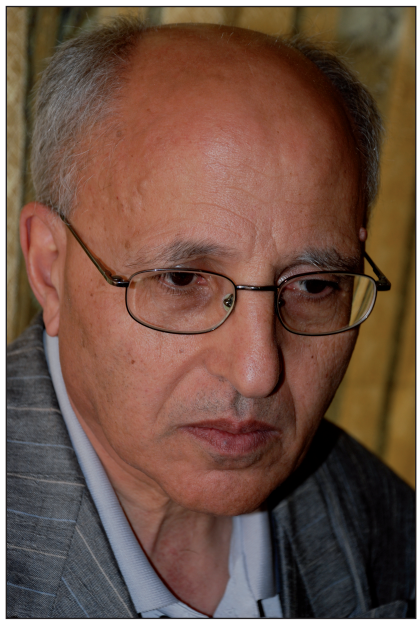
'SHOW US YOU'RE SERIOUS – OR STAY HOME'



Dr Mohamad Hassar, director of Moroccoís Pasteur Institute.

Picture: Chris Bateman

Any of the 42 health ministers attending the Global Ministerial Forum on Research for Health in Bamako, Mali, last year, who failed to push through laws for ethical research within a year, should be excluded from all future assemblies.

This was proposed by Dr Mohamad Hassar, director of Morocco's Pasteur Institute, who declared himself fed up with woolly policy proposals that 'never went anywhere', politically.

Hassar was speaking from the floor during a session aimed at promoting research for health by earning public trust through ethics and social justice. His proposal failed to make it into the distilled 'Bamako Call to Action' Declaration made on the final day of the conference.

Hassar's view of the forum's efficacy was cynical compared with that of Dr Timothy Evans, the WHO's Assistant Director-General for Information, Evidence and Research and the former Director for Health Equity at the Rockefeller Foundation.

Evans told *Izindaba* that the Forum, now in its third manifestation over 12 years (Bangkok and Mexico previously), was the 'ideal vehicle' for engaging and addressing politicians, who for example supported damaging denial of key scientific evidence. He was speaking in the context of the AIDS denialism and political heel dragging in South Africa until the dramatic cabinet and presidential turnaround in September last year.

South Africa's new health minister, Barbara Hogan, did not attend the Bamako Forum as she was already committed to an international gathering on tobacco control in Cape Town. A high-level delegation from her department did, however, along with a host of senior figures from the country's major research institutions and universities.

Dr Hassar said it was time to act on legislation for ethical research. 'We know what has to be done … there are several reports by the WHO, UNESCO … all countries should commit to passing legislation on ethics within one year or leave this world assembly of ministers of health. A country without such laws cannot claim to share our values. Such values have to be enacted to protect the population,' he said.

Commercial, not public interest driving research

Speaker after speaker in the session highlighted the burgeoning increase in commercial research driven by the hunger for new marketable technologies and of how few research subjects actually benefited from them.

Asia and Africa emerged as the two main target countries for commercial outfits that set up their own ethics committees wherever legislation was lacking.

Dr Aissatou Toure, chief of the immunology unit at the Pasteur Institute in Dakar, Senegal, said the theory of fundamental ethics of respect, informed and quality consent, autonomy, dignity, risk-benefit analyses and justice was seldom carried over into practice.

'For example, on the ground, if you simplify consent too much you end up with imprecision and misinformation, never mind the problems with scientific language and the translation and conceptual differences in spoken language.'

Socio-economic circumstances, hierarchical systems and respect for the authority of knowledge created an ethical minefield that could be ruthlessly manipulated without a government that had the political will to pass protective laws.

Dr Amar Jasani, of the *Indian Journal of Medical Ethics*, said protection was needed 'from the tyranny of sponsors and collaborators'.

In India lax regulations, low costs of clinical trials, large numbers of treatment-naïve patients and easily available scientific human resources with a large urban hospital infrastructure led to commercial research organisations burgeoning from a handful in 1995 to over 70 in 2005.

A lack of guidelines on compensation for research injuries meant that not a single person in India had been compensated (in spite of researchers being covered by insurance) for the past 5 years.

'Too many countries have decentralised structures to the extent that governments have offloaded responsibility – instead the commercial institutions determine who is appointed or replaced and provide the resources for the ethical committees,' Jasani added.

Describing this as a 'very, very dangerous practice', he said committee

A lack of guidelines on compensation for research injuries meant that not a single person in India had been compensated (in spite of researchers being covered by insurance) for the past 5 years.

members were often not aware of international best practice and had insufficient training.

It was 'essential' that the legal regulatory authority for research was integrated with ethics review committees through legislation so that policies and laws provided real power to independent ethics review committees.

Single-governance mechanism vital

Both private commercial ethics committees and market research organisations needed to fall under a single governance mechanism complemented by an accreditation body.

Jasani said that often the ethical guidelines of commercial outfits were 'totally different to ours – they ask us what the issues are and then promise to "take care" of them – I've been quite horrified sitting on the technical review committee'.

He called for regulators in developed countries to rigorously examine proof of ethical conduct for clinical trials in developing countries.

Questioning how pharmaceutical companies obtained marketing clearance without proof of post-trial benefits to participants and communities, Jasani said many companies were using guidelines from the 2000 Helsinki Declaration, simply because these were included in their laws, and not the updated versions.

Professor Jerome Singh, head of ethics and health law at the Centre for the AIDS Programme of Research in South Africa (Caprisa), said post-apartheid South Africa had made great strides to correct a racially skewed and unethical human research agenda.

Backed by several major statutory bodies there was a strong human rights culture via the Constitution that included a clause on ethical research and regular use of independent judicial review to check questionable commercial or government behaviour.

The Wisdom of Whores

Elizabeth Pisani, an epidemiologist and consultant working with HIV/AIDS in Asia and controversial author of *The Wisdom of Whores*, said too many researchers hid behind the rights of the individual to hoard data and prevent their use for the wider public good.

While protecting individual rights was a welcome 'step forward' from a decade ago, researchers spent too much time and effort 'obsessing about this', while forgetting that the point of research was to benefit the largest number of people.

Unlike public health, almost every other field of science was moving towards an open data policy, she said, citing physicists and geneticists as leading the way.

'One of the fig leaves we use in protecting the culture of data-hoarding is this idea that if we share it we'll somehow be compromising the rights of individuals and/or confidentiality – there's actually little evidence that this is ever the case.'

'We shut down Beijing to ensure that SARS didn't become a global pandemic

'One of the fig leaves we use in protecting the culture of data-hoarding is this idea that if we share it we'll somehow be compromising the rights of individuals and/or confidentiality – there's actually little evidence that this is ever the case.'



Elizabeth Pisani, an epidemiologist and consultant working with HIV/AIDS in Asia.
Picture: Chris Bateman

and there are numerous examples in XDR TB. We do have to make the point that it's unethical to collect data from people and not do anything with it,' Pisani argued.

She gave the example of her accompanying a government research team through Djakarta's red-light district when an influential and very angry local pimp confronted them with a pile of T-shirts given to his workers by researchers.

'He said we take a half hour of the girls' time doing incredibly invasive things and never do shit with the information – and they got nothing out of it but stupid T-shirts.'

Pisani grabbed headlines in South Africa when she accused the Treatment Action Campaign (TAC) of bias towards AIDS treatment at the expense of creating a market for HIV prevention. The TAC said she was being 'reductionist'.

Asked to suggest a practical way of addressing her concerns, she said ethical review boards should insist that data from research be used for public health. Review criteria should include quizzing researchers as to how they would translate their data into a public health benefit.

Chris Bateman