meet the challenge for Europe’s international research cooperation in the field of Neglected Infectious Diseases” was held on November 8-9, 2006, in Brussels. Organised by the European Commission with the support of the rapporteur for the European Parliament’s 2005 report on neglected diseases, John Bowis MEP, it was the first conference of its kind dedicated to NIDs.

The conference took place at a timely moment, with priorities being worked out for the EU’s new 7th Research Framework Programme (FP7) to apply from the start of 2007.

The large number of participants included representatives of the European Commission and European Parliament, other international institutions, NGOs, EU member states, the scientific community - both European and non-European - the pharmaceutical industry and SMEs interested in NIDs, as well as participants in EU-funded NID-related projects.

The event was an opportunity to discuss the whole complex of policy and scientific issues surrounding NIDs. While “neglected diseases” are not as high-profile as the so-called “Big Three” diseases – HIV/AIDS, malaria and tuberculosis (TB) - the conference highlighted the fact that millions of people, mainly poor people in the developing world, are suffering from a range of other infectious diseases that also need due attention. These diseases not only affect people’s health but are also damaging in wider socio-economic terms.

The overall objective of the conference was to strengthen and increase the impact of EU-funded international collaborative research on the control of NIDs. The conference looked in particular to:

- Discuss future European funding strategies for research on NIDs considering the European Parliament’s 2005 report on diseases in developing countries, and the international debate on NIDs
- Develop an agenda for NID-related EU funding in FP7

Day one of the conference focused on research policy issues (such as raising awareness and accessibility of funding), on funding models and on the accessibility of research findings and their translation into policy. Day two focused on scientific issues in two parallel sessions, one looking at disease-specific topics and the other health systems research priorities.

Key questions were raised, including how to put NIDs on the policy agenda and how to balance investment in NIDs vis-à-vis the “Big Three”. The wide-ranging discussions revealed a number of apparent dilemmas and a series of big challenges - but also pointed to potential opportunities.

The conference provided important input for the mapping the way ahead and establishing priorities – not just on disease-specific research but on other issues like how drugs can be made more affordable and accessible in poorer countries.

Participants endorsed a number of recommendations, not least stressing the importance of NIDs and the need to keep them as a high priority in FP7. Furthermore it was concluded that:

- Any classification of NIDs should be kept broad, open and flexible
- There should be a focus on applied research, linking basic research and health systems research in order to get research findings translated into policy and practice
- All stakeholders should be involved in setting priorities, especially those from disease-endemic countries
- The strengths of the INCO (INternational COoperation) programme, particularly the focus on equitable international partnership, should be maintained.

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Introduction – The scourge of neglected diseases

Neglected Infectious Diseases (NIDs) are not as high profile as the so-called “Big Three” diseases – HIV/AIDS, malaria and TB - and attract fewer resources. But they can be just as deadly and have terrible consequences for the developing world in particular, making them extremely important in terms of public health.

For people in Europe and elsewhere who may never have even heard of some of the diseases concerned, the figures will come as shock: NIDs are responsible for an estimated 500,000 deaths and millions of disabilities each year across the globe. For example, leishmania - a disease spread by sandfly bites - threatens 350 million men, women and children in 88 countries. It kills 80,000 people every year.

Such numbers are seen in many other neglected diseases that may be unpronounceable for the layman but are no less devastating: 200 million people are infected with schistosomiasis (or bilharzia), with 600 million at risk; 120 million are affected by filariasis (which can cause elephantiasis); sleeping sickness threatens millions of people in 36 African countries, with 150,000 people dying each year; river blindness, as its name implies, shortens life and destroys the sight of millions, especially in Africa. And the list goes on.

Such diseases are closely linked to poverty and under-development - such as a lack of access to safe drinking water – and may be exacerbated by conflict. A sanitary environment and control of the vectors that spread diseases are still the most effective means of combating most NIDs.

Diseases may be “neglected” in different senses and for a variety of reasons. It may be the scarce resources developing countries have at their disposal to tackle NIDs. It may be that, overshadowed by the “Big Three”, they are not a high enough health policy or research priority. It may be the lack of interest in drug development, owing to fears that there is little point in developing new drugs that few people in developing countries will be able to afford.

As the conference showed, much of the disease burden falls on developing countries, but investment in research and development for these diseases has been utterly inadequate. Worldwide spending on health research - estimated at \$106 billion for 2004 - has in fact never been so high, but NIDs are getting only a small slice of the cake. The oft-cited “90/10 gap” demonstrates the imbalance in sharp relief: just 10% of global investment in health research is directed towards diseases that account for 90% of the global disease burden. And there is in general a lack of public funding for disease research.

Another alarming statistic is that of the 1,556 new drugs developed from 1975 to 2004, tropical diseases and TB accounted for only 1.3% of them, despite making up 12% of the world’s disease burden.

Some NIDs already have treatments, but these may involve archaic or even toxic drugs. Or even where effective treatments or preventive measures do exist - like anti-malaria impregnated bed nets - these may be difficult to afford or deliver to those in need. Basic research is important but a “delivery gap” also has to be addressed.

A compounding factor is the weakness of developing countries’ health systems, which, combined with a lack of appropriate control measures, means insufficient preventive and curative care.



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The “90/10 gap”

“It is estimated that less than 10% of the world’s biomedical research funds are dedicated to addressing problems that are responsible for 90% of the world’s burden of disease” – European Parliament report

New hope?

Could it be that the term “Big Four” will soon be common currency, giving hitherto neglected diseases a more prominent place alongside the “Big Three”? It is too early to say, but there does seem to be an increasing awareness of the NID gap, as shown by the European Parliament’s resolution adopted in 2005 on “Major and Neglected Diseases in Developing Countries”.

Drafted by the MEP John Bowis - who addressed the conference - the Parliament’s text called on the European Commission to broaden its approach on HIV/AIDS, malaria and TB to other neglected diseases.

Europe would indeed be well advised to take more than a passing interest in the NID problems of other countries. Recent experience shows all too clearly that diseases do not stop at borders, meaning the control of neglected diseases is of great importance for European citizens too.

It was against this backdrop that the November 8-9 conference looked to tackle the NIDs agenda. In particular, the event sought answers to a range of questions regarding future NID research funding:

- How to define NIDs? There are different definitions, so should it be for example “all except the ‘Big Three’”? “poverty-related infectious diseases”? or “tropical infectious diseases”?
- Does there need to be a specific shortlist of diseases or should there be a non-exclusive, open approach?
- How to link research on NIDs to the “Big Three”?

And those were not the only questions the conference would tackle, often turning on discussions about how to strike a balance between various dualisms or apparently competing - but not necessarily mutually exclusive - concepts: for example, should NIDs be seen as one group or as different individual diseases?

Are donations to developing countries invaluable or do they promote dependence? Whether to focus on routine health systems or disease-specific programmes? And - with co-infection often a problem - how to reconcile tackling single diseases with multiple pathology?

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Backing research and international cooperation at EU level

The conference was opened by the European Commission's Research Director-General José Manuel Silva Rodríguez, with introductions from the Commission's Hans Spoor (Acting Director of the International Cooperation Directorate of the Research Directorate-General) and Octavi Quintana Trias (Director of the Health Directorate of the Research Directorate-General). Ongoing international research cooperation in FP6 (INCO programme) and its NID component was presented by the scientific officers and conference organisers Anna Karaoglou and Albrecht Jahn.

The European Commission has - as explained in the first part of the conference - supported research on infectious diseases as part of the EU's international research cooperation since the early 1980s. Scientific and technological cooperation between the EU and developing countries began in 1982 with three successive Science and Technology for Development programmes. Alongside that, 1984 saw the launch of an International Scientific Cooperation initiative based on bilateral agreements between the EU and third countries. Over the years the EU has also developed a productive partnership with the World Health Organisation.

Introduced under the EU's 4th Framework Programme for research for 1994-1998, the INCO (International COoperation) programme became one of the few international research funding bodies focusing on the control of neglected infectious diseases. 27 NID-related INCO projects received total funding of some 45 million euro under the EU's 6th Framework Programme (FP6) for 2002-2006. Almost all of these projects were still ongoing by November 2006, as well as some projects from the previous FP5 for 1998-2002. INCO health projects under FP6 had global scope, with 46 partner countries taking part. The projects have helped link up public authorities, NGOs and other interested parties, spreading best practice.

Such projects covered a range of relatively little-known diseases including leishmaniasis, schistosomiasis, lymphatic filariasis, onchocerciasis, trypanosomiasis, dengue and haemorrhagic fever, echinococcosis, buruli ulcer and other childhood infections. Work included vector control, vaccines, and development of innovations like traps for tsetse flies and solar-powered disinfecting of drinking water.

One example of an EU-funded research project which has made a real difference in fighting NIDs is the 2.1 million euro "KALA-NET" project. This joins the multinational effort to control leishmania in Asia by developing and testing impregnated bed nets to prevent transmission. Meanwhile, the "DENCO" project involves researchers from Europe, Asia and Latin America and international organisations developing better clinical management guidelines on control of dengue fever.

The INCO programme has also covered health systems and health service disease control issues, generating research to inform planners and policy-makers alike. 12 projects on health systems/policy research worth a total of 20 million euro were launched under FP6 on themes including: health financing, access to health care, quality management, and health and migration.

The EU supports cross-sectoral research and development in its international cooperation, helping to build developing countries' own capacities. And - be it experimenting with an integrated health system in Thailand



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or developing a platform for inter-disciplinary research in West Africa – equality, access and quality of health-care have always been among the main aims.



OHENE ADJEI

Worming out filarial infections - WOLBACHFIL

Taking a new approach to treating filarial disease (lymphatic filariasis and onchocerciasis) through antibiotic targeting of wolbachia endosymbiotic bacteria was the subject of WOLBACHFIL - an example of an INCO-funded research project presented on the first morning of the conference by Achim Hoerauf from the Institute of Medical Microbiology, Immunology and Parasitology at the University Clinic Bonn, Germany, and Ohene Adjei of the Kumasi Centre for Collaborative Research, Ghana.

The results of human trials and studies of worm survival rates carried out in Ghana were outlined, pointing to new answers for research as well as providing benefits for patients and training of students.

Some 120 million people are infected by lymphatic filariasis (or elephantiasis) - which can cause enlargement of the limbs, genitalia and breasts and internal damage to the kidneys and lymphatic system – and over 40 million of them are seriously incapacitated and disfigured. Onchocerciasis (or river blindness) - which affects up to 37 million people – is also a major problem in developing countries. New drugs are needed.

Gearing up for the 7th Research Framework Programme

At the time of the conference, the EU's Seventh Framework Programme (FP7) for research proposed by the European Commission was still in the process of being agreed under the co-decision procedure between the EU Council of Ministers (EU member states) and the European Parliament. The FP7 work programmes were subsequently adopted and published in December 2007.

The EU's 7th Framework Programme (FP7) for research for 2007-2013 has an expanded scope for international research cooperation, opening up all FP7 programmes to such cooperation and shifting management of INCO thematic projects from the INCO directorate to the relevant thematic directorates of the European Commission. International Cooperation Partner Countries (ICPCs) can take part in collaborative projects with EU member states (involving at least three participants from EU member or associated states) and receive EU funding.

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There is also provision for other specific international cooperation actions. Strategic FP7 objectives include addressing specific problems of third countries or of a global character, and bridging the "90/10" research gap.

The FP7 covers the EU's financial period 2007-2013. The last projects must therefore start by the end of 2013 but can continue running beyond this time. The last FP7 projects are expected to reach their conclusion by 2020/21, providing a long-term investment in research and results for many years to come.

Supporting work on neglected diseases in FP7

The Council and Parliament decision on the FP7 confirmed NIDs as an integral part of the Programme's health theme, referring to "specific cooperation actions... aiming at reinforcing the research capacities of... developing and emerging countries, focusing on their particular needs in fields such as health, including research into neglected diseases".

There are a variety of avenues for NID-related projects in FP7. One is via the general programmes for biomedical and health research. Possible entry points include detection, diagnosis and monitoring, therapeutic approaches and therapies under the "biotechnology, generic tools and technologies" pillar; and infectious diseases under the "translating research for human health" pillar. (The third pillar concerns "Optimising the delivery of healthcare to European citizens"; broken down into: enhanced health promotion and disease prevention; translating clinical research into clinical practice; and quality, efficiency and solidarity of health systems).

There are also specific international cooperation actions in FP7 providing for collaboration with developing countries, involving at least two participants from two different EU member states or associated countries and two partners from two different ICPCs. International NID research projects can take advantage of a 64 million euro budget for the first two years of the "Health" draft work programme for specific international cooperation actions.

It was confirmed at the conference that the FP7 "Health" work programme for 2007-2008 would mainly cover infectious agents of the Trypanosomatidae family (deadline for submitting proposals 18 September, 2007), that is:

- Human African trypanosomiasis (or sleeping sickness), a disease spread via tsetse fly bites affecting the central nervous system
- American trypanosomiasis (or Chagas disease), prevalent in Central and South America
- and leishmaniasis, the group of diseases caused by leishmania parasites, transmitted by sandfly bites; the most life-threatening form is the deadly visceral leishmaniasis – or kala-azar – that attacks the immune system.

The final work programme on health and the respective deadline for submitting proposals can be found at: http://cordis.europa.eu/fp7/cooperation/health_en.html

Subsequent calls for proposals under FP7 - taking into account the results of the conference among other sources - were expected to cover other NIDs like:



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- Dengue, a mosquito-borne infection found in tropical and sub-tropical regions, mainly in urban and semi-urban areas; it is a major threat to public health throughout South East Asia and Latin America and the subject of an alarming global spread in recent decades
- Schistosomiasis (or bilharzia)
- Onchocerciasis (or river blindness)
- Filariasis
- Leprosy
- Buruli ulcer, an emerging health threat and disease of the poor in remote rural areas
- Soil-transmitted helminths
- Childhood infections

Promoting health systems research

The European Commission said at the conference that indicative topics for future calls for proposals under the FP7 health theme also included specific international cooperation actions for health systems research. The objective was to support research to provide a scientific base for ICPCs to improve their health service delivery, including accessibility, effectiveness, efficiency and quality of care and user-friendliness. Research would also cover public health concepts and interventions beyond health services through cross-sectoral and multi-disciplinary research approaches. Global initiatives such as the UN Millennium Development Goals would be taken into account.

First calls (with a deadline of 18 September, 2007) will cover:

- Universal and equitable access to health care and health financing
- Health care intervention research
- Optimising hospital care - Health care intervention research
- Improving prenatal and maternal care.

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JOHN BOWIS

Bringing neglected diseases in from the cold – MEP's view

John Bowis MEP told the conference that the international community was right to focus on tackling the "Big Three" killer diseases AIDS, malaria and TB. But it should not forget that at least 1 billion people - one sixth of the world's population - suffered from one or more neglected tropical diseases. Such diseases affected the poorest and most vulnerable in tropical and subtropical regions of the world. He said the burden of these diseases, some of which reinforced AIDS and TB, was "incalculable" and the challenge "daunting". But the conference showed that Europe was committed and willing to play its part.

Some diseases, the MEP explained, were "neglected" not in the sense of being developing country diseases - for which there had been little incentive for the research and development of drugs and other treatments - but those diseases that were global and for which the developed world had affordable access to drugs and specialist treatment and care but which were out of reach in low-income countries. For these diseases, ways had to be found to ensure low-cost access in such countries.

Options to improve access to, and affordability of services and treatments included exploring the use of differential or tiered pricing, voluntary licensing agreements, technology transfer and an increase in local capacity for production. The reasons for inadequate access were complex and included the effects of international and national pricing policies, tariffs, taxation and the implementation of intellectual property rights agreements.

Mr Bowis pointed out that of the 1,393 new drugs that reached the market between 1975 and 1999, only 13 - less than 1% - were approved for tropical diseases. Since then there had been progress but "a new sense of urgency for a wider range of diseases" was needed.

"Urgent action is needed to develop new drugs, tests and vaccines that are adapted to developing countries' needs, and to make them available at affordable prices", Mr Bowis underlined. This would not be cheap, he warned, with an estimated 250 million euro needed over ten years to develop medicines, including for Chagas disease, leishmaniasis and trypanosomiasis.

Another problem was that there had been a limited viable market for pharmaceutical research and development (R&D) investment in infectious, tropical diseases. And policies had tended to focus on how to get the Research part of R&D off the ground but had often failed to support the Development process, for example by not supporting existing neglected disease initiatives that were already working on new drugs.

Some of the solutions, Mr Bowis continued, were to be found through Public-Private Partnerships (PPPs). PPP-driven projects should result in eight or nine new drugs in the next four years, though mainly for malaria and TB. He advocated harnessing the best of the public sector (in the «R» of R&D) with the best of the private sector (in the «D») and applying successful models to the most neglected diseases.

The European Parliament had pushed, Mr Bowis explained, for explicit reference to be made in FP7 to neglected



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diseases in terms of the medical needs of developing countries. A strong commitment to research into neglected diseases in FP7 was needed so that the strategy being discussed during the conference would have the political backing and financial support to be taken forward and implemented.

He pointed out that the European Commission's support under the Research Framework Programmes FP5 and FP6 – for over 50 projects to the tune of 70 million euro – was important work but only a fraction of the combined budget of the two research programmes of 32.5 billion euro. Mr Bowis welcomed the setting up of the European and Developing Countries Clinical Trials Partnership (EDCTP), noting that the European Parliament had called for EDCTP grant-funded activities not to be restricted to the “Big Three” diseases.

Mr Bowis talked of “renewed hope” when, after much negotiation, the World Health Assembly (WHA) in May 2006 reached agreement on a text referring to «essential health research...towards a global strategy and plan of action». An intergovernmental working group would negotiate an action plan on research and development over the next two years, with a view to «securing an enhanced and sustainable basis for needs-driven, essential health R&D».

He called for the same dynamic approach to dealing with other major global diseases as had been seen in the response to SARS, the threat of bio-terrorism and avian flu and the setting up of the European Centre for Disease Prevention and Control. “And we need to look at our European contribution to the same surveillance, preparedness and research for the developing world”.

Tackling research policy issues

After the more introductory remarks of the first morning, the afternoon session on day one of the conference got to grips with NID-related research policy issues. Following a series of presentations, a round table debate looked at questions like how to put NIDs on the political agenda; how to continue public-private partnership; and how to balance investment in NID research as against the “Big Three”.

Bruno Gryseels of the Institute of Tropical Medicine, Antwerp, Belgium, set out to identify what Europe could contribute to research on NIDs. He stressed the need for scientific excellence and quality research leading to innovative tools and strategies and new knowledge. He pointed to the potential insights that research could bring into human immunology in general.



SHYAM SUNDAR

Shyam Sundar of the Institute of Medical Sciences, Banaras Hindu University, India, speaking on NID research in Asia, said diseases were “neglected” because of different health, business and research priorities in the developed as against the developing world. Yet the EU could be the leader in showing the world how to fill the “90/10 gap”, and could win credibility by helping to build up the capacities of developing countries and transferring technology.

Unni Karunakara of Médecins Sans Frontières pointed to problems of availability and access to drugs, denying that increased intellectual property protection necessarily meant increased incentives for innovation. There had been a “market failure” due to the lack of profit in NIDs, and a “paradigm shift” was needed. The EU should ensure new and sustainable funding for NID research, development and delivery.

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Rob Ridley of the World Health Organisation (WHO) pointed to a growing strategic dialogue on health between the WHO and the European Commission. He put forward a vision of “an effective global research effort on infectious diseases of poverty in which disease endemic countries play a pivotal role”. There were new players, initiatives and drug developments in the global research environment but a danger of fragmentation.

Els Torreale of the Drugs for Neglected Diseases initiative (DNDi) described Europe’s “modest contribution” to worldwide spending on health research. Most of the funding for product development partnerships (PDPs) came from philanthropic organisations and so far the EU had been virtually absent from PDPs for neglected diseases. The EU seemed willing to address R&D for neglected diseases but concrete action was needed.

Michael Hollingdale of the National Institute of Health/National Institute of Allergy and Infectious Diseases, US, outlined strategies for NID research funding in the US. He said he was looking for cooperation between Europe and the US, while it was developing countries that should establish the priorities.

Robert Sebbag of Sanofi-Aventis, France, said that the pharmaceutical industry was not just a monster only looking for profit, describing his firm’s efforts on research and development and pricing, and talking of the industry’s responsibility to innovate and offer access to products. But he warned policy-makers that the vaccines of tomorrow would be expensive and sophisticated – huge investments were needed, and now.

Chairing the **round table** discussion, **Sohail Luka** of the European Commission’s Research Directorate-General described a number of apparent dilemmas or challenges surrounding NIDs. Politicians like John Bowis were trying to rally voters around a cause that did not directly affect them. The pharmaceutical industry was being called upon to invest in products that people in developing countries did not have the money to buy. Researchers might be interested in NIDs but offered money to work on other not-so-neglected diseases. Meanwhile, patients often had to choose between dying from a particular disease and suffering from the side effects of an inadequate drug.

The various comments from the round table panel and the conference floor nonetheless produced a number of pointers for resolving such dilemmas. Part of the task was to make people aware that human health was a prerequisite for economic health: curing people of debilitating disease would contribute to economic development, and that in turn would reduce dependence on international aid.

Moreover, the dilemmas would not be resolved if there were no viable market in developing countries – and that meant building sustainable, accessible health systems, as well as strengthening infrastructure and capacity. Training and health education was also needed.

Developing countries had to give sufficient priority to health, and it was important that donor governments and foundations maintained their support while avoiding creating a dependence of the South on the North. It was stressed that FP7 must maintain a spirit of international cooperation and foster true partnership between the developed and developing world. And developing country scientists had to be involved in setting research priorities.



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Recommendations for NID-related research

Day two of the conference focused on scientific issues in two parallel sessions, one on disease-specific issues and the other on health systems research priorities. The two sessions produced broadly similar recommendations and key messages for future FP7 activity, confirming, for example, the need to link health systems and disease-specific approaches.

The programme on **page 2** provides an overview of presentations and presenters. All presentations can be found on the conference website at: http://teamwork.intbase.com/0606_02/index.php

Disease-specific session

The disease-specific session saw a comprehensive discussion of fourteen different diseases, including various childhood infections, as well as viral infections, helminths, leishmaniasis, trypanosomiasis and other NIDs like leptospirosis, plague and buruli ulcer. The presentations summarised the current research on epidemiology as well as on disease control interventions in their respective areas and identified future research needs and priorities.

In the field of childhood infections, such as diarrhoea, respiratory tract infections and meningitis, emphasis was placed on the development of **inexpensive diagnostic tools, vaccination, quantification of the burden of disease and** its long-term consequences and preventive interventions.

Presentations on dengue fever identified further research needs particularly in the area of implementation research - how to bring new tools into clinical and vector control practice - and policy/health systems research related to improving surveillance and outbreak management. Emphasis was also placed on the development of dengue diagnostics and the study of dengue immune response in apparent clinical manifestations compared to clinical disease.

Attention was also drawn among other things to the importance of viral hemorrhagic fevers, particularly Marburg, Ebola, Lassa, Crimean Congo hemorrhagic fever and hanta virus - infections with high fatality rates. It was explained that prevention and control of these diseases should be possible through work on simple diagnostic tests and the careful analysis of transmission routes, particularly of the animal hosts.

The field of helminth infections was covered with presentations on schistosomiasis (with which about 170 million people worldwide are infected), onchocercosis and echinococcosis. Current control programmes based on mass treatment faced problems due to increasing drug resistance and weak public health systems. Clinical issues such as the development and validation of guidelines and new treatment principles also needed further attention.

A report on visceral leishmaniasis in India showed that, after more than 30 years of incessant transmission of the disease, vector control strategies had proved ineffective. Tools for diagnosing active disease were sorely needed, as well as surveillance of drug resistance in parasites. Combination therapy with short treatment courses might postpone resistance, and should be looked into in the short term, as there were no new compounds in the clinical development pipeline.

African sleeping sickness and Chagas disease in Latin America, the main variants of trypanosomiasis, are as severe as they are difficult to treat; there was thus a need for research on vector biology and sustainable vector

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control strategies as well as improved tools for diagnosis, prognosis and treatment. In addition, there was still a lack of epidemiological research on geographical distribution and related burden of disease. A range of innovative methods for vector control was presented.



AXEL KROEGER

Disease-specific recommendations

The disease-specific session participants agreed a set of conclusions and recommendations for FP7 NID-related activities that were subsequently presented to the whole conference.

The recommendations, reproduced below and presented by the rapporteur Professor **Axel Kroeger** (TDR, Geneva), notably responded to one of the key questions for the conference – how NIDs should be defined – by confirming participants' preference to work with an open and flexible selection of NIDs as a basis for selecting priorities, rather than attempting to set in stone a definitive, exclusive list.

The importance of involving scientists from countries where NIDs are endemic when setting priorities was also stressed. And the recommendations built a bridge to the other parallel session in referring to the link with health systems research.

Conceptual and operational issues:

- Importance of NIDs:

Keep NIDs as high priority in FP7 research with adequate funding because of major contribution to global burden of disease and in order to contribute to reaching the Millennium Development Goals

- Broad concept of NID:

Operate with a broad and open list of NIDs as current estimates of disease burden and other priority estimations are not precise enough

- Priority-setting:

Encourage dialogue with stakeholders including particularly DEC (Disease-Endemic Country) scientists and control programmes

- Predictability and transparency of the [FP7 "Health"] work programme:

Areas to be covered in forthcoming calls should be announced at the start of FP7

- Long-term investment needed in research projects, with impact orientation

- Complementarity:

Seek synergism with other funding initiatives

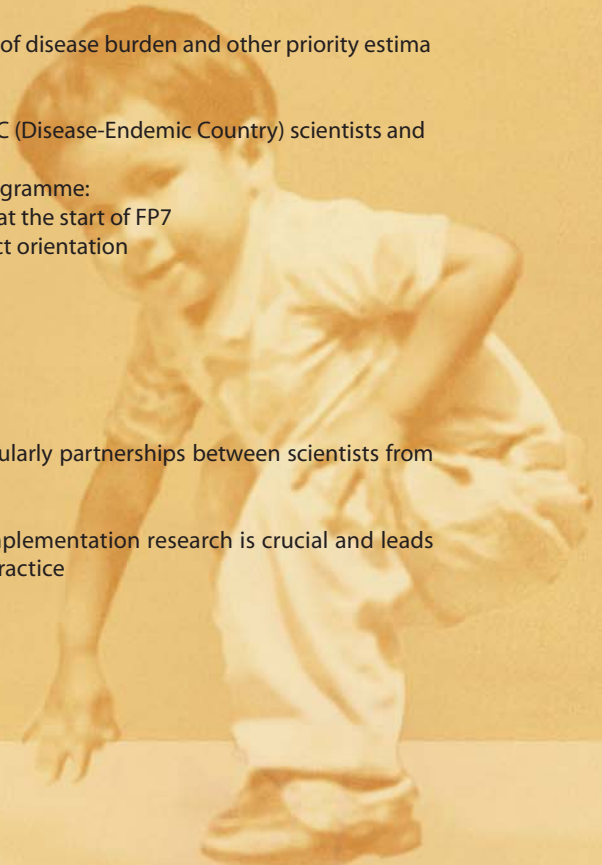
Approach

- Partnership:

Maintain the strengths of the current INCO programme, particularly partnerships between scientists from the EU and DECs

- Link health systems and basic research:

Encourage applied research as the link between basic and implementation research is crucial and leads ultimately to translation of research findings into policy and practice





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Health systems and health policy research needs

The second parallel session touched on a whole host of issues related to health systems and health policy research needs, looking at control of NIDs from a public health perspective; integration of NID control with control of the “Big Three”; NIDs and environmental health; trans-disciplinary approaches to NID control; accessibility and integration of control programmes in general health services; novel approaches to financing NID control; the WHA resolution on essential health research and intellectual property rights; and North-South partnership in research on NIDs. Speakers also outlined experience of NID control in Latin America, Burkina Faso and Tanzania.

The core message was that there was a need for investment in health systems and health systems research. Policies had to take into account the weak health structures and human resources of developing countries. There was growing evidence that existing interventions were not as effective as they could be because health systems were unable to cope with money or programmes, and due to problems of sustainable medical access and coverage. The big challenge was to get local health services responding to local needs.

It was suggested that an approach focusing on certain diseases in a “vertical” way - such as through mass campaigns - and one focusing on routine health systems in a “horizontal” way, need not be mutually exclusive. Campaigns against specific diseases could have a significant temporary impact and different campaigns could be “hooked up” for added efficiency. But such campaigns were also limited in time and place, and hence unsustainable, potentially even undermining local health systems. On the other hand, strengthening health systems in general might be seen as more costly and slow but could bring greater long-term benefits. Any specific campaigns should therefore have a built-in transition to routine health services, and dependence on campaigns should be reduced.

Speakers also variously: described the link between NIDs and poverty and environmental conditions; said that integrating disease-centred health programmes into general health facilities presented opportunities as long as the process was genuine and well-conceived; underlined the need for innovative partnerships between health and other sectors; pointed to the importance of carrying out field studies to be able to check the epidemiological situation and see whether any diseases were emerging or re-emerging; outlined the concept of Advance Market Commitments (AMCs) between stakeholders (donors/developing country governments) and industry designed to guarantee future financing for producing affordable vaccines; and emphasised the need to strengthen partnership in research between North and South given the latter’s lack of tools, laboratories and trained personnel.

Reporting for this session, **Hans Jochen Diesfeld** of the University of Heidelberg, Germany, welcomed the fact that the disease-specific panel had underlined the importance of health systems research, noting what he said was the traditional schism in the research community between health and disease. Systems research, he pointed out, could refer to research concerning the totality of the population in a certain environment rather than just health services as such. Close collaboration was called for between disease-centred research and health systems research.



HANS JOCHEN DIESFELD

Professor Diesfeld concluded that a more systemic approach to health had to be maintained in FP7. Researchers and policy-makers in disease-endemic countries should have more of a say in setting priorities to ensure the relevance of research proposals. And systems research people should also be involved so as to be able to ensure adequate funding vis-à-vis disease-specific research.

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He also pointed to the importance of translating health system research results into policy and practice, and to the role the EU could play as a kind of “advocate” if the European Commission’s Research Directorate-General and its Development counterpart could get together to make sure countries were able to implement research results.

Professor Diesfeld also concluded that there should be an open rather than a closed list of NIDs. The disease situation varied from country to country and region to region, making it impossible to generalise.

Health systems and health policy research recommendations

From the presentations and discussions in the health systems/health policy research session Professor Diesfeld derived the following recommendations:

- Health systems and health policy research have to be an integral part of the research portfolio of FP7
- Disease-centred research protocols, as far as applicable, have to be checked against health systems and health policy demands
- Thematic approaches have to take cognisance of, and respect priority setting by DEC (Disease-Endemic Country) partners
- Cooperation at equal level with DEC partners is a condition *sine qua non* in order to assure DEC relevance
- The principles for international research collaboration as developed under the INCO programme should be strengthened, namely: balanced participation; fair sharing of resources; joint project management; and shared intellectual ownership.

Conclusions: NIDs a high priority

Summarising the two panel sessions and subsequent plenary debate, Dr **Mamadou Traore** of Mali’s Ministry of Health outlined the following conclusions:

- General agreement that NIDs should be put high on the agenda
- Any list of NIDs should be left open
- The need to link basic research and health systems research: there should not be an artificial division between the two, and strengthening health systems was very important
- Priority-setting should get all stakeholders involved, especially those from disease-endemic countries
- Meaningful rather than “cosmetic” partnerships were needed.





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Mapping the way ahead for NID research

The concluding plenary debate of the conference looked at NID research priorities and suggestions for FP7. Broadly endorsing the conclusions reached by the earlier parallel sessions, the discussion highlighted the importance of research on NIDs while confirming that the challenge was as big as ever. It was a complex issue posing a number of difficult questions.

As for defining neglected diseases, the consensus view was that the list should not be limited but kept open for constant updating. It would be wrong to start “cherry-picking”, especially given that people often suffered from more than one disease.

It was felt that setting priorities was not an easy task, especially as they could change over time and from place to place. In general, participants believed that public leadership was needed to bring countries together and take part in setting priorities. And there was a need for a strategy bringing together different stakeholders - politicians, NGOs, researchers, industry, funding agencies - into a coordinated and global approach on NIDs.

Involving policy-makers in developing countries was seen as particularly important. Conference delegates underlined that it was important not to lose any spirit of partnership with developing countries when the change in INCO management took place. At the same time, governments in developing countries would have to pay due attention to health, and define and include NIDs in their own priorities to be able to take proper advantage of funding opportunities. Meanwhile, coordination between different EU actors was also called for.

It emerged that there was no single overarching inventory of NID research, meaning research activities could overlap or be scattered and dispersed. The creation of such an inventory or database - covering what had already been done and scientific work that was still ongoing - would establish a more targeted approach and avoid repetition. It would help in setting priorities by identifying any research gaps and any diseases that were not or only insufficiently covered. And it could form the basis for more concerted global action.

Another strand in the debate was that it was important to bridge the “implementation gap” and get research results translated into policy-making and action on the ground – given problems like existing fundamental research not being applied; drug candidates getting stuck in the approvals pipeline; or drugs not reaching patients.

The discussions pointed to the importance of closer interaction between research on diseases and research on health care systems. FP7 should increase research on health care systems for NIDs. Translational research was needed to bridge the gap between basic research and useful applications. And long-term investment in research was needed, with impact orientation.



ROUND TABLE DISCUSSION

Closing the conference, **Janez Potocnik**, European Commissioner for Science and Research, told participants they had taken an important step forward in preparing for FP7 by drawing up an agenda for FP7 NID funding. He remarked among other things that the conference’s discussions on future funding strategies for NID research would help the European Commission reflect on what the EU should do in the future to confront these diseases.

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Websites

please feel free to visit our websites at:

Conference: http://teamwork.intbase.com/0606_02/
(This website includes all the presentations of the conference)

International Cooperation: <http://ec.europa.eu/research/lscp/index.cfm>

FP7-Work programme: http://cordis.europa.eu/fp7/home_en.html

For further inquiries: <http://ec.europa.eu/research/index.cfm?pg=enquiries&lg=en>

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