

### Violent numbers in Brazil

- Homicides are now the first cause of death from other than natural causes (36% of such deaths), followed by traffic accidents (26%). In the 1980s, it was the other way round: traffic accidents were the first cause (33%), followed by homicides (17%).
- Men account for 84% of deaths from other than natural causes.
- For every 15 men of 20–29 years old who die by shooting, there is only one woman who dies in this way.
- The homicide rate among youths rose from 30% of deaths in 1990 to 49% in 2000.
- 75% of the deaths caused by accidents and violence occur in urban areas.
- According to the Ministry of Health, about 8% of the expenses for public hospital stays — without taking into account emergency wards — are incurred by accidents and violence.

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and the wounded arrive lacerated in the emergency wards; the public hospitals do not always possess the appropriate training for such multiply traumatized victims.”

According to Maria Helena Prado de Mello Jorge, epidemiologist at the University of São Paulo, the national policy has a comprehensive vision, including action in related areas such as justice and education. None of these areas, nor the health sector alone, could eliminate the high crime rate in the country. A multisectoral vision like that of the national project is indispensable. Others point out that the “national policy for the reduction of accidents and violence” is still in its initial phase of implementation. Only if it is fully implemented by the government will it have a significant impact on the reduction of the morbidity and mortality rates. ■

Claudia Jurberg, *Rio de Janeiro*

### New non-profit organization will support research to combat neglected diseases

Of 1393 new pharmaceuticals marketed between 1975 and 1999, only 16 were for tropical diseases and tuberculosis. This finding from an exhaustive review of international, European and American medical databases was published in *The Lancet*, 2002, 359: 2188-94. There will be “no sustainable solution” for diseases that predominantly affect poor people in the South without an international pharmaceutical policy for all neglected diseases, say the authors. They have been working for the past three years on a Drugs for Neglected Diseases Working Group for the medical charity Médecins Sans Frontières (MSF), which aims to set up a new body to tackle this problem.

Piero Olliaro of the UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR), who was one of the authors, told the *Bulletin*: “In the first place you have to distinguish between diseases where public-private partnerships have a chance of working, like malaria and tuberculosis, and diseases which are not prevalent enough, which aren’t visible enough, which have no advocacy; and they don’t stand a chance. That’s where — we are saying — something new is needed. The public sector really has to take the lead for neglected diseases like sleeping sickness or Chagas disease.”

However Olliaro admits there can still be public-private breakthroughs — as there was recently for visceral leishmaniasis (kala azar). TDR, the Indian Council for Medical Research and the German company Zentaris (previously ASTA Medica) supported research in India which earlier this year yielded oral miltefosine, a failed cancer drug which has now been shown to cure kala azar 98% of the time, with few side-effects.

“So even for the neglected diseases you will bump occasionally into something you can develop” said Olliaro; “but to do that systematically we’re saying that the public sector must take the lead with significant amounts of money to discover those products, and then to make sure they are turned into effective and affordable drugs”.

In partial response, MSF is catalysing the creation of a new entity — the Drugs for Neglected Diseases initiative, known as DNDi — to help do the research and create the needed products. The body will be a joint undertaking of MSF and several public research institutes in the North and the South. The actual drug development work is to be done by a wide range of public and private partners, including the pharmaceutical industry.

While DNDi primarily aims to build on public responsibility and public sector research capacity, industry remains important because of its massive catalogues of active compounds, compound development and testing schemes and scientists.

“We have met extensively with the pharmaceutical industry — we are looking for their close attention and support, through the cooperation of individual groups in the pharmaceutical industry” said Yves Champey, director of the feasibility study for DNDi. “Because what we will need, project by project, will be clearly not money, but access to industry expertise and special tools.”

Champey told the *Bulletin* that the organization should be ready to go into operation by mid-2003. He and the DNDi team have been in close contact with TDR and WHO “from the very beginning”, and they are now working to see how the two can be “active members” of the initiative.

Seed money for setting up DNDi will come from MSF, but the bulk of the actual R&D work will be financed project by project, with funding from governments, international organizations and large foundations. “And there will be one additional funding path: raising money from ordinary individuals, at \$20, \$50 a time, will be one of our big sources of money. I don’t know what proportion. This will be one of our striking differences” Champey said.

Apart from the fund-raising techniques, DNDi’s objectives may seem little different from those of existing organizations like TDR. “We do not pretend to be better, we will simply try to add to their efforts” said Champey.

Carlos Morel, Director of TDR, told the *Bulletin*: “TDR, WHO and DNDi are working on a memorandum of understanding between us. MSF have been in drug access issues for a long time, but the DNDi is a different kind of venture. There’ll be a DND Working Group meeting in Rio de Janeiro in December, and we hope by then any remaining issues will be resolved.”

DNDi will be a separate organization from MSF - which will be only one of the six to eight founding organizations. MSF is a fieldwork and campaigning organization, often opposed to the special interests of the pharmaceutical industry, whereas DNDi needs to establish friendly relations with companies.

TDR believes the best approach is to squeeze the most out of each source, both public and private, says Rob Ridley, Coordinator for Product Research and Development at TDR. "Our experience is that if you have a very specific proposal that may do some good, that's professionally thought through, then very often companies are more than willing to participate. In fact most of TDR's successes have resulted from major input from industrial partners."

TDR is already working with industry on two scientifically related neglected diseases – leishmaniasis and trypanosomiasis, both caused by "kinetoplastid" organisms. "We received a fairly substantial sum from Aventis for work related to African trypanosomiasis (sleeping sickness); and we've had some seed funding from industry to push forward and try to identify products for kinetoplastids as a whole" said Ridley.

David Heymann, Executive Director for Communicable Diseases at WHO, adds "We need better tools for neglected diseases, but we shouldn't forget that we've also had some great donations of existing drugs. We need to use every tool we've got. To see an end to diseases that have been around for centuries is an opportunity we just can't miss." ■

Robert Walgate, *Bulletin*

## Europe finds US\$ 200 million to support African clinical trials

At long last the European and Developing Countries Clinical Trials Partnership (EDCTP) is set to begin its work next year, with a focus on Africa. The European Commissioners — the top bureaucrats of the European Union — approved what should be a US\$ 200 million four-year programme, with more to come if nations and donors, including industry, are prepared to support it.

Professor Antoni Trilla of the University of Barcelona is the Coordinator of the EDCTP. He and his colleagues describe its five main objectives as: first, supporting the networking and pooling of trials within the EU (largely Phase I trials); second, supporting the networking and pooling of trials in Africa; third, supporting the

development of infrastructures for trials in Africa, especially through capacity-building and training; fourth, actually sponsoring new clinical trials, attracting external sources of co-financing, particularly with the European biopharmaceutical industry; and fifth, developing a European, rather than national, presence in international initiatives for research and development to combat HIV/AIDS, tuberculosis and malaria.

But despite three years of gestation — and a final positive meeting with the Director-General of WHO, Gro Harlem Brundtland, this June — the EDCTP is still not completely approved: the next hurdles will be acceptance by the European Parliament in October, and then by the final political governing body of the 14-state European Union, the Council of Ministers, plus one outside partner — Norway. Approval is scheduled for "early next year", and Commission staff are expecting no difficulties.

Marie-Paule Kieny, director of the WHO Initiative for Vaccine Research, says: "We've had several meetings with the EDCTP but programmes of this size at the EU usually take months to materialize!" Nevertheless the programme will be welcome. "There are clinical trial sites in Africa for testing for each of the three diseases, but they are scattered, the resources are not enough and the networking is poor" says Kieny. "And the EDCTP has impressive funding".

The EDCTP has in fact billed itself as a US\$ 600 million programme, but only US\$ 200 million of this will come from the Commission itself, and data on the source of the other US\$ 400 million are somewhat hazy. US\$ 200 million is to be added by member states, but there is no guarantee they will cough up — and, if they do, whether it will be new money. The remaining US\$ 200 is hoped for from industry or other partners.

José Esparza, who has been responsible for HIV/AIDS vaccinology at WHO but now deals with all viral vaccines, has also been involved in the partnership. "At the beginning the idea was very European" — coordinating European trials programmes — and WHO and African partners had to press harder for "a meaningful participation" of developing countries in the programme. "But I think they are going in that direction".

Antoni Trilla confirms that while the governance structure will involve

a Steering Committee with two representatives from each European Union country, there will also be a Working Group with fifteen Europeans and fifteen Africans, a Management Group with five Europeans and five Africans, and a Coordination Team consisting of one African and one European.

But, no doubt making the task of EU officials look even harder and more time-consuming, Esparza believes that yet more coordination is required: "The EDCTP can only succeed if they coordinate with other efforts. The last thing we want to see is Americans and Europeans and others fighting for sites in Africa ... But it's a good initiative and we are strongly supporting it."

What's really needed, according to WHO experts, is to develop and coordinate African trial sites. "What is a trial site? It is a population with the appropriate epidemiology of the disease you want to work on. You can't study leishmaniasis in Switzerland!" said Esparza. "Then you need the scientific infrastructure, political support, and community support in the region. Those four things will make a working trial site."

But, he said, you need to consider ethics, which entails community involvement. This is becoming essential. The concept of a "site" is "something that is evolving" says Esparza. "In the past a site was where foreign investigators could come to a country and do research to take their samples back home and publish a paper. That concept has gone. The sites we're talking about, and that EDCTP wants to develop, are ones with *ownership* in the country, as that's the only way to ensure continuity, and the appropriate investment of time and resources."

Marie-Paule Kieny also argues that Africa needs to build the capability to do some of the immunological testing on-site, "which is still often done in Europe or the US". Kieny would like to see the EDCTP support networking of existing and new facilities. "For example the International AIDS Vaccine Initiative is investing in Kenya and Uganda to do very complex immunological analysis. This kind of capacity could be used for more than one disease. So I'd like to investigate networking these. EDCTP should be helping us with that." ■

Robert Walgate, *Bulletin*