



EDCTP

European & Developing Countries Clinical Trials Partnership

STAKEHOLDER MEETING

REPORT ON
NEGLECTED INFECTIOUS DISEASES

THE HAGUE, THE NETHERLANDS

27-28 JUNE 2013



Towards the second EDCTP programme

The EDCTP Stakeholder Meeting on Neglected Infectious Diseases is part of a series of thematic stakeholder meetings planned to contribute to the shaping of the strategy and funding approach of the second EDCTP programme. EDCTP will hold further stakeholder meetings on HIV/AIDS, tuberculosis and other mycobacterial infections and malaria, as well as on research ethics review and capacity building.

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EDCTP was created in 2003 as a European response to the global health crisis caused by the three main poverty-related diseases (PRDs) of HIV/AIDS, tuberculosis and malaria. Currently

EDCTP is a partnership between 16 European countries, the European Union and sub-Saharan African countries. The aim of the programme is to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics against HIV/AIDS, tuberculosis and malaria through a balanced partnership of European national research programmes on PRDs with their African counterparts in collaboration with the pharmaceutical industry and like-minded organisations.

The second EDCTP programme is expected to start in January 2014 as part of the European research framework programme Horizon 2020. Its scope is based on the current objectives and achievements and will be expanded to include: all clinical trial phases I-IV including health services optimisation research; other neglected infectious diseases; closer collaboration with industry, like-minded product development partners and development agencies; and collaborative research with other developing countries outside sub-Saharan Africa when possible and desirable.

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Acronyms and abbreviations

| | |
|--------------------|---|
| DFID | Department for International Development (United Kingdom) |
| DNDi | Drugs for Neglected Diseases initiative |
| EDCTP | European & Developing Countries Clinical Trials Partnership |
| EDCTP ₂ | second EDCTP programme, expected to start 2014 |
| FIND | Foundation for Innovative New Diagnostics |
| FP7 | Seventh Framework Programme of the European Union for the funding of research and technological development in Europe |
| GAVI | Global Alliance for Vaccines and Immunization |
| INDEPTH | International Network for the Demographic Evaluation of Populations and their Health |
| IP | intellectual property |
| IVI | International Vaccine Institute (Republic of Korea) |
| LAMP | loop-mediated isothermal amplification |
| MDA | mass drug administration |
| MRC | Medical Research Council (United Kingdom) |
| NIDs | neglected infectious diseases (as per but not limited to the WHO list) |
| NoE | network of excellence |
| NTDs | neglected tropical diseases |
| PDP | product development partnership |
| R&D | research and development |
| TDR | UN Special Programme for Research and Training in Tropical Diseases |

1. Executive summary

The meeting was part of the preparations for the second programme of the European & Developing Countries Clinical Trials Partnership. The two-day event was attended by 52 and 54 participants on the first and second day, respectively, including researchers, representatives of product development partnerships and the pharmaceutical industry, policy makers, funding agencies and other like-minded organisations.

Discussions were structured around the following main presentations, after each of which there was lively debate involving many meeting participants.

- Prof. Achim Hoerauf – keynote address
- Dr Michael Makanga on plans and progress towards EDCTP2
- Dr Odile Leroy on vaccines ‘Capitalising on experience’
- Prof. Joseph N’dungu on diagnostics
- Dr Nathalie Strub Wourgaft on drugs
- Six short addresses on partnerships and collaborations
- Short introduction on capacity building from the Co-chairs and EDCTP.

The opinions and recommendations shared are summarised below within five main themes: Vaccines, Diagnostics and biomarkers, Drugs, Partnerships, and Capacity building.

Vaccines

Challenges

- Complex organisms and changing disease epidemiology
- The portfolio of potential new vaccine products is very limited
- Difficulties in sourcing funding to move promising products from pre-clinical to clinical studies

- The costs involved in undertaking trials in Africa are increasing
- The ‘extra-neglected diseases’ which have so far received particularly little attention: e.g. snakebite and mycetoma.

Recommended actions

- Advocacy for funding
- Improve mapping of disease prevalence and public health importance
- Systematic reviews of previous studies
- Research should include assessment of the non-specific immunological and clinical effects of vaccines
- Evaluation of responses is required in a range of settings
- The development of vaccines from inactivated parasites should be investigated
- The development of human challenge models should be considered
- Vaccination of the vector and intermediate/alternative hosts should be considered
- Compare the impact of anthelmintic treatment given before or at the time of vaccination
- Agreements are needed on access to and affordability of vaccines that have been trialled using public funds.

Diagnostics and biomarkers

- Effective diagnostic tests (based on appropriate biomarkers) are needed for several different purposes, varying with disease characteristics and epidemiology
- Studies are needed to evaluate new or existing tests; disease-specific target product profiles are also needed
- Specific issues to be addressed regarding human African trypanosomiasis include restaging, test of cure and the need to obtain less invasive methods that circumvent use of lumbar puncture

- NIDs affect very poor and sometimes remote populations, for whom tests must be made available free of charge
- Measures of transmission rates should be developed
- Tests are required to make possible monitoring in intermediate/alternate hosts and vectors
- Prioritising tests for support is complex – not only prevalence but also the complexity and severity of diseases should be considered
- The development of simple multiplex platforms, ideally capable of using supplies from multiple companies, would greatly assist in activities in the field
- Disease-specific suggestions were also made for new products available for investigation.

Drugs

General action points

- Advocacy is needed to restart development of potentially useful drugs that have “lost their champion”
- Research is needed on: new drugs, re-purposing existing drugs, drug combinations, potential clinical adverse effects, use in young children, and use in pregnancy
- Health services implementation studies are required: to validate strategies that fit with the epidemiological situation; in which interventions are integrated with national control programmes; in which integrated control of NIDs is a feature; in which pharmacovigilance is an important part
- Normal laboratory ranges for Africa should be established
- It was noted that research is also needed on interventions other than drugs: e.g. vector control, sanitation, and combination

interventions against individual or multiple diseases.

Disease-specific action points

- Leishmaniasis:
 - many products are in the pipeline but attrition should be allowed for
 - the aim should be an oral treatment for visceral and cutaneous leishmaniasis
 - effective treatment is needed for visceral leishmaniasis in HIV-infected patients
 - combination treatments will still be needed
 - field studies of oral drugs are required.
- Filariases:
 - continue moxidectin research
 - Wolbachia research must continue, including use in combination with antibiotics
 - the Drugs for Neglected Diseases initiative (DNDi) is also active in this area and collaboration should be considered.
- Schistosomiasis:
 - the potential for praziquantel resistance is a concern
 - cure rates are often poor
 - paediatric formulation needed.
- Soil-transmitted helminthiases:
 - cure rates are often poor
 - the potential for albendazole/mebendazole resistance is a concern.
- Trachoma:
 - the potential for drug resistance is a concern.
- Yaws:
 - Can a lower dose of azithromycin be effective?
- Mycetoma:
 - New antifungals could be trialled.

Partnerships

Requirements for successful partnerships:

- Trust and friendship
- Equality
- Common objectives
- Clear agreements on responsibilities
- Agreement on intellectual property and profits
- Keeping the interests of all partners in mind
- Contributions made according to means
- Balanced governance
- Costs managed effectively
- Must deliver more than the sum of parts.

Capacity building

- Support integrated projects; research infrastructure development; short-term and long-term training (masters, PhDs and post-doctoral training); and baseline studies to support development of future clinical trial centres
- Train mid-level staff involved in clinical trial teams: nurses, laboratory managers, project and finance managers etc.
- Senior fellowships
- Regional Networks of Excellence (NoEs): consider a link to DNDi platforms; include research management support
- Mentorship fellowship scheme: consider collaboration with TDR to broaden experience offered
- Ethics capacity building: take note of vulnerable groups and populations
- Epidemiology, statistics and modelling capability
- Improve the regulatory environment for field testing of diagnostic products and development of combination treatments

- Clinical trials capacity needs to be improved with regard to: monitoring, provision of sponsorship, trial platforms, phase I trials
- Capacity building is needed to make possible the immunological studies required in vaccine trials
- Appropriate courses to be made available as follows include: short courses on immunology and vaccinology; courses in French; distance learning (web-based and dual approach); courses in which the talents and experience of retired personnel are put to use
- Technology transfer
- Good manufacturing practice
- Pharmacovigilance
- Quality assurance capacity for diagnostics
- EDCTP audit
- Career development: fellowships through partnerships; 'adaptability' through training
- Social science
- Partnership capacity to be developed with regard to: legal aspects; knowledge of IP; better balance of benefits
- Information about capacity should be shared through funder-related and industry-related websites.
- Engage with national institutions (universities, research institutes, vector control programmes), whether EDCTP funded or not, so that completed projects will leave behind infrastructure and human capacity capable of supporting new projects.

The breadth of the recommendations made by participants in all five areas was considered to be remarkable and will inform EDCTP in the planning of the second phase of its programme.

2. First day

The meeting was the first of five thematic stakeholder meetings held as part of the European & Developing Countries Clinical Trials Partnership's preparations for its second phase of development (EDCTP2). The two-day event took place in The Hague and was hosted by the Dutch Ministry of Foreign Affairs. It was attended by 52 and 54 participants on the first and second day, respectively, including researchers from academia, representatives of product development partnerships and the pharmaceutical industry, policy makers, funding agencies and other like-minded organisations.

Introductory remarks

In the meeting's brief opening session, the Chair of the EDCTP General Assembly Professor Hannah Akuffo said its task was to identify key challenges and opportunities for EDCTP in advancing research into the neglected infectious diseases (NIDs), and the financial strategies that would be required. EDCTP Executive Director Professor Charles Mgone expressed his thanks to participants attending the meeting, including representatives of EU member states and industry. He spoke of his wish for the gathering to produce 'concrete conclusions'. Speaking as Co-chair of the meeting, Professor John Gyapong, Pro-Vice-Chancellor (Research Innovation & Development) of the University of Ghana, said he hoped for an engaging discussion, in which participants getting to know each other would play an important part.

Keynote address: Prof. Achim Hoerauf

Professor Achim Hoerauf noted the scale of the combined burden due to NIDs, which predominantly affect the world's poorest

people; he described NIDs as 'a problem for those left behind' [by economic growth]. He has, however, been heartened by recent initiatives to address the issue by the World Health Organization and others; the London Declaration in 2012 established a road map of targets to be met by 2020, to which donors pledged commitments totalling \$784. Advocacy activities, with the involvement of celebrity figures, have also been stepped up. He went on to highlight the achievements of organisations such as the Drugs for Neglected Diseases initiative (DNDi). EDCTP should definitely include NIDs in the next phase of its programme!

Referring to the kinetoplastid diseases, he noted that human African trypanosomiasis is one NID in which the level of research has increased in recent years. Leishmaniasis treatment has also progressed but there is still much room for improvement. Chagas disease is becoming more common, though not as yet in Africa, and requires expanded research efforts.

Soil-transmitted helminths are not as easy to treat as sometimes claimed; drug efficacy is species-dependent with a higher cure rate seen against ascariasis than trichuriasis. Food-borne trematodes do not receive sufficient attention from researchers, given the numbers of people at risk; tribendimidine is showing promise but more trials needed before changes in treatment policy can be recommended. There is already an effective drug for schistosomiasis – praziquantel – but finding a safe and effective formulation for children remains a priority.

Professor Hoerauf discussed in more detail the needs and opportunities for the development of new drugs for filarial diseases – onchocerciasis, lymphatic filariasis and loiasis. These diseases are still responsible for high disease burdens, especially in Africa's forest regions where it is difficult to reach those who needed treatment. He reviewed the current state of mass drug

administration (MDA) campaigns to eliminate onchocerciasis and lymphatic filariasis. Many of those targeted for treatment have yet to be reached. One problem is that infection tends to occur in clusters – rates in adjoining villages can vary considerably – which makes estimates of prevalence unreliable. There are fears that ivermectin efficacy may now be suboptimal in some areas. Trials of combination therapies are proceeding. New tools are much needed. Professor Hoerauf went on to discuss the need for an effective macrofilaricide and to describe his own work and that of others on *Wolbachia* endosymbionts of filarial nematodes, which offers a new approach involving treatment with doxycycline. The Anti-*Wolbachia* Consortium (AWOL) funded by the Bill & Melinda Gates Foundation brings together both academic and industrial partners active in this field.) The timeline for research and control initiatives in this area must be better defined.

Helminth parasites are ‘masters of immunomodulation’, which is a barrier to vaccine research. Nevertheless, if developed, use of a vaccine would be the most cost-effective way forward; one advantage would be that vaccines would be more suitable than drug treatment for children, who are the most vulnerable to infection. He discussed some of the current vaccine candidates for onchocerciasis and lymphatic filariasis (CPI, RAL2, Ov103) and the work of the Transatlantic Product Development Partnership for a River Blindness Vaccine.

Professor Hoerauf concluded with some points on NID research more generally. Money spent on new drugs and delivery systems could have a considerable impact and endgame strategies might then become feasible. Combination therapies are often not properly tested in trials. More research is also needed on the potential re-purposing of older drugs for use against NIDs; he gave as an example the use of flubendazole against onchocerciasis. Coinfection was a further issue needing more research;

co-infection with the ‘big three’ infectious diseases varies in its impact on individual NIDs. Key research needs vary between NIDs; thus for some more effective diagnosis is the highest priority, while for others it is research and development or implementation research. He called for funding for NID research and control to be ring-fenced to ensure that progress is made.

Comments

In the discussion that followed Professor Hoerauf’s presentation the following points were agreed.

- Different types of research are needed, from the ‘bench’ onwards
- The drug needs of children and pregnant or lactating women require particular attention
- Implementation research is often neglected and should be expanded
- Trials of combination treatments should be a priority
- Adverse events should receive full consideration in study design
- Ethical issues should never be neglected
- The re-purposing of old drugs offers great potential
- Research is needed that takes account of national context
- Measuring efficacy can be problematic and agreed standards are needed
- The identification of biomarkers for diagnostics is a leading priority
- Vaccine development and implementation will be crucial
- Capacity building – especially human capacity – must continue to be an important feature of EDCTP-supported research.

Plans and progress towards EDCTP2: Dr Michael Makanga

Dr Michael Makanga, EDCTP Director of South-South Cooperation and Head of Africa Office, spoke of the mission, objectives and scope of EDCTP and gave a summary of the grants given and trials supported so far, also outlining the importance of the regional Networks of Excellence (NoEs). The concept of partnership is seen as the basis of the programme.

The second phase of the programme (EDCTP2) is expected to begin in 2014. It will therefore overlap with the first phase, which continues until March 2015. The NID Stakeholder Meeting, and the other forthcoming stakeholder meetings, will play an important part in the planning of EDCTP2. Features of EDCTP2 will include larger and more costly phase III clinical trials, extension of activities to cover NIDs and also phase IV trials, activities initiated by participating states, and an increased number of integrated activities and projects conducted jointly with partners. Criteria for establishing priorities for action will include disease prevalence, product opportunities, balancing immediate and long-term priorities, and maintaining a balance among clinical trial phases.

Comments

Michael Makanga responded to a number of questioners who sought further details on EDCTP procedures, and the role anticipated for EDCTP within the broader range of European research funding programmes.

The Co-chair, Prof. Elliott said the next phase of the meeting would be to identify both the most pressing needs in NID research and the potential new products already in the pipeline. She added that, while there are different views

on which infectious diseases should be called 'neglected', it would be helpful to adopt as a starting point for discussion the WHO list of 17 NIDs, from which, however, three diseases could be omitted – Chagas disease (not found in Africa) and the mycobacterial diseases leprosy and Buruli ulcer (to be discussed, along with tuberculosis, at a stakeholder meeting in October). It is also understood that mycetoma is likely to be added to the WHO NID list.

Vaccines: Dr Odile Leroy – 'Capitalising on experience'

Dr Odile Leroy, Executive Director of the European Vaccine Initiative (EVI), described the work of EVI, which has resulted from a broadening of its remit. She noted that infectious diseases affecting the world's poorest people have been considered under various groupings – 'poverty-related diseases', 'neglected tropical diseases' and 'diseases of poverty' – and went on to discuss the difficulties in identifying priority diseases and priority research needs. Burden (for which expanded mapping activities are needed) is not the only issue of concern; feasibility is also crucial. She illustrated this point with reference to visceral leishmaniasis.

She went on to consider the various stages in NID research: basic, applied, pre-clinical, clinical trials, licensure and launch. She outlined the following priorities:

- conduct research on pathogen biology and pathogen-host interactions
- develop standardised assays and reagents
- identify and validate correlates of protection
- develop systematic criteria for prioritising and down-selecting
- standardise clinical trial endpoints to enable comparison among trials
- develop robust, accessible process development capacity.

Dr Leroy concluded by noting that advocacy efforts will be required to win increased support for NID research.

Comments

The following issues were then raised by several participants.

- The cost of conducting vaccine trials in Africa is increasing. We need to understand better why this is happening. Insurance costs may be partly responsible
- Non-specific effects as well as specific effects of vaccines should be considered: e.g. live vaccines may reduce child mortality more than can be explained by the prevention of the targeted specific disease
- GAVI is a major player in vaccine programmes and ways must be found to collaborate with this organisation
- Access to adequate manufacturing capabilities is essential
- There is a need for more epidemiological research; for example the burden due to leishmaniasis remains unclear. Mapping of trachoma can be done using mobile phones to collect data. Opportunities are often lost to gather data; trachoma researchers for example can take blood samples in the course of their own activities. Surveillance must continue even after vaccination/treatment programmes are in place
- There was strong support for the standardisation of laboratory assays. Endpoints represent another area where there is a need for harmonisation
- There is a need for African institutions to sponsor vaccine trials
- We can learn many lessons from vaccine research on other diseases, including malaria, measles and meningitis A
- We need to understand vaccine mechanism, but there is a reluctance to fund such research
- Sometimes improving water and sanitation might offer more gains than vaccine research
- Snakebite is a neglected condition; more research is needed and, contrary to the commonly held view, clinical trials are possible
- Mycetoma is another infection where vaccine research is needed
- Hookworm vaccine candidates now exist and trials are planned
- There have been no trials of trachoma vaccine trials since the 1960s but a phase I trial of a new candidate is planned
- Human African trypanosomiasis was said [by DNDi] to be not a priority for vaccine research, as treatment is considered to be a better option and case numbers are already reducing
- As MDA has not led to onchocerciasis eradication in some areas, vaccine efforts should be supported. This is one case where encouraging bench results have been achieved but have not been built upon due to lack of funding
- Systematic reviews should be conducted of research already done; for example leishmaniasis vaccine studies
- Three categories of *vaccine studies* were identified:
 - candidates already available: e.g. hookworm (a Sabin product is ready for phase I trial); leishmaniasis (several products available)
 - low priority as there is potential for control/ elimination without vaccine: e.g. human African trypanosomiasis and trachoma
 - worth consideration: e.g. *Echinococcus* (which could in theory be controlled through hygiene measures but it is hard to impose hygiene on children)
- Vector control is sometimes more appropriate than vaccination programmes.

There were also pleas that EDCTP should support research against a much wider range of diseases, including diarrhoeal disease and acute respiratory infections. This, however, fell outside the remit of the present meeting on NIDs.

Speaking as Co-chair, Alison Elliott said leishmaniasis stood out as a priority area for vaccine research. She asked participants for any information they had on the pipeline for other diseases, specifically naming dengue, rabies and yaws, but no responses were forthcoming. She also identified a list of key points – see Box 1.

Box 1: Vaccine – key points

Challenges

- The changing epidemiology of NIDs and the complexity of the organisms responsible
- The current product portfolio is very limited
- Lack of funding to move potential vaccines through to trial stage
- The increasing cost of running trials in Africa
- The ‘extra-neglected’ diseases (e.g. snakebite and mycetoma) receive very little attention.

Recommended actions

- Expand advocacy
- Improve mapping programmes
- Systematic reviews of earlier studies
- Assessment of the non-specific immunological and clinical effects of vaccines
- Evaluation of responses in a range of settings
- Development of vaccines from inactivated parasites
- Consider vaccination of vector and intermediate/alternative hosts
- Secure agreements on access to and affordability of vaccines that have been trialled using public funds.

Diagnostics: Prof. Joseph N’dungu

Professor Joseph N’dungu, Head at the Foundation for Innovative New Diagnostics (FIND) for human African trypanosomiasis and other neglected diseases, stressed the importance of quality diagnostics; without diagnosis individuals will not be treated and there will be public health implications; if syndromic treatment is the policy adopted then many people will receive treatment inappropriately. He offered FIND’s work on human African trypanosomiasis diagnosis as a model. He outlined FIND’s approach to priority setting; unmet needs and feasibility are both important but may result in different rank positions.

The stages in FIND’s diagnostic pipeline are: feasibility, development, evaluation, demonstration, WHO approval, accelerated roll-out and uptake. But with NIDs it is less straightforward; there are no existing platforms so platforms created for other diseases must be used. Proof of concept is required, after which partnerships can be established; different partners may be required according to the stage of development. For example, FIND’s human African trypanosomiasis rapid LAMP test required academic, industry and endemic-country partnerships. Funders, WHO and national Ministries of Health were also involved.

Comments

It was noted that diagnostics research does not follow exactly the same product development approach that is adopted with drugs (clinical trial phases I-IV). Nevertheless, the pathways are very similar and diagnostic and treatment researchers have much to learn from each other. Diagnostics pose new challenges for EDCTP; for example the programme has previously not much worked with public health labs.

Priorities for diagnostic research vary with the disease in question. There are two categories

Box 2: Diagnosis – key points

- Effective diagnostic tests (based on appropriate biomarkers) are needed for several different purposes, varying with disease characteristics and epidemiology
- Studies are needed to evaluate new or existing tests; disease-specific target product profiles are also needed
- Specific issues to be addressed regarding human African trypanosomiasis include restaging, test of cure and the fear of lumbar puncture
- NIDs affect very poor and sometimes remote populations, for whom tests must be made available free of charge
- Measures of transmission rates should be developed
- Tests are required to make possible monitoring in intermediate/alternate hosts and vectors
- Prioritising tests for support is complex – not only prevalence but also the complexity and severity of diseases should be considered
- The development of simple multiplex platforms, ideally capable of using supplies from multiple companies, would greatly assist in diagnostic activities in the field. It might be possible to establish partnerships with industry to enable use of platforms available in Europe for processing large numbers of samples
- Disease-specific suggestions were also made for new products available for investigation.

of NID: those (such as human African trypanosomiasis and leishmaniasis) where the need is to be able to diagnose individuals, determine stage, and demonstrate cure; and those (such as filarial diseases) where there are MDA programmes, so point-of-care tests are less important but tests are needed to detect the development of resistance and to determine when elimination has been achieved. Tests are also needed that will identify sub-clinical/asymptomatic infections and the stage of infection, and to monitor populations post-elimination. And it is necessary to establish whether a newly diagnosed case is re-infection or relapse. Obtaining funding for all this is challenging.

Other points made in the discussion were as follows.

- Human African trypanosomiasis is an example of a disease affecting people who are poor and live in remote areas. Accessing affordable treatment is a real problem. They cannot afford a test and do not want one that involves lumbar puncture
- Other examples of NIDs where there is a pressing need for better tests are soil-transmitted helminthiasis, schistosomiasis and mycetoma
- The regulatory procedures for diagnostics are not as stringent but there is still an approval process and this should be followed. Indeed it should be strengthened to ensure quality

- Burden is of course important in determining priorities but we have to be careful how we define burden (with leprosy for example there was no clear decision on the criterion for elimination), and it must not be the only consideration
- Diagnostic tests must be affordable and simple to use. People in the field do not have time to study slides closely. New urine testing now available for schistosomiasis is an example of what can be achieved. Cross-cutting multiplex platforms would in particular make things simpler in the clinic
- It was again agreed that identifying new biomarkers is a priority in order to develop new tests
- Some promising developments at bench stage have not been pursued. We need to find out why
- A new area for diagnostic research now emerging is environmental DNA-based testing, which could have a great impact in control programmes
- Diagnostic advances have tended to lag behind treatment
- New tests will have limited impact if there is no functioning public health system.

Summing up, Prof. Elliott noted that much of the discussion had been general; relatively little had been said on specific diseases. She also identified a number of key points – see Box 2.

3. Second day

Introduction to the second day: Marja Esveld

Ms Marja Esveld, Senior Policy Advisor of the Department for Social Development, Ministry of Health, Welfare and Sports, made reference to the continuing global economic problems. Speaking as EDCTP General Assembly representative for the Netherlands, she said it would be necessary for funding bodies to coordinate and align their research agendas and harmonise approaches. The work of EDCTP2 would be important in its own right but would also encourage individual member states to align their agendas. She looked forward to a new era in which PDPs would work more closely together and draw on each others' strengths.

DNDi presentation: Dr Nathalie Strub Wourgaft

Dr Nathalie Strub Wourgaft, Medical Director of the Drugs for Neglected Diseases initiative (DNDi), presented data from a forthcoming DNDi review of new products currently at clinical trial stage. Thirty-four (27.6%) of such trials concern NTDs, compared with 37 on malaria, 19 on tuberculosis and 15 on diarrhoeal diseases. DNDi categorises research need into three groups: 0 – diseases where there are no critical research gaps as preventive interventions and at least three treatments are available; 1 – diseases where there are R&D gaps but some ongoing clinical trials; 2 – diseases where there are critical gaps but no ongoing research.

The presentation continued with a description of DNDi's portfolio-building model and its current portfolio 'landscape'. Dr Strub Wourgaft

gave particular detail on DNDi's visceral leishmaniasis programme. Progress is also being made on human African trypanosomiasis; the target is oral treatment plus a rapid diagnostic test by 2016. A filariasis programme (including macrofilaricide research) is also under way.

Amongst the issues highlighted by Dr Strub Wourgaft were the needs for reliable surrogate markers of efficacy and to better define normal laboratory ranges. Areas where more research is needed include paediatric clinical development studies, late-stage trials and pharmacovigilance studies.

DNDi has three clinical platforms to strengthen research capacity in endemic countries; the platforms help define needs and DNDi does not proceed with programmes unless the platforms agree on the need. Like EDCTP, DNDi is committed to a partnership approach.

Comments

- There was strong agreement regarding the need for better reference values; studies are needed with healthy African people to establish appropriate 'normal' values. However, it was cautioned that some of the data currently being collected that is found to deviate markedly from accepted reference points could be the result of inaccurately performed tests. Poor nutritional status could also be responsible for many instances of low values recorded. (DNDi has compiled data from unpublished papers on which it has based its own reference values, but this is still only on an 'unofficial' basis)
- Many drugs are given in combination form, and it is often necessary to treat patients for more than one condition concurrently. The issue of drug–drug interaction therefore needs more consideration. Clinical trials of combined visceral leishmaniasis-HIV trials are one instance where studies have been done in a pragmatic way, establishing

1 Defined here as: cutaneous leishmaniasis (10 trials), dengue (6), visceral leishmaniasis (4), Chagas (3), schistosomiasis (3), rabies (2), echinococcosis (1), hookworm (1), human African trypanosomiasis (1), lymphatic filariasis (1), onchocerciasis (1), and cysticercosis/taeniasis (1).

that the combinations used are safe and well-tolerated

- Clinical trials on special patient populations especially children, pregnant women and lactating mothers though challenging need to be done
- The dangers of the emergence of drug resistant strains must always be kept in mind. Combination therapies still offer the best hope in reducing the rise of resistance
- There are many institutes in Europe with excellent facilities which could contribute to NID research
- Praziquantel is held in high regard as a treatment for schistosomiasis but cure rates are never 100% and can be as low as 20%. There is a strong case for developing a new treatment. Similarly a better lymphatic filariasis treatment than albendazole is required.
- There are anti-fungal drugs (azoles) in use for other conditions which have yet to be trialled against mycetoma. Combination therapy for this disease should be trialled (e.g. terbanafine plus an azole)
- EDCTP was encouraged to collaborate with DNDi to minimise duplication of efforts.
- Africa needs more centres able to conduct phase I clinical trials
- The development of improved drugs will have limited impact unless NID control programmes are integrated within effective health services.

Prof. Gyapong asked, as Co-chair, that if anyone had further information concerning drugs that were in the pipeline then they should share it with EDCTP. Prof. Charles Mgone also requested that people should tell EDCTP what they thought the partnership should do to advance NID research. The other Co-chair, Prof. Elliott, identified key points from the discussion on drugs – see Box 3.

Box 3: Drugs – key points

General action points

- Advocacy for restarting development of potentially useful drugs that have ‘lost their champion’
- Research is needed on: both new drugs and re-purposing existing drugs; drug combinations, including combinations of old and new drugs; potential clinical adverse effects, especially of long-term treatment; use in young children (for which suitable formulations will be needed); use in pregnancy (international guidelines should be used but applied locally through national authorities); drug resistance
- Implementation studies are also required: to validate strategies that fit with the epidemiological situation; in which interventions are integrated with national control programmes; in which integrated control of NIDs is a feature; in which pharmacovigilance is an important part
- Normal laboratory ranges for Africa should be established
- Areas where research is needed on interventions other than drugs: vector control; sanitation improvements; combination interventions against individual diseases; combination interventions against multiple diseases.

Disease-specific action points

- Leishmaniasis
 - Many products are in the pipeline, but the attrition rate should be allowed for;

the aim should be an oral treatment (used in combination form) for visceral leishmaniasis and for *Leishmania braziliensis* and *L. tropica* cutaneous leishmaniasis

- The treatment of visceral leishmaniasis in HIV-infected patients
 - *L. aethiops*
 - FP7 drug discovery.
- Human African trypanosomiasis
 - Oral treatments in clinical development and implementation
 - Combination treatments will still be needed
 - Field studies of oral drugs.
- Filariasis
 - Continue moxidectin research
 - *Wolbachia* research must continue, including use in combination with antibiotics
 - DNDi is also active in this area and collaboration should be considered.
- Schistosomiasis
 - Praziquantel resistance
 - Poor cure rate
 - Paediatric formulation
 - FP7 candidates.
- Soil-transmitted helminthiases
 - Even worse cure rates for some
 - Albendazole/mebendazole resistance.
- Trachoma
 - Drug resistance.
- Yaws
 - Can a lower dose of azithromycin be effective?
- Mycetoma
 - New antifungals could be trialled.

Partnerships and collaborations: panel presentations

Representatives from six key organisations then gave brief accounts of their present position regarding NIDs.

Dr Ole Olesen, principal scientific officer for global health research at the European Commission’s Directorate-General for Research & Development, spoke of the forthcoming Horizon 2020 funding programme which begins in 2014. He said EDCTP was the

strongest example of the type of North-South collaboration that the EC wants to encourage. Discussing the requirements for a good partnership, he likened partnership to marriage – it takes time to find the right partner and hard work is then needed for the partnership to flourish, and for the divorce rate to be kept low.

Dr Morven Roberts, programme manager for global health infections and global health trials with the United Kingdom’s Medical Research Council (MRC), spoke of the need for ‘mature and structured’ partnerships. She cited MRC’s collaboration with the Department

for International Development. MRC is mainly interested in phase II-IV clinical trials and needs investigators to work in consortia – academics, national programmes, health ministries, health facilities, patients. To power clinical trials adequately patients often have to be recruited in more than one country. MRC believes that getting affordable products into health care policy and practice is more important than publication of papers in high-impact journals. Capacity building is a cross-cutting theme in MRC programmes.

Dr Jutta Reinhard-Rupp, head of access to health R&D partnerships at Merck Serono, spoke as representative of a consortium developing a new paediatric formulation of praziquantel. (The present formulation is a big tablet unsuitable for children, who can be infected as early as three months old.) The consortium is seeking additional funding and also manufacturers in endemic countries, including in Africa. There is still much to be settled including how the product will be provided; as it is for individual case management, not mass drug administration, donation is unlikely to be feasible. Industry has to rethink how it goes about R&D, particularly with regard to NIDs and to paediatrics.

Ms Martina Gliber, international partnership manager for Fondation Mérieux, welcomed EDCTP's move into NID research and also its focus on collaboration, capacity building, access and affordability. Partnership is needed across the board including partnerships between scientists with different expertise. Fondation Mérieux set up a scholarship programme for African postdoctoral researchers in 2008. In establishing partnerships it is necessary to have memoranda of understanding to define responsibilities. Adaptability is important, depending on the partner; one size does not fit all.

Dr Christain Loucq, Director-General of the International Vaccine Institute, explained that IVI is an independent programme (with 25 signatories) based in South Korea, where it receives support from the government and from industry. He said donors should have regular updates on progress to keep them motivated. IVI's three-way partnership to develop a dengue vaccine is progressing but money remains a problem; funders change constantly and they change their priorities. Building a back-up plan is important in case funders pull out. He urged scientists to talk to others in different specialities; for example, diagnostic researchers often had no links with those focused on drugs. Sometimes funders can bring them together. IVI had learned many lessons from its experience to date, one of which was the need to strengthen pharmacovigilance in Africa. He also noted the importance of collaborating with GAVI, noting that GAVI had its own ways of working that many do not understand.

Dr John Reeder, Director of the UN Special Programme for Research and Training in Tropical Diseases (TDR), welcomed EDCTP's addition of NIDs to its portfolio, which now closely resembles that of TDR; he looked forward to EDCTP-TDR collaboration. He spoke of the importance of building an evidence base for new interventions; African countries should be supported to generate such evidence themselves. While the meeting had been very broad in its coverage of diseases and types of intervention, there was no need for EDCTP to involve itself in everything; it should establish the areas in which others are already active and seek to collaborate. He also noted that one theme of the meeting was the need to predict change – will the treatment continue to work, when mass drug administration can be stopped, etc. He described some of TDR's latest initiatives and hoped to be able to collaborate with many of the institutions represented at the meeting. He concluded that there should

be ‘no research without capacity building and no capacity building without research’.

Comments on panel contributions: how to work in partnership

The discussion largely concerned how the organisations concerned might collaborate with EDCTP. Most frequently mentioned was the need for more funding. EDCTP gives grants for clinical trials, but also aims to bring in additional support from other partners. Cofunding is likely to become more important as many programmes need more finance than one funder can provide. Charles Mgone pointed out, however, that partnership means more than just being a funder; development of lasting partnerships is a long-term investment requiring mutual respect of all partners involved and balanced sharing of responsibilities and benefits. Also mentioned was the need to stimulate entrepreneurship in Africa and to create a sense of ownership. More effort was needed to bring francophone African countries into partnerships. Industry partnerships with EDCTP should also be expanded; the Sanofi-WHO partnership on visceral leishmaniasis research was suggested as a model. Spain could be asked to collaborate in visceral leishmaniasis research as it has the necessary expertise. It was agreed that EDCTP has a role to play in partnerships as an honest broker. EDCTP was urged to avoid creating another ‘silo’ for NIDs – lessons, experience and skills should all be shared. No one organisation should try to do everything; working as a team leads to greater efficiency.

Key requirements for a successful partnership identified by Co-chair Alison Elliott are presented in Box 4.

Box 4: Partnerships – key requirements for success

- Trust and mutual respect
- Equality
- Common objectives
- Clear agreements on responsibilities
- Agreement on IP and profits
- Keeping the interests of all partners in mind
- Contributions made according to means
- Balanced governance
- Costs managed effectively
- Must deliver more than the sum of parts
- Maintain interaction with end users/ implementers.

Capacity building

Michael Makanga said the following capacity building measures had been part of EDCTP’s programme so far.

1. Capacity building and networking components were included within all trial support, both short and long-term (the latter including MSc, PhD and postdoctoral training)
2. The Senior Fellowship scheme, in which research projects, infrastructure development, training of research team members and salaries of team members are supported, enables hands-on learning
3. The NoEs also have infrastructure development and training activities that built both laboratory and clinical skills in the fields of HIV, malaria, TB and cross-cutting disciplines that support proficiency in clinical research
4. An EDCTP mentorship scheme in collaboration with pharmaceutical company partners is forthcoming; the intention is that those trained will gain experience of conducting regulatory clinical trials

-
5. Ethics capacity development – including training, infrastructure development, improved coordination and mapping of ethics capacity in Africa – is also provided.

Co-chair Alison Elliott said that capacity building had been mentioned as a priority in all the sessions of the meeting so far. Topics already raised had included:

- research ethics
- regulatory capacity – e.g. for field testing of diagnostic products
- models for clinical trials
- platforms for trials
- capacity for monitoring
- good manufacturing capacity
- pharmacovigilance for drugs and quality assurance for diagnostics
- fellowships and their role in creating ‘adaptable’ people
- training on epidemiology and biostatistics.

Further contributions from the floor were then invited and the following issues received attention.

- Sustaining technical capacity is a key issue; EDCTP–DNDi collaboration could assist here
- Care must be taken so that capacity building does not result in the creation of a separate ‘silo’ for NID research
- Hands-on training within the pharmaceutical industry is desirable; for example there is EU funding for such training in vaccinology that it is not presently open to non-EU nationals but could perhaps be opened to African researchers
- A database should be maintained, perhaps by WHO, containing the details of all those who have been trained. This would assist in finding employment and in putting skills to use; industry would also find it useful. Trial registers could perhaps offer a starting point for such an exercise. The HERO

website (www.the-hero.org) was mentioned as another possibility. EDCTP is already considering this issue

- Good practice should be identified and monitored as part of capacity building programmes
- While most of the capacity building discussion focused on human capacity, equipment and other resources available should also be strengthened. Technicians must be trained to maintain equipment
- There is no need for a separate EDCTP scheme for masters and PhD training on NIDs; such training can be provided through expansion of existing arrangements
- Management skills, especially finance, should also be considered – likewise skills for quality assurance and audit
- The importance of epidemiological training received strong support from the meeting. The distance learning course in epidemiological analysis of the London School of Hygiene & Tropical Medicine was mentioned as being particularly useful. The School will be launching a mixed-mode course combining distance learning with face-to-face teaching in Tanzania. More such courses are needed in the French language; there is one run jointly by the universities of Burkina Faso and Montpellier. EDCTP has supported such courses and provided scholarships. In some US-based courses, students move from country to country to gain hands-on experience; this has much to recommend it
- The industry would also benefit from improved availability of people trained in epidemiology; presently companies are often unable to decide where best to site their own trials because of a lack of epidemiological data
- Much of the work in clinical trials is done by trial nurses and more could be achieved if the number of suitably trained nurses is increased

- The concept of training adaptable individuals (i.e. professionals with skills that can be used across several disease areas) proved controversial. An increased number of generalists who can move from one study to another could offer many advantages in terms of efficiency. However, while for example people who have been trained in the running of a malaria trial can use their skills in clinical trials on other diseases, specialist skills are needed to, again for

example, diagnose the ocular manifestations of onchocerciasis. Adaptability is desirable but not always feasible.

Key issues for capacity building identified by Prof. Elliott are summarised in Box 5.

Box 5: Capacity building – key issues

- Supporting integrated projects (research infrastructure development; short-term and long-term training (Masters, PhDs and post-doctoral training); and baseline studies to support development of future clinical trial centres)
- Training mid-level staff: nurses, laboratory managers, project and finance managers, etc.
- Senior fellowships
- Regional NoEs: consider a link to DNDi disease platforms; include research management support
- Mentorship fellowship scheme: consider collaboration with TDR to broaden experience offered
- Ethics capacity building: take note of vulnerable groups and populations
- Epidemiology, statistics and modelling capability
- Improve the regulatory environment for field testing of diagnostic products and development of combination treatments
- Clinical trials capacity needs to be improved with regard to: monitoring, provision of sponsorship, trial platforms, phase I trials
- Capacity building to make possible the immunological studies required in vaccine trials
- Appropriate courses to be made available as follows include: short courses on immunology and vaccinology; courses in French; distance learning (web-based and dual approach); courses in which the talents and experience of retired personnel are put to use
- Technology transfer
- Good manufacturing practice
- Pharmacovigilance
- Quality assurance capacity for diagnostics
- Audits for potential clinical trials' sponsors
- Career development: fellowships through partnerships; 'adaptability' through training
- Social science
- Partnership capacity to be developed with regard to: legal aspects; knowledge of IP; there should be a real balance of benefits
- Information about capacity should be shared through funder-related and industry-related websites.

4. Conclusion of the meeting

The meeting ended with a comprehensive summary compiled by Co-chair Alison Elliott of the main issues identified and recommendations that were made. This summary formed the basis of the executive summary at the beginning of this report.

The main recommendations are summarised for the following themes: Vaccines, Diagnostics and Biomarkers, Drugs, and Capacity Building.

Vaccines

- Improve mapping of disease prevalence and public health importance
- Systematic reviews of previous studies
- Research should include assessment of the non-specific immunological and clinical effects of vaccines
- Evaluation of responses is required in a range of settings
- Development of vaccines from inactivated parasites should be investigated
- Development of human challenge models should be considered
- Vaccination of the vector and intermediate/alternative hosts should be considered
- Compare the impact of anti-helminthic treatment given before or at the time of vaccination
- Agreements are needed on access to and affordability of vaccines that have been trialled using public funds.

Diagnostics and biomarkers

- Effective diagnostic tests (based on appropriate biomarkers) are needed for several different purposes, varying with disease characteristics and epidemiology
- Studies are needed to evaluate new or existing tests; disease-specific target product profiles are also needed
- Specific issues to be addressed regarding human African trypanosomiasis include re-staging, test of cure and the need to obtain

less invasive methods that circumvent use of lumbar puncture

- NIDs affect very poor and sometimes remote populations, for whom tests must be made available free of charge
- Measures of transmission rates should be developed
- Tests are required to make possible monitoring in intermediate/alternate hosts and vectors
- Prioritising tests for support is complex – not only prevalence but also the complexity and severity of diseases should be considered
- The development of simple multiplex platforms, ideally capable of using supplies from multiple companies, would greatly assist in activities in the field
- Disease-specific suggestions were also made for new products available for investigation.

Drugs

General recommendations

- Advocacy is needed to restart development of potentially useful drugs that have “lost their champions”
- Research is needed on: new drugs, re-purposing existing drugs, drug combinations, potential clinical adverse effects, use in young children, and use in pregnancy
- Health services implementation studies are required: to validate strategies that fit with the epidemiological situation; in which interventions are integrated with national control programmes; in which integrated control of NIDs is a feature; in which pharmacovigilance is an important part
- Normal laboratory ranges for Africa and Africa sub-regions need to be established
- Research is needed on alternative and complementary interventions to drugs: e.g. vector control, sanitation, and combination interventions against individual or multiple diseases.

Disease-specific recommendations

- Leishmaniasis:
 - Many products are in the pipeline but attrition should be allowed for
 - The aim should be an oral treatment for visceral and cutaneous leishmaniasis
 - Effective treatment is needed for visceral leishmaniasis in HIV-infected patients
 - Combination treatments are still needed
 - Field studies of oral drugs are required.
- Filariases:
 - Continue moxidectin research
 - Wolbachia research must continue, including use in combination with antibiotics
 - The Drugs for Neglected Diseases initiative (DNDi) is active in this area and collaboration should be encouraged.
- Schistosomiasis:
 - The potential for praziquantel resistance and reduced efficacy is a concern
 - Paediatric formulation is needed.
- Soil-transmitted helminthiasis:
 - Cure rates are often low
 - The potential for albendazole/mebendazole resistance is a concern.
- Trachoma:
 - The potential for drug resistance is a concern.
- Yaws:
 - Need to investigate efficacy and effectiveness of a lower dose of azithromycin
- Mycetoma:
 - Need to do clinical evaluations of new antifungals.

Capacity building

- Support integrated projects; research infrastructure development; short-term and long-term training (Master's, PhD and post-doctoral training); and baseline studies to support development of future clinical trial centres
- Support training for mid-level staff involved in clinical trial teams: nurses, laboratory managers, project managers, and finance managers among others.
- Training is particularly needed in epidemiology, statistics, modelling capability, immunology and vaccinology
- Support senior scientists and mentorship/career development fellowships. For the latter collaboration with other organisations like WHO TDR should be encouraged to broaden experience offered
- Support Regional Networks of Excellence (NoEs) and encourage linkage with existing regional disease platforms
- Ethics capacity building taking note of vulnerable groups and populations. NIDS tend to afflict the poorest of the poor and their rights need to be protected
- Improve the regulatory environment for field testing of diagnostic products and development of combination treatments
- Clinical trials capacity needs to be improved with regard to monitoring, provision of sponsorship, trial platforms, phase I trials infrastructure
- Pharmacovigilance, social science studies and quality assurance capacity for diagnostics
- Partnership capacity to be developed with regard to: legal aspects; knowledge of IP; better balance of benefits
- Information about capacity should be shared through funder-related and industry-related websites
- Engage with national institutions (universities, research institutes, vector control programmes), whether EDCTP funded or not,

so that completed projects will leave behind infrastructure and human capacity capable of supporting new projects.

These recommendations will inform EDCTP in the planning of the second phase of its programme.

Annex 1. List of participants

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