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Scientific misconduct: a new approach to prevention

The disclosure of faked skin-transplants in white mice at the Sloan-Kettering institute in New York in 1974 introduced the modern story of scientific fraud in medicine.¹ Despite much publicity—including reports, recommendations, and the setting-up of organisations to manage allegations—new and egregious examples continue to surface.² Clearly, although the precise frequency is unknown, the scientific community has failed to prevent misconduct, possibly because misconduct represents a range of issues at the edge of which many scientists have been. Nevertheless, the public is unlikely to continue tolerating an unethical waste of its resources, which at times has verged on the criminal¹ and all too often has been shrugged aside by the profession's leaders.³ Hence, in addition to continuing and enhancing present activities, a new approach is needed. Has the time now come to apply the lessons of epidemiology?

More than 20 years ago, the British epidemiologist Geoffrey Rose published his landmark article 'Sick individuals and sick populations'.⁴ Rose advocated a population strategy instead of a high-risk approach in preventive medicine, which was based on his theory that the causes of incidence might differ from the causes of cases. Analysing data from 52 populations, Rose and Day recorded a strong correlation between prevalence of deviation and the population mean for blood pressure, bodyweight, sodium intake, and alcohol consumption.⁵ They concluded that "the frequency of 'cases' can be understood only in the context of a population's characteristics. The population thus carries a collective responsibility for its own health and well-being, including that of its deviants."⁵ Rose further developed his strategy of preventive medicine, concluding that: "a population strategy of prevention is necessary whenever risk is widely diffused through the whole population".⁶ He defined the

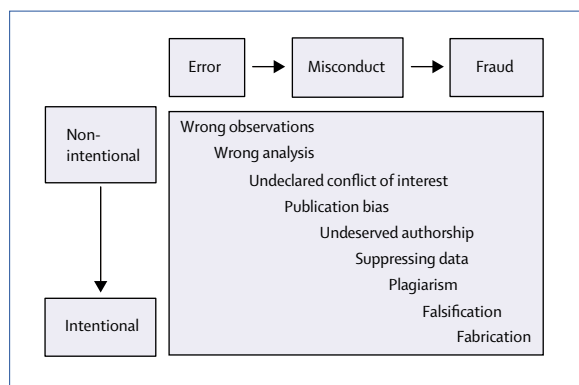


Figure: Slippery slope between honest errors and intentional fraud, with examples in the middle

Horizontal axis represents extent of deviation from acceptable scientific behaviour. Vertical axis represents extent of blame, from excusable errors, via non-intentional but still blameable deviance, to wilful actions.

prevention paradox—a preventive measure that brings large benefit to the community but offers little to every participant. Minor changes in the right direction by most of the population are more effective than major changes by a few individuals.⁶ Although Rose's ideas have been challenged,^{7,8} they remain highly relevant for thinking about prevention.

From meeting with research managers and leaders of research departments, and reading about incidents of revealed misconduct, one can easily get the idea that those caught for fraud are seen as bad apples, for whom leaders have no responsibility. Many people believe there is a distinct line between ethical and non-ethical behaviour. This notion is not the case. In our opinion, scientific misconduct—or rather, conduct inconsistent with accepted scientific standards—is a continuum ranging from honest errors to outright fraud (figure). To be sure, honest errors are inevitable whereas intentional fraudulent behaviour is obviously unethical and illegal. In real life, there is a long grey zone from white to black, with laxity, negligence, and recklessness all being used to characterise non-intentional, but still egregious, deviations from accepted standards. A survey of US scientists showed that a third of respondents admitted to have engaged in unethical research behaviour within the previous 3 years.⁹ 15.5% admitted changing the design, methodology, or results in response to pressure from a funding source, and 10% admitted inappropriately assigning authorship credit.

If we think of scientific misconduct as an unhealthy condition that has different grades of seriousness and is diffused through the scientific community, we can

apply Rose's strategy for mass prevention. Moving the whole research community in the right direction should then reduce the number of serious cases. The most important outcome of our suggestion is to impose a heavier responsibility than currently applied on all institutions and their leaders for ensuring ethical and sound research environments, and avoiding minor breaches of good scientific practice. The research community must take a collective responsibility even for its deviants.

The practical results of this approach are manifold. First, the existence of scientific misconduct should not be downplayed. Its occurrence cannot and should not be hidden. All research institutions must hold regular seminars and discussions on the causes, outcomes, and consequences of scientific misconduct.

Second, a strict definition (restricted to fabrication, falsification, and plagiarism) might be suitable for legal action against individuals. However, a wide definition (eg, all breaches of accepted scientific practice) should be used for prevention.

Third, current guidelines and regulation should be simplified and made readily available to researchers. Research training must include ethical and legal issues. Supervision of young researchers should be improved. Senior researchers serve as models and examples for their juniors, and they have a particular responsibility for demonstrating sound ethical behaviour. Attention should be paid to issues such as open declarations of conflicts of interest and, crucially, guidelines for authorship. Inappropriate authorship is an underestimated example of grey-zone activities. A fifth of reports in prestigious international journals name people who do not fulfil authorship criteria (guest authors), whereas individuals who should have been included (ghost authors) are missing in a tenth.¹⁰

Fourth, effective and independent mechanisms for investigation of suspected incidents of serious scientific misconduct should be set up at a national level in all countries. Clear and open methods to manage whistleblowers should be in place, with a designated disinterested individual to complain to when needed.

Finally, most important is perhaps a thorough discussion of the academic system of reward and merit. How can the emphasis on productivity and the number of publications be reduced, and how can a more healthy culture of transparency and ethics be established?

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An appropriate research agenda for heart disease in Africa

The landmark global burden of disease report in 1996 drew attention to the importance of degenerative cardiovascular diseases as causes of present and future morbidity and mortality in developing countries.¹ It alerted the global community to the fact that atherosclerotic vascular disease, previously considered important only in the developed world, was increasing in importance as a cause of death and disability in developing nations. Importantly, the report predicted that degenerative cardiovascular disease would become a major issue in those countries over the next decades, which would warrant urgent preventive measures. Several publications address these issues, and the matter is sometimes an undisputed topic of discussion and presentations at national and international meetings.^{2,3}

The anticipated epidemic of atherosclerotic cardiac disease has, however, not yet manifested in most of the population of sub-Saharan Africa. In the INTERHEART study, researchers investigated ethnic differences in risk factors in patients with myocardial infarction and showed that risk factors are the same in all individuals irrespective of ethnic origin.⁴ In Africa, the investigation was undertaken in nine sub-Saharan countries.⁵ An attempt was made to enrol as many black African patients as possible, both to study the hypothesis that risk factors are universal and because atherosclerotic cardiac disease has traditionally been deemed uncommon in this population⁶ but reported by some workers to be increasing in prevalence.^{7,8} Between 1999 and 2003, very few (n=144) cases of acute myocardial infarction were identified in the large black African population of the region, despite the best efforts of the investigators.

Most cases were reported in minority populations of coloured, white, and Indian people in sub-Saharan Africa. There are many possible explanations for this finding, but the most persuasive is simply that atherosclerotic coronary disease—at least in its most striking and most clinically obvious manifestation of acute myocardial infarction—is not common in most black African people on the continent. This suggestion provides an historic opportunity for the primordial prevention of atherosclerotic cardiovascular disease in sub-Saharan Africa.

Where and how should resources in research into heart disease be directed in sub-Saharan Africa? On the basis of INTERHEART, the mechanisms of degenerative vascular disease in other ethnic groups will probably be the same in black African individuals as in all other human beings, and successful strategies to combat vascular degenerative disease do not need to be retested. There is a real danger that emphasis on degenerative vascular disease, which could become important in the future, might divert financial and human resources from research into non-atherosclerotic cardiac disorders, which presently are important as causes of death and disability in black African people. Rheumatic heart disease, the cardiomyopathies, and tuberculous pericarditis are the major causes of heart disease in black African populations. They cause great morbidity and mortality in young, economically active people, but with isolated exceptions, they are largely neglected targets of epidemiological, aetiological, and therapeutic research.^{9–11}

Innovative research is needed into cardiac disorders that are either common or unique in black African