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Precautionary measures

Major African campaigns targeting malaria and HIV could help millions, but key concerns over their long-term effects should not be forgotten.

More than one million healthy children in Africa participated in a bold initiative this year when they took antimalarial drugs during the rainy season. The hope is that a few months of preemptive doses could help them to fight off a disease that kills some 600,000 people throughout Africa each year. At the same time, health campaigns in 14 nations in eastern and southern Africa are circumcising millions of men in an attempt to stem the spread of HIV, which infects more than one-quarter of people aged 15–49 in some of those countries. The malaria and HIV efforts have the potential to gain the upper hand on two stubborn health scourges, but only if funders and organizers heed the lessons of past failures.

Nature this week publishes two reports from the ground. They are written by reporters who travelled to Africa to examine the benefits of these health campaigns — as well as concerns that have emerged about them. In the malaria effort (see page 186), one of the biggest worries has been that giving medications to children will promote the spread of resistant forms of the malaria parasite, quickly rendering the drugs ineffective. That happened during the 1950s and 1960s, when doctors performed prevention experiments for malaria in Africa and South America. The current campaign is based on trials that started in 2002 and took steps to avoid spreading resistance to front-line treatments by providing a cocktail of older antimalarial drugs, and only during the rainy season.

The success seen in the clinical trials, however, is not guaranteed as the programme is scaled up to cover possibly more than 20 million children in parts of Africa. Six nations started giving antimalarials this year, but treated just a fraction of their intended recipients because of funding and organization problems. This raises concerns that the programmes will not carry out the ancillary monitoring efforts needed to ensure success. Funding must be provided to track whether the large-scale prevention campaign reduces the number of malaria cases as hoped, and to ensure that resistant forms of the parasite do not spread more quickly than anticipated. The problem is that funders are typically less interested in supporting follow-up studies than in testing ideas and carrying out interventions. And monitoring has long been a weak point for malaria: global surveillance catches just 10% of the estimated global malaria cases each year.

In the circumcision campaign (see page 182), several trials showed that the procedure reduces the risk of HIV transmission from women to men by a substantial 50–60%. That level of protection is so large that international aid organizations, the United Nations and donor countries such as the United States have poured more than US$100 million into campaigns that seek to circumcise 20 million men in 14 target countries by 2015. But some researchers worry that the massive programmes will not yield the same benefits as the small, intensive trials. A prime concern is the message that men and women are getting about the effectiveness of the procedure. Campaign organizers have mounted major advertising efforts to encourage more acceptance of circumcision. In Zambia, billboards proclaim that a circumcised individual is 'a man who cares'. In Tanzania, he is '60% more man'.

The advertisements have succeeded in getting millions of men through the clinic doors, but the messages have also generated confusion. Many women in several of the target countries assume incorrectly that circumcision helps to protect them against acquiring HIV, and so they think that condoms are less necessary than they once were. Several studies have shown that men overestimate the amount of protection they gain through circumcision. And in Tanzania, the phrase '60% more man' is taken to mean that a circumcised man has more sexual partners — not the kind of message that will cut down on HIV transmission.

"Funders are typically less interested in supporting follow-up studies."

During the preliminary trials, clinics took steps to avert confusion by providing substantial counselling about the risks and benefits of circumcision before and after the procedure and in periodic follow-up visits. Men received testing and treatment for HIV and for several other sexually transmitted infections. But in the scaled-up campaign, circumcision providers typically give only one counselling session related to the procedure, and another with an HIV test. Behavioural researchers say that men require more counselling and that campaign organizers should also target information towards women to clear up misconceptions.

Just as with the preventive malaria drugs, there must be sufficient monitoring to track whether circumcision is as effective at reducing HIV transmission as it was during the smaller trials. Early signs are positive, and that is good news for millions of African men and women. ■

Data deadline

Time is running out to comment on the NIH's plan for sharing genomic data.

A little-noticed proposal promises to have a huge impact on how science is done in the 'big data' era. In September, the US National Institutes of Health (NIH) released draft guidelines on the sharing of genomic data. The guidelines, which have been in the works for five years, are a necessary and valuable update to the agency's stance on how researchers who receive its funds must share data produced by projects that use array-based and high-throughput technologies. They cover a huge swathe of research, including sequencing human and non-human genomes, genes and gene variants, as well as transcriptomic, epigenomic and gene-expression data.

The issues related to collecting and sharing such data are complex,

and the guidelines touch on most of the controversial topics in large-scale biology research today.

One of the key issues is when to share. The draft policy says that researchers must have shared their data by the time those data are published in a formal manuscript. However, there are earlier release deadlines for some data types, such as raw sequence data from non-human organisms and the initial analysis of some human sequence data, both of which must be shared within six months of submission to an approved repository. This is a thorny issue, and the NIH cannot please everybody. Some researchers favour the early release of more data, whereas others fear that releasing data ahead of publication will leave them vulnerable to being scooped.

Another major issue is how to protect the identity of those whose data are shared — especially as it is now clear that it is possible to identify people from anonymous data (see *Nature* http://doi.org/px4; 2013). The guidelines say that researchers should tell study participants that their data "may be shared broadly for future research purposes", and let them know whether it will be shared through an open- or controlled-access mechanism. It asks researchers to gain explicit consent from patients who agree to share their data through open-access mechanisms. And, importantly, it sets a new bar for informed consent on de-identified materials, including cell lines and clinical specimens. Such research has historically been exempt from informed-consent requirements, but the guidelines ask researchers to obtain consent for future research on these materials, too.

This is a potentially major step, and one that this publication supports (see *Nature* **486,** 293; 2012). It is true that some researchers who have relied on clinical specimens will see it as an impediment to valuable research. But similarly, some advocates of more transparent informed-consent rules will not like the fact that the guidelines allow researchers to opt out of this requirement if they give "compelling scientific reasons" for so doing.

A third aspect relates to how long the data should be shared for. Researchers who rely on controlled-access data sets often complain about periodically having to renew their requests for access. The guidelines maintain this standard, offering access to such data for one year at a time. This is unlikely to please those who have argued that legitimate scientists should be able to access larger tranches of data and for longer periods of time — although the NIH has responded that scientists who take this position are sometimes not aware of the restrictions on all of the data sets that they plan to use (see *Nature* **497,** 172–174; 2013).

"This is a thorny issue, and the NIH cannot please everybody."

Once finalized, the regulations will become part of a patchwork of international research regulation on the sharing of genomic data. The United Kingdom, for instance, is still deciding how much information from its 100K Genome Project will be released and whether researchers will be able to access both sequencing results and the relevant personal health records. At the same time, US open-genomics evangelist George Church is expanding his Personal Genome Project to Canada and Europe, raising questions such as whether the project will be able to access records from centralized health systems (see go.nature.com/izmgpo). By contrast, informed-consent regulations in other parts of the world are still being developed, leaving a question mark over whether the United States will become an easier place for genomics researchers to work than other parts of the world.

In that context, the US proposals will have a major impact on the work of *Nature*'s readers. Yet, according to the NIH's Office of Science Policy, as of 7 November, just 18 comments had been received on the guidelines. That is a poor response to such an important issue. The policy will affect many more scientists and *Nature* urges them to submit their responses to the proposals before the deadline of 20 November. ■

Keep asking

Prejudice, not evidence, is too often the basis for government drug policies.

Rob Ford, mayor of Toronto, Canada, caused a sensation last week when he told journalists, "Yes, I have smoked crack cocaine" — and refused to resign. The reporters smelled blood: Ford had long denied drug use, despite repeated rumours. "I wasn't lying," he said when confronted. "You didn't ask the correct questions."

The debate over the control and regulation of drugs is typified, perhaps more than any other in science policy, by a need to ask the correct questions. Politicians and the moralizing media tend to seek the black-or-white certainty of whether or not a drug poses a threat. Researchers often prefer to present risks as relative, and some argue that it is hypocritical to proscribe one compound while promoting, however tacitly, the consumption of another that may have similar — or more potent — effects.

From time to time the answer changes because of other factors, and this is where the question becomes less important than who is asking it. The television drama *Breaking Bad* has brought the abuse of methamphetamine to popular attention, but the government of Japan, for example, has long been well aware of the drug's effects. In fact, during the Second World War it encouraged the manufacture of the compound and distributed it to the country's soldiers and civilian workers in a handy tablet form called *hiropon*. "For night work and other times demanding mental alertness. For overexertion," a typical wartime advert read. "The most powerful new amphetamine on the market!"

At the end of the war, Japanese manufacturers sold the stimulant as a cure for all manner of civilian ills, targeting, among others, juveniles disturbed by the country's dramatic post-war social change. Yet within a few years, a government U-turn introduced tough laws making the drug illegal, with harsh penalties for possession. Official propaganda now called on citizens to help the authorities to "wipe out the evil of stimulant drugs!". Widespread abuse and signs of addiction gave the authorities a legitimate reason to act. But, as historian Jeffrey Alexander of the University of Wisconsin–Parkside pointed out in a paper this year (J. W. Alexander *Int. J. Drug Policy* **24,** 238–243; 2013), there was another, more sinister motive: the deliberate cultivation of a media-fuelled drug panic to justify the arrest and deportation of Korean and Taiwanese immigrants, who were disproportionately blamed for making and selling methamphetamine.

Similar social pressures played a part in the crafting of US legislation against marijuana, which was first popular with Mexican labourers and black musicians. Prejudice is one of a number of issues contributing to policies on drugs that are explored by two books reviewed by Andrew Robinson on page 194. The books explain, he says, that "a drug's acceptability to mainstream society fluctuates more owing to social and cultural trends than to medical knowledge". For example, the United States infamously banned alcohol during the prohibition era of the 1920s and 1930s, a move that would have been unlikely in the United Kingdom because of the "complex British attitude to drunkenness".

This attitude was highlighted in 2009 by the UK government's then-drug adviser David Nutt, who argued publicly that alcohol and tobacco were more harmful than LSD, ecstasy and cannabis. His opinion earned him the sack. Last week, it also earned him the 2013 John Maddox Prize for Standing Up for Science, which recognizes the promotion of science in the public interest, and was set up with the help of this publication. Someone has to keep asking the correct questions. ■

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