

Researchers argue that unsafe injections spread HIV more than unsafe sex

Three recent studies challenge the assumption that the main cause of the spread of HIV in Africa is unprotected sex. They argue that it is unsafe injections, which transmit the infection on a far larger scale than has previously been thought.

Most experts assume that unsafe sex between men and women is responsible for 90% of HIV infections in sub-Saharan Africa. The medical reuse of contaminated needles and syringes is thought to account for another 5%. The authors of the controversial trio of papers recently published in the *International Journal of STD and AIDS* (2003;14;144-73) take a radically different view.

Using data culled from two decades' worth of studies, researchers led by Pennsylvania-based consultant David Gisselquist estimate that sexual transmission causes only 30% of the HIV infections in Africa. They also argue that contaminated needles and syringes used for medical treatments led to 48% of the HIV infections through 1988, when, Gisselquist says, scientists first labelled unprotected sex as the main driver of the African epidemic.

Gisselquist and his colleagues highlighted their argument with anomalies in the epidemiology of HIV south of the Sahara. For example, they note that HIV spread by 12% a year in Zimbabwe during the 1990s, while other sexually transmitted diseases declined by 25% and condom use increased. They mention the occurrence of HIV in infants whose mothers are not infected. And they point out that African countries with the best access to medical care sometimes have the highest rates of HIV infection.

"Botswana makes a tremendous effort to get health care to rural districts," says Gisselquist. "Yet, the country has the highest prevalence of HIV in the world and it is fairly evenly distributed across urban and rural districts. In most countries, there is a huge disparity between urban and rural rates of HIV."

Such examples are "associations, not cause and effect," says Catherine Hankins, Associate Director of Strategic Information at UNAIDS. She also disputes the methodology the researchers used to estimate the contribution of unsafe injections: "They don't present new data or findings — they take data from studies designed to answer other kinds of questions."

While estimates of 5% versus 48% are "not even in the same ballpark," says Hankins, there is common ground. Experts agree that non-sexual transmission of HIV infection needs to be accurately assessed. To date, no epidemiology study, in Africa or elsewhere, has attempted to determine the proportion of HIV coming from unsafe injections. "In the absence of appropriate data," says Yvan Hutin of the Blood Safety and Clinical Technology Department at WHO, "various opinions can be expressed."

To get a better handle on the problem, on 13 March WHO and UNAIDS brought together several experts, including Gisselquist, for a two-day workshop focused on unsafe injection practices and HIV infection. The participants reaffirmed that unsafe sexual practices are responsible for the vast majority of HIV infections in sub-Saharan Africa, and that the promotion of safer sex must remain the mainstay of prevention programmes (see WHO News, p. 311). They also discussed ways to determine the magnitude of the problem of unsafe injections, collect the necessary scientific data and eliminate it altogether. Hutin, who heads the Safe Injection Global Network, or SIGN, estimates that 6.4 billion sets of needles and syringes are needed each year in developing countries to ensure that all injections are safe. ■

Charlene Crabb, *Paris*

No deal in sight on cheap drugs for poor countries

Trade talks on giving poorer nations access to cheap life-saving drugs broke down on 20 February after the United States, under pressure from its powerful

pharmaceutical lobby, rejected a new set of proposals.

Negotiators said it was unlikely a deal could be reached before September, when trade ministers gather for the next ministerial meeting of the World Trade Organization (WTO) in Cancun, Mexico. "If it hadn't been for the US there would have been a solution that would have satisfied everyone else long ago, but now positions have become entrenched," said one United Nations official.

The US has faced widespread criticism for blocking the deal in December, forcing negotiators on the WTO's Trade-related Aspects of Intellectual Property Rights Council, known as TRIPS, to miss their deadline for agreement at the end of 2002. But diplomats say countries like France, Germany and Switzerland which also have large pharmaceuticals industries, were secretly relieved that the deal did not go ahead in its current form.

It was the second time negotiators from the 144 WTO member states met this year in an attempt to salvage the deal which was blocked by the US on 20 December last year. The trade agreement, which has been 18 months in the making, is aimed at saving the lives of millions of people with illnesses such as AIDS, malaria and TB who die because their countries cannot afford the drugs needed to treat them.

Diplomats from developing countries said further delay would cost millions more lives and could fuel antiglobalization protests such as those seen at the WTO Seattle meeting in 1999. "If they [the US] wait until Cancun it will become a politically explosive issue and they will run the risk of raising public opinion against them," said Faizel Ismail, the head of South Africa's delegation to the WTO.

At issue are precious drug patents that protect pharmaceutical companies' multimillion-dollar business by preventing their products from being reproduced and sold without permission. The aim of the talks is to give the world's poorest countries access to HIV/AIDS test kits and lifesaving drugs, as well as drugs for diseases such as Ebola haemorrhagic fever, African trypanosomiasis, cholera, dengue fever, and typhoid fever.



WHO/TDR/L. Maurice

A child on malaria medication in Viet Nam, restrained to prevent injury in case of convulsions.

Trade ministers of WTO member nations agreed at the last ministerial meeting in September 2001 in Doha, Qatar, to waive patents under certain circumstances so that cheap generic copies of such drugs could be produced for poor countries facing devastating epidemics and public health crises.

According to the Doha Declaration, a country that cannot afford to pay market prices for such drugs may issue "a compulsory licence" compelling a patent holder to license a producer to manufacture cheaper generic versions of the patented product.

The producer could be based in the licensing country, but would usually be in another developing country, such as Brazil, China or India with the capacity to manufacture drugs. Washington fears the system could be open to abuse and that drugs produced under compulsory licence for poor countries may be diverted to richer, more developed ones to undercut drug markets — something most countries argue is hypothetical and should be handled separately if and when it happens.

Observers also note that although the US was the only country to reject the draft agreement in December, several developing countries with large generic drug industries like Brazil and India have stood in the way of a compromise deal with the US. "The interests of countries like India and Brazil are not identical with those of poor developing countries which do not have the capacity to produce their own drugs," the UN official said on condition of anonymity.

His comments underscore another sticking point, which is the fear of industrialized countries that if the drugs included in the deal are limitless, poor countries might abuse the system by issuing compulsory licences on lifestyle drugs, such as Viagra, or non-infectious illnesses such as diabetes or asthma.

To avoid such a situation, the US has proposed limiting the deal to seven of the world's "worst" infectious diseases, including AIDS/HIV, malaria and TB. Most developing countries reject this, saying it is impossible to predetermine which are the "worst" epidemics, and insist they should be allowed to decide public health priorities for themselves. But some developing countries, like Brazil and India, with large generic drug industries, are opposed to limiting the number of diseases on the list for another reason.

"They have such huge generic drugs industries that they would like to see more diseases included so that they can sell as many drugs as possible," the UN official explained, adding: "This does not help poorer countries that are desperately in need of these drugs either".

Developing countries have also rejected a proposal by the European Union to ask WHO to decide whether the public health situation in a poor country qualified: "No one can predict when a situation will become serious for many countries. We don't want to limit the scope of countries. Once you start making a list, you exclude others," Mr Faizel from the South African delegation said.

In an attempt to reconcile the concerns of both the US and poorer countries, Eduardo Perez Motta, Chairman of the TRIPS council, drafted a statement in addition to the original trade agreement. In it, all countries reaffirm their commitment to the international patents system and make it clear that the waiver on patent rules was intended primarily for use in national health emergencies, such as the HIV/AIDS pandemic. ■

Fiona Fleck, *Geneva*

Scientific publishers consider censoring "dangerous" research

In what some consider a pre-emptive strike to avert heavy-handed US government regulations, more than 20 publishers of leading scientific journals — including *Science*, *Nature* and the *Proceedings of the National Academy of Sciences* (PNAS) — committed themselves to rejecting data that could be misused for bioterror attacks. In their joint "Statement on Scientific Publication and Security" the editors and publishers stressed, however, that the journals have an obligation to "protect the integrity of the scientific process by publishing manuscripts of high quality, in sufficient detail to permit reproducibility" because "open publication brings benefits not only to public health but also to efforts to combat terrorism."

The announcement — made public during the annual meeting of the American Association for the Advancement of Science (AAAS) in Denver in mid-February and subsequently published in several key journals — calls for "self-governance" by the scientific community as an alternative to government control of forthcoming articles. "It is up to us in the scientific community to define the standards and to establish the framework to ensure that critical information is withheld from terrorists while permitting the continued advancement of biomedical research and the protection of public health," said Dr Ronald Atlas, president of the American Society for Microbiology, one of the strongest advocates of self-policing measures. "This is work in progress, however, and we will have to continually seek to improve the

process and, more specifically, define what sort of information might constitute a dangerous 'cookbook' for terrorists."

The joint statement was signed by, among others, editors of the *New England Journal of Medicine*, the *Journal of Virology*, the *Journal of the American Medical Association*, and Nobel Laureate Harold Varmus, president of the Memorial Sloan-Kettering Cancer Center in New York. It urges editors to modify articles or to decline to publish them if potential risks outweigh the benefits resulting from the publication of, say, the identification of a virulence cluster in a certain pathogen.

Critics of the new publication guidelines contend, however, that editors and referees would by no means be capable of objectively assessing what constitutes potentially "dangerous" science, that is, identify papers that were likely to cause more harm than good. "I've studied these things for 50 years, and I couldn't make that judgement, and I don't see how editors of journals can do either. The job of journals is to judge the scientific quality of things, not to act as people who censor or make these kind of decisions, which are more political than they are scientific," said Dr Stanley Falkow, a microbiologist at Stanford University, in the *New York Times*.

The new publication guidelines are the first tangible result from a January invitation-only workshop held at the US National Academy of Sciences (NAS) in Washington, DC, which brought together scientists and policy-makers to discuss the potential conflict between scientific openness — a cornerstone of the scientific process — and national security. At Dr Atlas's request the workshop had been convened to bridge an ever-widening gap between the two camps over how to balance the needs of scientists for free access to research data and the demands from government officials for more secrecy with respect to sensitive information.

At the January meeting, government officials encouraged the scientific community to draw up a self-censorship scheme of sorts, to safeguard scientific information from falling into the hands of terrorists. "We were warned ... that if we don't watch out, the government could misunderstand our work and put the screws on," Dr Eckard Wimmer, a microbiologist at the State

University of New York at Stony Brook, told the *New York Times*. Dr Wimmer, a signatory of the joint statement, considers it an important step "to avoid such damaging action by the government."

As to whether the new guidelines will drastically change the way scientific data are published remains to be seen, though. So far, it does not look as if they will. In the past two months editors at the PNAS "flagged" 20 submissions — less than 1% of all submitted manuscripts — which dealt with diseases and pathogens that could pose a risk to public health. Yet after careful review the Editorial Board of the journal decided to publish them unaltered. Similarly, in the years 2001 and 2002, out of 14 000 submissions to the 11 journals published by the American Society for Microbiology, only two, that is, less than 0.015%, gave cause for concern. They were both published with minor modifications, according to Dr Atlas.

Meanwhile even editors who support the new publishing policies seem to be worried that being overly restrictive might in itself do more harm than good. "Any work of value to terrorists will also be of value in countering terrorism," said Dr Nicholas Cozzarelli, the Editor-in-Chief of PNAS. Dr Falkow couldn't agree more. "Ignorance is not a good defence. Knowledge is." ■

Michael Hagmann, *Zurich*

Legal interest expands from tobacco to obesity

McDonald's breathed a sigh of relief in January when a US District Judge dismissed a suit blaming the fast-food giant for the obesity and health problems of two New York teenagers. The company could not be held responsible for customers' excesses, said Judge Robert Sweet, but it could be so for any harm caused if the food were substantially less healthy than it appeared.

The *New York Times* quoted from Judge Sweet's 65-page opinion in which he calls Chicken McNuggets a "McFrankenstein creation" laced with dubious ingredients such as TBHQ, a flavourless 'stabilizer,' and dimethylpolysiloxane, an 'anti-foaming agent,' and containing twice as much fat as a hamburger. The plaintiffs' lawyer has amended the suit following the judge's advice.

Legal experts had thought for a long time that the food industry was immune to litigation efforts like those waged against the tobacco industry, eventually with considerable effect. But the recent spate of lawsuits is changing some minds. Many think now that it's just a matter of time before diet-related litigation starts succeeding.



A case in which energy intake appears to exceed energy expenditure.

Global illness and death attributed to obesity and its related conditions (which include diabetes, cardiovascular disease and high blood pressure) are approaching tobacco's lethal impact. While smoking kills almost five million people a year, obesity kills three million and the number is growing, according to WHO's *World Health Report 2002 — reducing risks, promoting healthy life*. A billion people in the world are overweight. Of the 300 million who are obese, more than half live in developing countries. Obesity was ranked tenth in the report's list of global disease risk factors, with maternal and child underweight in first place and tobacco use in fourth.

In her book *Food politics*, Marion Nestle, Chair of the Department of Nutrition and Food Studies at New York University, argues that the food industry spends billions of dollars on marketing products of questionable health value to an unsuspecting public. "The public is hopelessly confused," she says, "and it's to the advantage of the food industry to keep them that way."

She thinks diet-related litigation will eventually be successful and is already having an impact. "Business groups are terrified," she reports. "They're introducing healthier products and changing their marketing techniques as fast as they can. They feel guiltiest about what they're marketing to kids."

Children consume more soft drinks, snacks and other foods with little or no nutritional benefit than adults do, and childhood obesity, together with the illnesses it causes, is on the rise.

“Type-II diabetes used to be called adult-onset,” says Ian Darnton-Hill, visiting Associate Professor of nutrition at Columbia University in New York, “but now we’re seeing it in teenagers.” While some say the harm of tobacco on human health is much clearer than diet-related risk, a child who develops diabetes has no chance of quitting — the disease is there for life.

However, the analogy between the tobacco and the food industries is limited. “Tobacco kills half its regular users if consumed as recommended,” explained Derek Yach, WHO’s executive director of Noncommunicable Diseases and Mental Health. “But food is not tobacco. We all need food for living and we all want to enjoy the food we eat. Further, our early interaction with the food and allied sectors suggests that we will find solutions to the problems of nutrition-related diseases together.”

WHO is devising a global strategy on diet, physical activity and health to be presented to the World Health Assembly in May 2004. Much of it will be based on an expert report on diet, nutrition and the prevention of chronic diseases issued by WHO and the Food and Agriculture Organization on 3 March. Summarizing the findings of more than 30 science and food industry experts from around the world, the report stresses the need for countries to develop national guidelines which promote a diet low in saturated fats and sugars and high in fruits and vegetables while encouraging an active lifestyle.

“Now that we have the science, it’s time for action,” says Pekka Puska, director of WHO’s Noncommunicable Disease Prevention and Health Promotion, “instead of building more hospitals we need to put these recommendations into practice so that we can avoid unnecessary illness and death.”

On 1 March, WHO’s Member States agreed to the Framework Convention on Tobacco Control, a groundbreaking set of public health rules designed to curb tobacco advertising and promotion. The Convention may provide inspiration for the food industry as well. ■

Diana Willensky, *Rome*

Assisted suicide seekers turn to Switzerland

Swiss law is becoming a major reference point for those seeking to legalize medically assisted suicide. Lord Joel Joffe, who on 20 February introduced a Patient Assisted Dying Bill in the UK parliament, cited the case of Reginald Crew, who had ended his life with medical assistance in Zurich in January. This and other much publicized cases, Joffe said, reflected “the pressing need to allow terminally ill competent adults greater choice in the manner of their death”.

Crew was a 74-year-old paraplegic using a wheelchair and in constant pain. He had flown in January from Liverpool in the UK to Zurich with his wife and daughter, and ended his life there with a doctor’s help in a flat rented by Dignitas, a euthanasia association. Dignitas was founded in 1998 by Ludwig Minelli, a retired journalist and lawyer. Minelli says the aim of his association is to help others die with a dignity they cannot find in their own countries. It now has 2500 members. In the year 2000, three foreigners committed suicide with medical assistance in Zurich, followed by 38 in 2001, and 55 in 2002.

Article 115 of the Swiss Penal Code states that assisting someone to commit suicide is punishable if done for selfish motives, implying that if the motive is not selfish such assistance is legal. Most of the members of Dignitas, a strictly non-profit organization, are German, reflecting the relative stringency of that country’s law.

The German Penal Code does not refer to euthanasia but to “homicide on demand”, and states that if it is committed at the explicit and serious request of the victim it carries a penalty of between six months and five years of prison. The law governing euthanasia in England and Wales comes under the Homicide Act of 1957 and the Suicide Act of 1961, both of which make it a criminal offence. It carries a prison sentence of up to 14 years under the Suicide Act.

Belgium, the State of Oregon in the USA and the Netherlands are usually cited as places in which euthanasia is

legal, but other restrictions make it less accessible to foreigners. “The laws that once existed in most countries against suicide had practical as well as moral roots, since without such a prohibition people’s willingness to keep going in the face of hardship would be greatly reduced and society would be weakened,” explains Alex Capron, Director of WHO’s new Ethics and Health unit. “Today, suicide has generally been decriminalized, though aiding suicide is still prohibited, out of a sense that potential suicides are often depressed and vulnerable.”

Of the over 100 cases of assisted suicide by foreigners that have taken place in Zurich only one is under legal scrutiny by the Swiss authorities, on the grounds that the patient may not have been terminally ill. Win Crew, on the other hand, who accompanied her husband to his death in Zurich, is under investigation by the Merseyside (Liverpool) police.

Does the loophole in Swiss law imply a surprising new chapter in Switzerland’s long history of humanitarianism and international cooperation? It is helping to stimulate debate about the law, but perhaps the real debate should be about “the need for all patients to have access to appropriate alternatives,” Capron says. “These include hospice care, palliative care, and the whole range of other resources for care when cure is no longer possible. They also include, in most countries, the patient’s right to decline further use of expensive medical technology.” ■

Desmond Avery, *Bulletin*