

Whistleblowing in academic medicine

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Although medical centres have established boards, special committees, and offices for the review and redress of breaches in ethical behaviour, these mechanisms repeatedly prove themselves ineffective in addressing research misconduct within the institutions of academic medicine. As the authors see it, institutional design: (1) systematically ignores serious ethical problems, (2) makes whistleblowers into institutional enemies and punishes them, and (3) thereby fails to provide an ethical environment.

The authors present and discuss cases of academic medicine failing to address unethical behaviour in academic science and, thereby, illustrate the scope and seriousness of the problem. The Olivieri/Apotex affair is just another instance of academic medicine's dereliction in a case of scientific fraud and misconduct. Instead of vigorously supporting their faculty member in her efforts to honestly communicate her findings and to protect patients from the risks associated with the use of the study drug, the University of Toronto collaborated with the Apotex company's "stalling tactics," closed down Dr Olivieri's laboratory, harassed her, and ultimately dismissed her.

The authors argue that the incentives for addressing problematic behaviour have to be revised in order to effect a change in the current pattern of response that occurs in academic medicine. An externally imposed realignment of incentives could convert the perception of the whistleblower, from their present caste as the enemy within, into a new position, as valued friend of the institution. The authors explain how such a correction could encourage appropriate reactions to scientific misconduct from academic medicine.

A search through the literature of the last decade provides merely a handful of references to whistleblowing, primarily single page comments. Although medical centres have established institutional review boards (IRBs) to review ethical considerations of experimentation with human subjects, and institutional animal care and use committees (IACUCs) to oversee the ethical use of animals in research and education, little institutional energy has been directed to the ethical oversight of academic behaviour as such. This is not to say that venues for employee grievances and hearing complaints about harassment do not exist: they do, but they are seldom used, they subject the user to bias, and they quite often remain ineffective. Nor is it to say that instances of blatant inappropriate behaviour are never addressed: sometimes they are. We are making a claim of a different sort. Academic medicine has failed to consistently, effectively, and appropriately respond to unethical behaviour. As we see it, institutional design (1) systematically ignores serious ethical problems, (2) regards whistleblowers as enemies of the institution and punishes them, and (3) thereby fails to provide an ethical environment.

A series of cases of academic medicine failing to respond properly to unethical behaviour in clinical research that have been discussed in the literature illustrate the scope and seriousness of the problem. The Olivieri/Apotex affair is just another instance of academic medicine's ethical failure in cases of scientific fraud and misconduct. This case involves funding from a private pharmaceutical company, other cases do not. Yet the significant similarity is that in each instance, instead of supporting the individual who reported a serious ethical problem relating to research, the institution responded with the punishment of the whistleblowers. Recent history, as is illustrated by a series of cases that ultimately reached public attention, makes it unmistakably clear that there can be grave consequences for faculty, students, and staff who report discrepancies and concerns about unethical research behaviour. On 30 October 1995

a report from the Research Triangle Institute on "Consequences of Whistleblowing for the Whistleblower in Misconduct in Science Cases"¹ reported some of the personal costs of whistleblowing, as did the 5 January 1996 issue of *Science*,² as well as a 1999 issue of *Science and Engineering Ethics*.³ Whistleblowers are ostracised, pressured to drop allegations, and threatened with counter-allegations. They lose desirable assignments, have their research support reduced and their promotions and raises denied. Their contracts are not renewed, and they are fired.⁴ Whistleblowers are obvious targets, especially in a time of financial cutbacks, re-engineering and downsizing, and everyone knows it.

To effect a change in the current status quo the incentives for addressing problematic behaviour have to be changed. Ethically appropriate reactions to researcher misconduct would be far more likely if whistleblowers could be seen as helpful colleagues and as valued friends of the institution instead of its enemies. We advocate this kind of transformation, not only to address the misdeeds of academic medicine but to create a moral environment for all who have to work in it and learn from it.

THE OLIVIERI/APOTEX AFFAIR

In 1989, with Dr Nancy Olivieri serving as the principle investigator, she and her colleagues began to study the effectiveness of deferiprone as a treatment for thalassaemia. When evidence started to accumulate in 1996 to suggest the drug was ineffective or causing harmful liver toxicity in some patients, Dr Olivieri reported her findings and she attempted to amend the informed consent documents for the study to reflect the risks. Apotex Inc, the drug manufacturer, disputed her stand and tried to suppress her evidence.

Then, instead of vigorously supporting their faculty member in her efforts to honestly communicate her findings and to protect patients from the risks associated with the use of the drug, the University of Toronto collaborated with the

company's "stalling tactics," closed down Dr Olivieri's laboratory, harassed her, and ultimately dismissed her from employment. Dr Olivieri's numerous attempts to address the issues through the university's dispute mediation mechanism all came to nothing. With the support of the University of Toronto Faculty Association, Dr Olivieri brought the matter before the Canadian Association of University Teachers. The University of Toronto did not change its stance toward Dr Olivieri until the publication of *The Olivieri Report* by the Canadian Association of University Teachers in October 2001 absolved Dr Olivieri of any wrongdoing and found serious fault with the university.⁵ Subsequently, Dr Olivieri was restored to her position as director of the Hemoglobinopathy Research Program at the University of Toronto affiliate Hospital for Sick Children.

ADDITIONAL CASES

In December 1983, Dr Robert Sprague of the University of Illinois realised that his grant collaborator, Dr Stephen Breuning, then at the University of Pittsburgh, had been falsifying research.⁶⁻⁷ Their studies had focused on the effects of commonly prescribed medication and the effects of their withdrawal on movement disorders in institutionalised, severely handicapped, and retarded individuals. Published data from this research had been employed as the rationale for changing such patients' treatment.

In a detailed letter Dr Sprague reported his concerns to his grant monitor at the National Institute of Mental Health (NIMH). She, in return, telephoned and wrote to the appropriate person at the University of Pittsburgh, explaining that the charges were "serious and required investigation". But after just a hearing and no investigation, the University of Pittsburgh found "no serious fault with Dr Breuning's activities here in Pittsburgh" (Sprague R L,⁶ p 115).

When the NIMH finally issued its report in April 1987, almost three and a half years after the problem was brought to its attention, Dr Breuning was condemned for "having knowingly, wilfully, and repeatedly engaged in misleading and deceptive practices" (Sprague R L,⁶ p 117). Dr Sprague, the whistleblower, was also condemned, however, for "failure to oversee" (Sprague R L,⁶ p 117). Then Dr Sprague lost the NIMH grant he had held for 17 years, in spite of a favourable report and a score from the study section of the funding agency that would usually have been high enough to ensure a funding grant.

A third case involved Dr Pamela Berge. In 1987, as a Cornell University graduate student, she conducted her dissertation research at the University of Alabama, Birmingham (UAB) on risk factors that contribute to mother/child transmission of cytomegalovirus (CMV). At a scientific meeting in 1990, more than a year after Berge had received her degree from Cornell, she heard a presentation of her work by a UAB professor who gave Berge no attribution. When her own efforts and those of Cornell University to have UAB take appropriate action were ineffective, Berge went to court. In May 1995 a federal district court jury in Baltimore, Maryland, found for Berge and required that the UAB pay damages to her and to the government. The UAB's own investigation had found no misconduct even though a UAB faculty member had used Berge's work without any citation.⁸⁻¹⁰ A fourth case involved the Stanford University Mental Health Clinical Research Centre where money had been mishandled and research standards violated. In the first of a series of studies, a group of patients was classified as the experimental group. In subsequent papers and abstracts, and with the knowledge of the investigators, the same cohort was used as a "normal" control patient group. When a secretary brought this problem to the attention of the administration, Stanford set up a review committee. The committee called

what had been done "at best a serious lapse in scientific judgment", but found "no evidence of fraud."¹¹ In another study by the same research centre investigators, patients were tested with the results recorded under the names of other patients, and in another, patients who received medication were described as being off medication. Furthermore, there was no evidence for the performance of the psychiatric evaluations that were said to have been done, and one of the protocols was not performed as reported.

Several months after Stanford's review committee issued its report, the National Institute of Mental Health (NIMH) appointed a panel to review the Stanford findings. It identified several areas of concern, finding "the use of patients as experimental subjects in one paper and as normal control subjects in another ten papers and four abstracts" to be most significant. When the original experimental subjects were excluded from the papers in which they had been used as controls and the data re-analysed, the conclusions of three papers were invalidated.

Penalties were imposed on the principal investigator and the director of the research centre. Other investigators were merely found to have committed "an error in judgment". Although the NIMH absolved all the other collaborators of any responsibility, it admonished Stanford University, declaring that "...it would have been helpful if Stanford had more thoroughly pursued particular concerns in this case and arrived at conclusions as to responsibility for deviations from accepted scientific practices" (Zylke J W,¹¹ p 1910).

One issue raised by the Olivieri/Apotex affair and these three additional examples is the widespread disinclination of academic medical centres to be responsive and to responsibly pursue allegations regarding their faculty and staff. Another confounding problem is that making such complaints typically brings serious consequences for the one who brings the bad news. There are no effective means for registering these complaints without fear of reprisal. As Taubes describes the situation: "the scientific community has been struggling for a decade to prove that it can handle its own misconduct cases effectively".⁸ Obviously, it is not presently equipped to do the job.

WHY DOES THIS PATTERN REPEAT ITSELF?

These cases make it clear that institutions of academic medicine, from the University of Toronto, to Pittsburgh University, to Stanford University, to the University of Alabama at Birmingham, are willing to tolerate and conceal unethical behaviour. The reasons for this pattern of response are less obvious, and an amalgam of multiple explanations seems to provide the best account. Part of the answer lies in personal motivation, another part in institutional motivation, and a third in the historical practice of academic medicine.

Personal motivation

Individuals are subject to a number of influences which make them reluctant to blow the whistle. Just by living in a society and absorbing its culture we develop an aversion to exposing the misconduct of others. To some extent, we all have:

1. Learned the social significance of belonging to a group and adopted the attitude of identification and solidarity: "don't be a tattletail".
2. Absorbed the psychologically painful experience of disloyalty.
3. Learned obedience to the chain of command.
4. Developed fear of being exposed as the whistleblower and the shame that we associate with the "turncoat".
5. Become fearful of suffering accusation and retribution.

Institutional motivation

Confronting scientific misconduct or research fraud is a huge burden for institutions of academic medicine, something they very much want to avoid. Faculty, students, and employees all recognise the institutional reluctance to deal with such burdens and that gives them a reason to remain silent in the face of inappropriate behaviour. Institutions do not want anyone to blow the whistle because they want to avoid an array of negative consequences:¹²

1. Forfeiture of industry support or grants which add up to a financial loss to the institution.
2. Loss of standing and prestige associated with industry support, grants, and prominent faculty members.
3. Negative publicity from the association with a scandal.
4. The threat of retaliatory litigation that will require the institution to mount a costly defence.
5. Getting bogged down in a lengthy, time consuming process that subverts the expedient of management (“let’s move on”).

The practice of academic research and medicine

Researchers and physicians are acculturated to be loyal to their colleagues and not to blow the whistle on a fellow researcher or physician. A white wall of silence protects the secrets of these professions from public scrutiny and keeps the dirty linen from being aired. The medical environment, in particular, is permeated with shared understandings of protocols for what physicians should do.

1. Confidentiality and privacy are basic elements of medical ethics and defining features of the doctor/patient relationship. Habitual attention to these concerns inculcates the disposition in doctors not to raise questions with third parties.
2. Physicians must believe in their own judgment in order to practise medicine. A degree of confidence (or courage) is an invaluable asset in confronting their daunting responsibilities, and confidence (or arrogance) has, therefore, become a tolerated feature of medical practice.
3. Urgency and the risk to life and limb are facts of medical practice. They make obedience to authority essential. When deviation from prescribed orders may cause death or loss of function, the model of the doctor as the “captain” of the ship is justified.
4. Historically, doctors have worked as independent agents. They do not like to have their own judgment and authority challenged. Therefore, they tend to be reluctant to challenge the judgment or behaviour of their peers.
5. In academic medicine professionals rely upon their institutional superiors for their academic standing and the resources to pursue their careers. Furthermore, the economics of medical practice make many physicians reliant upon their referral network. These realities of academic medicine make whistleblowing extraordinarily dangerous because it puts an entire career in jeopardy.

HOW TO RESPOND

These formidable obstacles will have to be overcome if academic medicine is effectively to tackle the problem of responding appropriately to research misconduct. Institutions have taken some steps to address the problem. They have established educational programmes, harassment

committees, grievance boards, standards officers, and ombudsmen. Unfortunately, these well intentioned measures may miss the heart of the problem if: (1) these avenues are seldom used to deal with problems, and (2) the bodies responsible tend to duck the issues and support their institutions when complainants ask for their help. That said, we do not know how many instances of whistleblowing are investigated and handled with appropriate attention as reports of these are never published. What we do know is that some unethical behaviour continues, aggressive assaults on whistleblowers also continue, and that, at least sometimes, there is an official administrative suppression of the truth.

In the US, the difficulty of responding appropriately is further compounded by both federal and state legislation for the protection of the whistleblower being seriously problematic. The law considers scientific misconduct cases from the perspective of criminal sanctions and meting out punishment. This approach makes the subject of a misconduct hearing into “the accused” who must then be protected with all of the safeguards accorded a defendant in a criminal case. Adjudicating misconduct on this model calls upon rigid legal standards for the determination of criminal guilt, that is, the standard of guilty beyond reasonable doubt. Reasonable suspicion, or some other less explicit standard, would be more fitting for the self policing of the professions of medicine and science, which rely upon society’s special trust. The law sets the legal standard for compliance with professional ideals much too low and the legal standard of proof of misconduct, much too high.^{13–15} The attitude of the professions and institutions policing themselves should, however, be the opposite. Like Caesar’s wife, the professional’s behaviour should not even appear immoral.¹⁶

Another obstacle created by the present regulations is that they leave the whistleblower with the burden of proof of misconduct.¹⁷ This is a grossly unrealistic demand in light of the financial and emotional resources and energy required to maintain a battle against the establishment, the personal pain and suffering that the whistleblower invariably endures, and the hostility of the assaults from the social and cultural environments in which medical research is practised.

To effect a change in the status quo, the incentives for addressing problematic behaviour have to be realigned. From the institutional responses that have been reported we should know that the whistleblower is seen as the enemy from within. That attitude leads to attacks on whistleblowers and a protective defence of culprits. If the institutional incentives could be changed and the whistleblower could come to be seen as an important ally of the institution, appropriate reactions would be more likely. None of the literature that we have examined seems to notice this way out of the problem. See, for example, Dandekar N.¹⁸

In the US, institutional animal care and use committees (IACUCs) provide a useful model of the realignment of forces that we could strive to achieve. Within the institutions of academic medicine these committees are responsible for assuring that animal care and research complies with an array of guidelines, mandates, and regulations. Everyone in the institution whose research involves the use of animals is acutely aware that all of the institution’s animal activities, and the funding for those activities, could be suspended if an unannounced inspection by state or federal authorities revealed some unacceptable behaviour towards animals. A complaint to an outside agency, the media, or an animal rights organisation could have even more ruinous consequences.

This animal research model focuses responsibility for moral behaviour on institutions rather than individuals and thereby significantly transforms the institutional incentives. Under

this structure, IACUCs and whistleblowers become crucial and valued agents that alert and protect the institution. The one whose inappropriate behaviour puts everyone else in jeopardy becomes the intolerable risk to the institution. When unacceptable animal use is noticed, people who want it to be stopped are free to report it promptly. Whistleblowers are privately thanked and offenders are educated and coerced into doing things the right way.

In all of the examples discussed above of misconduct in medical research, it was necessary for the whistleblowers to go outside the academic institutions to address the misconduct and punish the guilty parties because their own institutions preferred sweeping their dirt under the rug. Similar cases are reported and discussed by Beardsley T in a paper in *Scientific American*.¹⁹ Responses came after action from the outside, after the fact, after significant delay, after whitewashing, and after punishment of the whistleblower.

The IACUC model works in the opposite way by effectively engaging outside forces to support the desired behaviour. It applies outside pressure to institutions to identify and correct unethical behaviour. The outside pressure enables institutions to coerce those who might be inclined to do the wrong thing into reforming their behaviour so that further misconduct is prevented. The use of incentives from the outside is far more effective in creating a moral environment for academic medicine than the current mechanisms. Now we tolerate inappropriate behaviour so long as no one within the institution is foolhardy enough to blow a whistle. Now we only resort to policing from outside agencies to punish the misconduct of a few egregious violations.

The point of this observation is that medical institutions operate in a political environment. Political systems should aim at manipulating the natural and artificial incentives that move individuals so that they behave in socially desirable ways. The current arrangement of incentives works against and not for the social good. They “censure rather than encourage” whistleblowing behaviour (Poon P,¹⁷ p 93) and, thereby, coerce the administrators and employees of academic medicine to do what they should not. Forces that shape behaviour within academic medicine now induce their population to conceal misconduct and to silence or discredit whistleblowers. A solution to this problem lies, first, in recognising the structure of the predicament and, then, in addressing it effectively. In this situation, a change in incentives is required and such a change can only be effected by a significant force from outside the system.

Presently, no one is attempting to create and empower the coercive structure that could effect the necessary transformation of incentives. Existing accreditation agencies could, however, be authorised to take on an expanded role in preventing academic and clinical misconduct. The largest change would come from assigning responsibility for misconduct to the institution instead of just the individual. If that were done and if the accreditation agencies demonstrated the will to investigate the institutions, and to seriously punish them for unacceptable behaviour of faculty members or clinicians, and if, further, the threatened sanctions against the institutions were sufficiently severe, the balance of incentives could be realigned to overcome those incentives that have inclined institutions to collaborate with or turn a blind eye towards research misconduct. The National Institute of Health (NIH) and Office of Human Research Protections (OHRP) can take on a greater role in research oversight.

Physicians and scientist are reluctant to give up any measure of control over their own behaviour. They fiercely resist limitations on their liberty. In an environment where researchers are constrained to accommodate behaviour that they find profoundly objectionable, they are not free. They

need to open their eyes and recognise that their present independence is only an illusion. To recognise this fact of contemporary institutional life we need only to imagine the many administrators and health care professionals who felt compelled to comply with their institution’s cover up and who were silenced by their suppressive environment. Political philosophy points the way to a more farsighted approach. It teaches the lesson that empowering an oversight authority can be liberty enhancing.²⁰ By forceful policing from powerful extra-institutional review, academic medicine stands its best chance of becoming free to confront and constrain research misconduct.

CONCLUSION

The transformation we advocate is crucial not only to address the misdeeds of academic medicine but also to create a moral environment for all who have to work in it and learn from it. Besides the obvious issues of scientific fraud and callous disregard for the wellbeing of patients, a host of other unethical behaviours need to be addressed, including false allegations, harassment, partiality in resource allocation, and the abuse of graduate students. Academic medicine owes its faculty, students, patients, and staff an environment with a reasonably tolerable level of moral contamination, a place where people can feel free to do the right thing. Institutions have to protect people from having to cooperate with clearly immoral behaviour and having to wilfully affect moral blindness. We are realistic enough to recognise that our approach will not remedy all institutional ills. Our hope and expectation is merely that we can do better.

Academic medicine is also responsible for the training of tomorrow’s doctors and medical scientists. Because we want them to guide themselves by high professional standards and because so much of what they learn is communicated through the silent curriculum of learning from the behaviour that they see, we need to show our students how they ought to behave and to protect them from observing inappropriate behaviour being tolerated in academic medicine.

Good medical practice depends upon the promotion of peer examination. Asking questions invites thorough evaluation of clinical research and re-examination of clinical judgment. Both kinds of critical assessment ultimately translate into better patient care. This reflective model, which academic medicine publicly embraces in teaching rounds and clinical conferences must now also be made the rule for more personal and private clinical and research interactions. Perhaps it is most effective to criticise in private, but those who work within academic medicine must be free to criticise.

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ECHO

Cultural competence and antiracism training for child health professionals



Please visit the *Journal of Medical Ethics* website [www.jmedethics.com] for a link to the full text of this article.

The Race Relations (Amendment) Act 2000 requires all service providers to ensure equality of access. NHS trusts have a statutory duty to show how they intend to promote race equality and eliminate discrimination. Appropriate training of the workforce is of prime importance. Professional responses to training programmes for child service professionals in Cardiff and Huddersfield have been evaluated.

The Department of Child Health in Cardiff entered into a partnership with the local Race Equality Council in 1992 with the aim of improving services to ill or disabled children from ethnic minorities. A need for professional training was identified but available training materials were considered to be too rigidly based on knowledge of cultural differences and practice rather than promoting cultural awareness and understanding and self examination.

A new training course, the Equality Rights Equal Access (EREA) pack, was developed, the main aim of which was to promote cultural competence rather than providing lists of—for example, dietary or religious differences, or differences in naming people. Training is over one day and encourages trainees to explore their own attitudes, to recognise that their attitudes, and those of their clients, are determined by their own cultural conditioning, and to understand how racism affects services.

The Cardiff programme was piloted in 1995 in Cardiff, Bristol, and Birmingham and has been included in a MSc course in Child Health and other courses. Trainees' questionnaire responses at the end of the training day and 2–7 years later were largely positive, many stating that attending the course had changed their behaviour or practice.

In Huddersfield the programme has been incorporated into a project funded by the Department of Health. Trainees, who in the main had either a health or an education background, reported inadequate previous guidance or training in racial or cultural awareness. Almost all (87 of 89 replies) agreed that the course was good or excellent and their objectives were achieved.

The people who run this course are clearly enthusiastic about it and able to transmit their enthusiasm to many of the trainees. They realise that from a scientific point of view it would have been better to measure changes in professional behaviour after the course directly but they were unable to do that. They recommend that similar training should be incorporated into undergraduate and postgraduate curricula by universities and Royal Colleges.

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