

An investigative journalist looks at medical ethics

Duncan Campbell

"Doctor's new hope on AIDS," announced a headline in the *Daily Express* in 1987, when describing a treatment that has now been shown to be ineffective and unethical (p 1125). A few months later the *Daily Telegraph* informed its readers that Dr James Sharp, the doctor quoted in the first article, had conducted experiments that showed that AIDS could "at least be stabilised and possibly cured." Clearly the authors of these press reports did patients little service.

Characteristically, the reporters were interested in what was said to be new rather than in what was confirmed to be true.

Failure by the GMC

But what of the General Medical Council and its firm rules against medical self promotion? Section 62 of the guidance on *Professional Conduct and Discipline* (the "Blue Book") places an unequivocal duty on practitioners not to acquiesce in the publication of material commending their particular and personal skills or attainments. Arranging for such publicity is worse; and trying to "attract patients" or to achieve "financial benefit" is worse still. The Blue Book highlights the exceptional danger to patients of "raising illusory hopes of a cure."

As a medical outsider it seems to me that the newspaper articles reporting uncritically on (and quoting) Sharp constituted a frontal assault by him on each cardinal aspect of the GMC's cautions against self promotion. Not only did they breach the rules but they also occasioned the precise damage to patients that the rules were constructed to prevent and in the precise way that was anticipated by the council—by in effect advertising a "cure" to "people seeking medical attention [and] vulnerable to persuasive influence." Yet the council did nothing about the reports and neither did anyone else.

Failure by the profession

What of others in the profession? Many leading clinicians were aware that Sharp and his colleague, Iraqi veterinarian Jabar Sultan, were conducting an unethical and potentially harmful series of experiments on private patients. Others were aware that patients were being charged large sums of money. Others still were aware that the pair were attempting to report results that were, to say the least, questionable.

A cancer specialist experienced in the therapeutic techniques Sharp and Sultan were attempting to mimic had challenged them in a meeting to produce bodyscanner evidence of their claims to have achieved regression of solid tumours. A consultant virologist had given Sultan unequivocal advice not to carry out his proposed experiments in humans without the benefit of peer reviewed work in vitro first. A senior immunologist, consulted by the head of the medicine department at another hospital about the Sharp-Sultan project, told me that their scientific method might as well have been planned in harmony with the phases of the moon. He warned them that their project was unethical but later learnt that his warnings had been disregarded and that experiments had been done

in a series of patients. Another senior immunologist attended a Sharp-Sultan presentation and found that their scientific method was generally as well founded as their medical ethics. An experienced specialist in genitourinary medicine told me that he considered that terminally ill patients at his hospital were being fleeced.

The Blue Book places a duty on registered medical practitioners to inform "an appropriate body" in circumstances when there may be a "question of serious professional misconduct." Many of the more than 30 experienced scientists or doctors to whom we spoke were sufficiently concerned about the unethical activities of Sharp and Sultan to brand them (in private conversation) as everything from "Mickey Mouse" or "cowboys" to "gangsters." None of them saw the complete picture of what Sharp was doing. Nevertheless, they did not communicate any of their anxieties, however partial, to the GMC or to the *BMJ* or to whatever "appropriate body" might be available — until two weeks *after* my report was published and a parallel programme in the BBC television *Watchdog* series had been transmitted.

This reticence remained present throughout our investigation. Even on being presented with the mounting evidence of the questionable practices of Sharp and Sultan, very few doctors were prepared to state their views publicly. In striking contrast to their strongly held private opinions, those who did speak wanted predominantly to offer only generalised statements. Others, I should record, gave much essential help but were professionally compelled to stipulate that nothing they had said should be attributed to them. It was clear that the general reticence was largely specific to medical practitioners and medical culture. For example, a leading research immunologist and other scientists to whom we spoke were far less inhibited about making comments in public or on television.

When Sharp and Sultan attempted to publish in peer reviewed journals and later to solicit research funds from the Medical Research Council they were turned down. Those concerned with the reviewing quickly spotted the ethical and scientific flaws in their efforts. Yet still the GMC was not told, and prospective patients were left unprotected and harmed (at least financially). Nothing was done until the start of this year when a patient and a junior doctor who had watched this extraordinary quackery with mounting anxiety helped instigate the press investigation of Sharp's scientific credentials and medical methods.

Why no warning?

Why did senior doctors, reviewers, and others not warn anyone about Sharp and Sultan? A string of reasons are apparent. Firstly, current guidance in section 65 of the Blue Book warns that it may be serious professional misconduct for one practitioner to "disparage" the services of another "*irrespective of whether this may result in his own professional advantage.*" In other words, if a complaint to the GMC about misconduct is not thought likely to be investigated by the council (as most practitioners here clearly

expected) it becomes an offence for a concerned doctor to get in touch with the BBC or any other watchdog organisation, even if that doctor acts entirely in the interest of patients. The public is, in my view, entitled to conclude that this part of the present regulatory process scandalously sets aside the welfare of patients. It seems to be deliberately intended to silence doctors from disclosing legitimate matters of medical concern.

The effects of section 65 are not theoretical. Two doctors whom we consulted took legal advice or advice from the GMC about what they could say and were quickly counselled to say nothing at all. Shortly before publication a senior clinician pleaded with me to edit out a quote from him saying that what Sharp had done was unethical. Another clinician whose own patients' lifespans may have been shortened by the experiments of Sharp and Sultan withdrew completely the public comments he had been willing to make after the GMC and his medical defence society had explained section 65.

Need for GMC reform

But this does not of itself explain why no one warned the GMC of their anxieties about Sharp. To make a complaint to the council itself does not fall foul of section 65. The council, however, is a largely reactive body, which is generally known to be under-resourced and to expect that complaints will be accompanied by documentary or sworn evidence supporting them. When we asked the concerned specialists why they had not passed their fears on to the council it became clear that unavailability of its investigatory staff as much as an unwillingness to make adverse comments was what had deterred them.

The public has a widespread belief that the GMC exists to protect it. Perhaps not everyone shares this view of the purposes of the council. But it is clear that

without a professional medical standards inspectorate with powers and resources to investigate in advance of formal complaints being made the council cannot hope to offer the public the protection it is thought to provide.

I was told that the GMC had not taken on this role in the past, depending instead on existing NHS supervisory systems. Given the government's determination to commercialise medicine, the problem of supervising medical standards in the private sector must surely compel the introduction of a suitably resourced, nationally organised inspectorate. District health authorities, which currently license and inspect private hospitals and clinics, freely admit that they do not have the skills or resources to police them effectively. Not least the cost of employing medical and nursing supervisory officers to visit and check private hospitals and clinics is far greater than the licence fees hospitals must pay to be registered.

Private hospitals also acknowledge that they are lightly supervised and could easily mislead a district health authority. On this occasion a private hospital was misled by Dr Sharp. It now acknowledges that it was "questionable" whether it sufficiently checked his claims to have ethical or scientific approval for what he was doing.

But private hospitals are not required to have ethical or scientific committees to approve experiments or innovative treatments. In practice, many do not have such committees. In effect, these private hospitals operate as landlords and franchise operations to consultants, who rent their space and facilities. Although patients and the public will have obvious expectations about the standards of ethical medical care to be obtained in an institution using the name "hospital," mechanisms commensurate with those in the NHS to ensure that these standards are maintained do not exist. These matters need urgent legislation.

ANY QUESTIONS

Icing sugar contains up to 1.5% of aluminium sodium silicate. Would acid gastric juice release the aluminium for absorption into the bloodstream, and if so could any harm be caused?

Aluminium sodium silicate is added as an anticaking agent to some, but not all, icing sugars to ensure a smooth mix when the icing is prepared. It is an approved additive with an unlimited acceptable daily intake at present; it contains about 13% of aluminium so a typical iced cake could provide about 23 mg aluminium/100 g. The substance is virtually insoluble in water and solubilises only slowly in hot strong acid, so probably only a small amount of the aluminium is available for absorption into the body. In people with normal renal function the risks would almost certainly be small. —D A T SOUTHGATE, head, AFRC Institute of Food Research, Norwich

A woman had a boy who died in his first year of spinomuscular atrophy (Werdnig-Hoffman disease). What is the likelihood of future children developing the disease and is there an antenatal screening test for it?

The spinal muscular atrophies are clinically and genetically a heterogeneous group of disorders, but the acute progressive infantile form (proximal spinal muscular atrophy type I or Werdnig-Hoffman disease) is the most clear cut. The onset is from birth to 3 months or a little later, with severe hypotonia leading to death usually within one year and with a mean of seven months. The diagnosis of Werdnig-Hoffman disease rests on the clinical presentation, including the ages at onset and death, delayed nerve conduction, and finding muscle atrophy on biopsy.

Inheritance is through an autosomal recessive gene, the parents being unaffected carriers of the disease gene, and the affected children inheriting this gene from both parents. Such carriers have been estimated to have a frequency of one in 80 of the population. As with any autosomal recessive disease the carrier parents of an affected child will run a one in four risk that any further child will also be affected. Their unaffected children will have a two in three chance of being a carrier, like the parents. Whether the

other autosomal recessive types of proximal spinal muscular atrophy, especially those of childhood onset, are due to allelic mutations of the same gene or to genes at distinct loci is still not clear. We do not even know on which chromosome the Werdnig-Hoffman gene lies.

There is no means of prenatal diagnosis. Many mothers notice reduced fetal movements when carrying an affected fetus, but this subjective impression is not reliable or a sufficiently early method for prenatal diagnosis. I am not aware that any study of objective measurement of fetal movements in at risk pregnancies, whether by ultrasonography or other methods, has been conducted. I hope that eventually deoxyribonucleic acid markers linked to the gene for Werdnig-Hoffman disease, and even the disease gene itself, will be detected. When this is achieved prenatal diagnosis and carrier detection will become possible and ultimately the gene product will be identified. —M D'A CRAWFURD, consultant clinical geneticist, London

- 1 Emery AEH. Review: the nosology of the spinal muscular atrophies. *J Med Genet* 1971;8:481-95.
- 2 Pearn JH, Carter CO, Wilson J. The genetic identity of acute infantile spinal muscular atrophy. *Brain* 1973;96:463-70.
- 3 Pearn JH. Fetal movements and Werdnig-Hoffman disease. *J Neurol Sci* 1973;18:373-9.

Is acute traumatic perforation of the eardrum a recognised complication of pertussis in a child?

During coughing the pressure in the postnasal space does not usually rise much above the atmospheric pressure, as the mouth is usually open. Furthermore, the eustachian tube does not open during a cough. Middle ear pressure, however, does rise because of the reduced venous drainage and increased heart rate that occur during a paroxysm of coughing. The congestion is the cause of the soft tissue haemorrhages seen in pertussis. It is rare for this pressure rise to lead to a spontaneous rupture of the eardrum. Predisposing factors include a thin eardrum—usually as a result of a healed perforation—obstruction of the eustachian tube, and possible coincidental otitis media. When a traumatic rupture of the eardrum is seen doctors should remember the common causes such as damage from an instrument or a direct blow to the ear—sometimes non-accidental. —MAURICE HAWTHORNE, ear, nose, and throat surgeon, Middlesbrough