Clinical communication has become a cliché that suggests self-serving messages between doctors. What we are about is helping patients. This means talking and listening to colleagues directly. A tight communication loop, if you prefer jargon. The first thing you learn as a consultant is to be available[2] and to give feedback to general practitioners. You also learn that your team must include a good secretary and a good clinic clerk. Clerks already shift referrals to vacant slots if they are allowed to. Over-managing this process introduces errors and inefficiencies and hoovers up the extra money that the government (we read) is throwing at the service.

This proposal may not be a plot but the reasons behind it are desire for managerial control and ignorance of how efficient the system already is. Doctors are unlikely to protest. Hospital consultants just want to treat patients, who still manage to find us despite obstacles and delays. General practitioners want to get their referrals into a system—any system—and have neither the time nor the opportunity to redesign it. Those who should object are the patients, who will not receive high quality care if they are assessed as units of disease rather than treated as people.

Competing interest: The author has worked for the NHS for almost 35 years. He enjoys an excellent and productive relationship with local NHS managers and is married to a general practitioner.

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Global medicine

Regulation of biomedical research in Africa

Sylvester C Chima

In view of major violations of international ethical codes during biomedical research in developing countries, local and regional regulation frameworks and legislation are needed to interpret international guidelines

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Debate on biomedical research in Africa has focused on international ethical codes, such as the Declaration of Helsinki,[1 2] and recent abuses of major international ethical guidelines.[3–12] The declaration has been criticised for not fully protecting local populations—it requires only that researchers need be "aware of" other ethical and legal requirements; procedures for enforcement and penalties for breach of the declaration are absent; and the declaration, like all international ethical codes, does not have the force of law.[8 13–15] Biomedical research in Africa would benefit from regulations that provide guidance on the role of local research ethics committees, informed consent procedures, standards of care, and compensation for injuries arising from sponsored research. The African Union should consider legislation and directives on biomedical research, similar to directives developed by the European Union,[16] which are binding on but adaptable to the laws of individual states. These could enhance and simplify the regulatory and administrative provisions that govern biomedical research in Africa.

The case for local statutory regulation

The current debate on research ethics in Africa and other developing countries has focused on informed consent,[1–4 7 12 15] standards of care,[8–10 17 18] ethical review, and distributive justice.[4–12 15] To promote ethical research in Africa, appropriate legislative controls, increases in research capacity, new career structures, and appropriate allocation of resources may be needed. Although most developing countries adhere to international ethical codes, some research sponsors and regulatory agencies may ignore these codes to pursue national interests.[5 19] Some foreign researchers have taken advantage of the lack of local legislation and have ignored rudimentary local statutes.[20] This tendency by some researchers and sponsors to circumvent international guidelines suggests paternalism and double standards. When accused of unethical behaviour during trials of the drug trovafloxacin mesylate (Trovan) in Nigeria, Pfizer claimed that the trial did not aim to gather clinical data but to help sick children in a poor region of Nigeria.[12] Claimants in the ensuing case against Pfizer alleged that several children were denied effective alternative treatment so that clinical data could be obtained to support approval by the regulatory agency.[4] Act-Up Paris (an AIDS lobby group) accused researchers carrying out trials of tenofovir in Africa of unethical conduct, because treatment was not supplied after the study.[6] In a study by Merck in Guatemala on indinavir sulphate (Crixivan), arrangements were not in place for treatment to continue after the study, even though neither the participants nor the

The right to informed consent and US exceptionalism

"The right to informed consent is a fundamental human and legal right, which the judiciary takes very seriously. It would appear, however, that federal oversight agencies—Office of Human Research Protections and Food and Drug Administration—fail to enforce informed consent requirements by major American institutions—even when they have been caught in gross violation."[12]

Alliance for Human Research Protections, 2003

The need for research oversight and regulation

"When research involves human participants, the uncertainties inherent in any research study raise the prospect of unanticipated harm … Thus there can be a conflict between the need to test hypotheses and the requirement to respect and protect individuals who participate in research. This conflict and the resulting tension that can arise within the research enterprise suggest a need for guidance and oversight."[3]

US National Bioethics Advisory Commission, 2001

What is an ethics committee?

"An independent body in a member state, consisting of healthcare professionals and non-medical members, whose responsibilities it is to protect the rights, safety, and wellbeing of human subjects involved in a trial and provide public assurance of that protection by, among other things, expressing an opinion on the trial protocol, the suitability of the investigator and the adequacy of the facilities, and on methods and documents to be used to inform trial subjects and obtain their informed consent."[16]

Current EU definition of an ethics committee, 2001

government could afford the drugs on the open market.[11]

Disclosure of information to research participants is a legal requirement under United States federal regulations, but the National Bioethics Advisory Committee found that disclosures relating to diagnosis, risk, research design, and benefits after the trial were not always clearly presented in developing countries.[3] Thus countries in Africa need to introduce a framework for research governance, based on international guidelines and local cultural, medical, and legal realities. These regulations could provide guidance on forming local research ethics committees, informed consent procedures, standards of care in biomedical research, and aspects of distributive justice, such as post-trial benefits or compensation for injuries arising from research. Most problems in sponsored research among vulnerable populations occur in these areas, as illustrated by recent cases.[3–12 15 21] Regulations to govern these aspects of research have been introduced in Western countries—for example, a recent EU directive and US federal regulations.[3 16 19 21] Also, although many ethical dilemmas and issues on patients' rights may arise in research, certain rights may have only a prima facie standing and can be over-ridden by equally compelling moral considerations.

Local research ethics committees

The proposed African Union legislation and directives should include guidance on a system of ethics review that is suitable for African countries. Some African countries (for example, South Africa, Nigeria, Egypt, and Uganda) have established institutional review boards to oversee research, but these boards are resource intensive and unsustainable for most African countries. Initially, national and regional policies on research, which reflect local realities and can be applied by local ethics committees, should be developed. Ethics committees in Europe have been criticised for being slow, idiosyncratic, and poorly informed; this has led to arguments for a more harmonised committee process with a simplified research governance framework, as needed in Africa.[22] It is pointless to have many local research ethics committees if no effective national or regional policies exist to guide them. The ineffectiveness of ad hoc institutional review boards was highlighted by the Pfizer case—the local doctor involved later admitted to unethical practices, such as backdating the letter of approval from the review board. A national policy on biomedical research and clinical trials would have provided guidelines, minimised risks, and made provision for the compensation of research participants. The proposed African Union legislation or directive could emulate the EU directive, which gives guidance on the composition of local research ethics committees.

Standard of care

In England, the standard of care for medical treatment is legally defined. "The law lays down the general rules, which determine the standard of care which has to be attained, and it is for the court to apply that legal standard of care to its findings of fact so as to decide whether the defendant has attained that standard."[23]

The Bolam principle in English law states, "A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art … putting it the other way round a doctor is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion that takes a contrary view."[24] The definition of standard of care is different in jurisdictions such as the US, Canada, and Australia, which are governed by principles based on libertarian rights.

Reinterpreting the "standard of care"

Although the standard of care for clinical trials in Africa and other developing countries is controversial,[9 10 17 18] this standard should be based on best evidence from local practitioners skilled in the particular specialty or disease.[24] Some authors have argued that the US standard of care need not be emulated throughout the world; instead, a standard of care that is

Information disclosure

There can be no exception to the ordinary requirements of disclosure in the case of research as there may be in ordinary medical practice. Researchers do not have to balance the probable effect of lack of treatment against the risk involved in treatment itself. The example of risks being hidden from a patient when it is important that he should not worry is not applicable in the field of research. Subjects of medical experimentation are entitled to a full and frank disclosure of all the facts, probabilities, and opinions that a reasonable person might be expected to consider before giving consent.[25]

Halushka v University of Saskatchewan (1965)

Duty of researchers to participants in biomedical research

"Researchers cannot ever be permitted to completely immunize themselves by reliance on consents, especially when the information furnished to the subject, or the party consenting, is incomplete in a material respect. A researcher's duty is not created by or extinguished by, the consent of a research subject or institutional review board approval. The duty to a vulnerable subject is independent of consent, although obtaining of consent is one of the duties a researcher must perform … Such legal duties, and legal protections, might additionally be warranted because of the likely conflict of interest between the goal of the research experimenter and the health of the human subject, especially, but not exclusively, when such research is commercialized."[21]

Ericka Grimes and others v Kennedy Krieger Institute (2001)

achievable globally, which reduces economic inequalities, should be applied.[9 10 17 18] If no applicable local standard exists, the standard should be based on international recommendations subjected to local interpretation, rather than a "best proven" and unsustainable standard available in wealthy countries only.[9 10 17 18]

Consent to research

The centrality of consent in biomedical research has been recognised by all international codes since the Nuremberg Code and the Declaration of Helsinki.[1–4 15 16 21 25] All researchers should provide full disclosure.[25]

Participants in trials are entitled to all material information.[21] Consent forms should be in local languages and interpreters should be available for illiterate participants. Potential participants should be given adequate time and resources for reflection, before decisions are made regarding consent in non-emergency situations. Because of the vulnerability of participants from developing countries, researchers should adhere to international guidelines that are reinforced by local laws designed to protect the population.[1–4] Many US states have informed consent statutes, some of which have specific disclosure requirements for particular procedures, and US federal regulations require informed consent in biomedical research.[3 21] Similar legislation would be suitable for Africa.

Compensation and distributive justice

Participants from developing countries who sustain injury during sponsored research projects find it difficult to obtain compensation for negligent and unethical conduct.[4 7 12 15] Local legislation is needed to help resolve conflicts and personal injury claims arising from biomedical research. Compensation could form part of the terms of reference for local research ethics committees during the approval process. Legislation could be introduced to stipulate a compensation scheme like the one operated by the Association of British Pharmaceutical Industries—any healthy volunteer in a drug trial run by a member of the association will receive compensation for any injury that arises from that trial. The English Department of Health and Royal College of Physicians require written reassurance of compensation in proportion to risk.[15] The EU directive states that clinical trials may be undertaken only if provision has been made for insurance or indemnity to cover investigators and sponsors.[16]

Distributive justice is defined as fair, equitable, and appropriate treatment in light of what is due or owed a person.[10] US federal regulations partly deal with these issues by requiring that research participants are informed in advance about whether compensation is available. This information is not usually disclosed to research participants in developing countries.[3] Local regulations should specify what will happen to participants who are injured during a sponsored research project. The procedures for obtaining compensation in the developing world are formidable, and local legislation is needed for extra protection and timely compensation.[4 7 12 15]

Conclusions

The case resulting from trials of trovafloxacin mesylate (Abdullahi *v* Pfizer) in Nigeria illustrates some failures and inadequacies of local regulation of biomedical research in Africa, and it highlights the legal hurdles that face people claiming compensation for injuries during research under the current international law and conventions.[4 7 12 15] Research sponsors do not always follow international ethical codes and guidelines when research is carried out in developing countries.[4–7 15 19] If claimants do not obtain adequate compensation, communities may be unwilling to accept any treatments, even beneficial ones such as childhood immunisation for poliomyelitis.

Some people may argue that my suggestions discourage drug trials in Africa. The principles of respect for autonomy require that all people have the opportunity to determine what is done to their own body, in accordance with internationally recognised legal standards.[1–4 21 25] Research conducted contrary to these principles takes advantage of patients whose only fault is that they live in countries where research laws are lax and the quality of medical care is poor.[20] The suggested approach should not lead to an exodus of research sponsors from Africa. Instead it should encourage ethical conduct and provide a solid legal

Research ethics and the rights of people in developing countries

"When the US (or any developed country) proposes to sponsor or conduct research in another country, when the same research could not be conducted ethically in the sponsoring country, the ethical concerns are more profound, and the research accordingly requires more rigorous justification … Thus in the context of international research—and particularly when the population of a developing country has been sought as a source of research participants—US and international research ethics require not merely that research risks are reasonable in relation to potential benefits, but also that they respond to the health needs of the population being studied."[3]

US National Bioethics Advisory Commission, 2001

Summary points

Current guidelines for international research are undermined by exceptions that favour some researchers and sponsors in the developed world

Reliance on international legislation and guidelines does not adequately protect research participants in Africa

Local and regional regulatory frameworks and legislation are needed to interpret international guidelines in the light of local sociopolitical realities

New laws could focus on informed consent procedures, local research ethics committees, standards of care, and distributive justice (for example, compensation and post-trial benefits)

framework for future research in Africa, designed to safeguard researchers and participants.

If implemented, my recommendations will form part of the local transfer of skills, increase in research capacity, and distribution of benefits of research and technology transfer, as envisaged by the Helsinki Declaration, the Council for International Organizations of Medical Sciences, World Health Organization, and other sponsors of biomedical research.[1 2] Experimental medicine and biomedical research will always be hazardous but should be encouraged within a framework of respect for autonomy, justice, and human rights. Ethical practice and new advances in biomedicine are not mutually exclusive.

Contributors and sources: SCC is an African physician and scientist, with over 20 years' experience of working, studying, lecturing, and conducting biomedical research in Africa, the US, Europe, and the Caribbean. He has a longstanding interest in research on populations of African origin. SCC recently completed the LLM Medical Law programme at Northumbria University. This article arose in part from research conducted during his recent studies.

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A memorable patient

A rank offence

It was a hot summer day in south India, and the psychiatric outpatient clinic was crowded. The smell of fish alerted everyone to the arrival of a mother and daughter. They asked to see me, and I was encouraged to give them priority as the smell from the basket of fresh fish they had brought with them engulfed the whole area.

The daughter had been an inpatient several months previously with a manic episode that had proved difficult to control, and she had been assigned to me, then a registrar in the department. She was now well and taking the drugs that I had managed to obtain for free from a medical representative. She came from a poor family from a fishing village, and she and her mother had brought the fish for me as an expression of their gratitude. Apparently I had promised the worried mother that her daughter would get better and had stated, in jest, that I expected a nice meal with fried fish at their home.

To their great disappointment, I refused their gift, explaining that accepting gifts was frowned on in the department. This was not true—my professor had given me permission to do so (by this time everyone in the department was aware of their arrival). Instead, my refusal was based more on my embarrassment and concerns about the smell in my car were I to take the fish home.

Driving home later in the day, I noticed a crowd gathering around the same mother and daughter. They looked quite despondent and seemed to be giving the fish away for free. Although this incident happened more than 10 years ago, I cannot forget the expression on their faces as they sat in the hot sun giving away the fish that they had carried for more than 50 miles, probably having to change buses several times during their journey. I also cannot forgive myself.

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