The Shipman inquiry: implications for the public's trust in doctors

HAROLD Shipman was a medical practitioner who committed multiple murder. Nobody would suggest that this brands all general practitioners (GPs) as potential or real murderers. Yet, there can be few GPs who did not feel shame and anger when the verdict was announced and few members of the public who did not reflect on the case's implications for their own GP. The reason, of course, is that Shipman exploited and abused his patients' trust.

All doctors operate in an environment of trust. Our patients trust us with confidences and information. They trust us to apply up-to-date and effective technical skills to their problems. They trust us to care for them, medically and emotionally. Above all, they trust us to place their interests first and to advocate for them within our consultations and in the health service itself.[1]

If this is the basis of our discipline then cases such as Shipman's fundamentally question the core values of the doctor–patient relationship. If a patient cannot trust their GP not to deliberately harm them then how can they trust their doctor not to avoid accidental harm? Or covertly to deny them access to effective treatment on the grounds of, for example, cost?[2]

The public trusted the General Medical Council (GMC) to regulate our profession. While the Bristol case represented a significant tightening in the scope of regulation, it also starkly revealed its limitations.[3] The GMC has introduced performance procedures but few doctors have been through them. There is still a strong belief that there are some doctors, including GPs, who are unsafe yet who continue to practise.

The introduction of revalidation will help to restore the confidence and trust of the public and the government in professionally-led regulation. The recent consultation proposals for revalidation for clinical general practice[4] have been well received by the profession and have been overwhelmingly supported. We need to work towards a comprehensive system that promotes good care, detects problems early, and encourages all doctors to be keeping well above the minimum 'fitness to practise' level.

The most damaging revelation to come out of the Shipman inquiry may concern professional isolation. There is nothing wrong with single-handed practice — we must be robust in saying that clearly. Professional isolation is, however, indefensible. GPs can become isolated within partnerships. However, it is easier to become isolated as a locum or as a single-handed doctor. To restore confidence we will need to strengthen professional networks, which include continuing professional development, mentoring, and appraisal, to counter professional isolation.

In responding to the Chief Medical Officer's document, *Supporting Doctors, Protecting Patients*,[5] the Royal College of General Practitioners (RCGP), with the General Practitioners Committee and the Joint Committee for Postgraduate Training for General Practice, has espoused professionally-led regulation.[6] This is a partnership between the profession, the state, and the public that can restore confidence in an internal system of regulation. This report is available on the RCGP website.

Our patients also trusted the system for death certification. They expected that unusual individual deaths or patterns of deaths would be audited or explained. They thought that having three signatures, two from local GPs, on a cremation form was a safeguard against poor care or criminality. The failings of this system are likely to be exposed in the inquiry and the second signatory will probably have to be a doctor who is appointed, trained and paid for the task, and who makes appropriate enquiries.

One reflex response has been to single out deaths that occur within surgeries. While it would seem reasonable that all such deaths are routinely reported to the coroner, this particular aspect should not be allowed to obscure the basic principle. Whenever a doctor is unsure of the cause of death, or where the circumstances might raise legitimate, if unjustified, questions, the coroner must be informed. A restating and tightening of the implementation of this principle can be expected.

Every GP knows that the monitoring of death rates by an individual GP or by a practice is a blunt instrument.[7] There are many more revealing performance indicators, and death rates vary too widely year on year to be of routine value. Yet it does seem reasonable that death rates should form part of any clinical governance monitoring system. While variation may be due to chance, the possibility of patterns being detected and explanations sought cannot be ignored.

Lastly, the public trusted us to be responsible in our prescribing, especially of controlled drugs. The Shipman case has revealed a number of serious weaknesses in the current system and these will need to be examined in detail. The destruction of stocks of drugs after a patient dies, the availability of controlled drugs on private prescription, and the monitoring of the prescribing of controlled drugs on National Health Service prescriptions will all need to be examined and tightened up.

The Shipman inquiry will be chaired by Lord Lamming with Professor Hazel Glen and Dr Aneez Esmail as members. Dr Esmail is head of the academic Department Of General Practice in Manchester and has a strong reputation as a strategic and clear-minded thinker. The inquiry team will meet in private and will take evidence from relatives of those who died, but will publish a public report. Its findings will need to be taken seriously by all involved in the health services.

The immediate publicity surrounding the Shipman trial was dissipated by the announcement of the inquiry by the Secretary of State for Health, but the relative silence now should not be read as reassuring. This lull only represents the wait for action to restore the public's trust.

The RCGP will fully co-operate with the inquiry, supplying it with evidence and information. We will explore difficult areas of concern and reform. In both the short and medium term we must put in place systems and structures that ensure that the public's confidence and trust is regained and maintained. That is a considerable challenge for all of us.

MIKE PRINGLE

Chairman of Council, Royal College of General Practitioners

References

1. Royal College Of General Practitioners (Chairman: N Stott). *The nature of general medical practice. Report of a Working Party*. [Report from General Practice 27.] Exeter: RCGP, 1996.
2. Royal College of General Practitioners. *Rationing in the NHS*. London: RCGP, 1999. [http://www.rcgp.org.uk/publicat/bluebks/rationin.htm]
3. Smith R. All changed, changed utterly. *BMJ* 1998; **316:** 1917-1918.

4. Revalidation Working Group. *Revalidation for clinical general practice*. London: RCGP, 2000. [www.rcgp.org.uk/proposals/revalft/revalwrd6-1.doc]
5. Donaldson L. *Supporting doctors, protecting patients*. London: Department of Health, 1999.
6. Royal College of General Practitioners with the General Practitioners Committee of the BMA and the Joint Committee for Postgraduate Training for General Practice. *The future of professionally-led regulation for general practice. A discussion document*. London: RCGP, 2000. [http://www.rcgp.org.uk/college/rcc0016.htm]
7. Frankel S, Sterne J, Davey-Smith G. Mortality variations as a measure of GP performance: implications of the Shipman case. *BMJ* 2000; **320:** 489.

Address for correspondence

Mike Pringle, Royal College of General Practitioners, 14 Princes Gate, Hyde Park, London SW7 1PU.

The use of HRT in patients with breast cancer: yes, no, or sometimes?

FEW areas of scientific enquiry arouse as much passion and polemics as the relationship between hormone replacement therapy (HRT) and breast cancer. We now know that up to five years' use of HRT makes little difference to the risk of developing breast cancer, and a further 10 years' use results in an increased risk similar to that associated with increased alcohol consumption which, incidentally, is rarely touted as a risk factor.[1-3] In spite of the obvious benefits of HRT, the question of its prescription in patients with a diagnosis of breast cancer might be most diplomatically described as controversial. The reason for this is simple: oestrogen is thought to be the most important mitogen in the development of breast cancer, which is not only the common cancer in women in the Western world but is also the most frequent cause of death in middle-aged women in these countries.[4]

Overall, approximately 75% of breast tumours are oestrogen receptor-positive. The blocking of these receptors with tamoxifen results in a 50% annual reduction in the recurrence rate and a greater than 25% annual reduction in death rate such that patients with positive oestrogen receptors tend, on the basis of these simple statistics, to live longer.[5] Based on these facts, the argument against using HRT in patients treated for breast cancer would appear to be fairly persuasive. In addition, women with breast cancer and their doctors are uneasy about considering a treatment that may lead to an improved quality of life but may also harbour a survival disadvantage.

For patients who are oestrogen receptor-negative, oestrogen does not seem to stimulate cancer growth; therefore, prescription of HRT, with its attendant benefits on coronary arteries, bone density, and menopausal symptoms, should not confer an increased risk of disease relapse. Although this group is in the minority, the patients are usually younger than the oestrogen receptor-positive group and the physical and psychological issues of a premature menopause are therefore likely to be greater. Any hesitation involved in the use of HRT here would be secondary to the fact that women with one breast cancer are approximately four times more likely to develop a second primary cancer and it is well known from general population studies that prolonged use of HRT (i.e. for more than 10 years) confers an increased risk of developing the disease.

Women with positive oestrogen receptors are invariably given tamoxifen, either as part of primary treatment or on relapse of disease.[6] Although tamoxifen does have some oestrogenic effects in non-breast tissues, it is not as good as HRT (or raloxifene for that matter) in terms of a beneficial effect on bone density and lipid profile; on the other hand it is not too bad either, in that it has no effect on cardiac risk factors. If patients are premenopausal they may enter the menopause if prior chemotherapy has not already stopped their periods.

When discussing treatment options with patients it is often difficult not to introduce unwittingly some form of personal bias into a conversation, based on idiosyncratic preferences (which we all have) and one's knowledge of available evidence. The point with HRT prescribing in women with breast cancer and positive oestrogen receptors is that there is no real evidence and few doctors have much in the way of any personal experience. One gives the patient the little information that is available, and then it really is up to the patient to make up their own mind. Many oncologists therefore believe that in certain circumstances, such as severe menopausal symptoms, HRT can be prescribed for patients on tamoxifen who are being or have been treated for breast cancer. This is of particular relevance in women with good prognostic disease (small tumours, no lymph nodes involved, oestrogen receptor-positive, favourable histopathological features).

Newer agents may provide easier answers. Raloxifene is now on the market as a form of HRT.[7] A spin-off from tamoxifen, it has many of the benefits of HRT and is being investigated for possible anti-oestrogenic effects in breast cancer. At the moment, it would be unwise to prescribe it instead of tamoxifen: no compound has yet proved itself in a randomised trial to be more efficacious than tamoxifen.[4] However, it may have a more gentle side-effect profile and may play an increasingly important role if it survives the outcome of the STAR trial designed to observe its effect in breast cancer. Unfortunately, it does not appear to show an improvement in controlling vasoactive symptoms, such as hot flushes.

Given the issues involved, it is advisable for an oncologist to be included in these decisions. Tamoxifen plus HRT may sound like an absurd combination but it will not be surprising for most readers to learn that the story is not quite as straightforward as tamoxifen blocking the receptors that 'feed' the breast cancer, a theory originally proposed by Professor Antoine Lacassagne in 1936.[8] We now refer to drugs such as tamoxifen and raloxifene as selective oestrogen receptor modulators (SERMS) and their effects are highly tissue-specific. One can speculate that, in time, there will be every possible combination of tamoxifen, raloxifene, low-dose HRT, and higher dose HRT preparations on the market. However, breast cancer is one disease where evidence has drastically changed what we do from day to day, (for example, lumpectomy and radiotherapy instead of radical mastectomy, with tamoxifen for at least five years) and it is difficult to predict the results of trials. A trial is currently underway at the Royal Marsden Hospital comparing the addition of HRT with no addition of HRT after treatment for early breast cancer. In terms of an answer to the question posed in the title, the jury is still out.

JUSTIN STEBBING
R KATE GREGORY

Specialist Registrars, The Breast Unit, Department of Medicine, The Royal Marsden Hospital, London.

References

1. Brinton LA, Hoover RM, Szklo M, Fraumeni JF. Menopausal estrogen use and risk of breast cancer. *Cancer* 1981; **47:** 2517-2522.
2. Nomura AMY, Kolonel LN, Hirohata T, Lee J. The association of replacement estrogens with breast cancer. *Int J Cancer* 1986; **37:** 49-53.
3. Collabarative Group on Hormonal Factors in Breast Cancer. Breast cancer and hormone replacement therapy: collaborative reanalysis of data from 51 epidemiological studies of 52,705 women with breast cancer and 108,411 women without breast cancer. *Lancet* 1997; **350:** 1047-1059.
4. Fossati R, Confalonieri C, Torri V, *et al*. Cytotoxic and hormonal treatment for metastatic breast cancer: a systematic review of published randomised trials involving 31,510 women. *J Clin Oncol* 1998; **16:** 3469-3460.
5. Early Breast Cancer Collaborative Group. Tamoxifen for early breast cancer: an overview of the randomised trials. *Lancet* 1998; **351:** 1451-1467.
6. Kent Osborne K. Tamoxifen in the treatment of breast cancer. *N Engl J Med* 1998; **339:** 1609-1618.
7. Delmas PD, Bjarnason NH, Mitlak BH, *et al*. Effects of raloxifene on bone mineral density, serum cholesterol concentrations, and uterine endometrium in post-menopausal women. *N Engl J Med* 1997; **337(23):** 1641.
8. Lacassagne A. Hormonal pathogenesis of adenocarcinoma of the breast. *Am J Cancer* 1936; **27:** 217-225.

Address for correspondence

Dr Justin Stebbing, The Breast Unit, Department of Medicine, The Royal Marsden Hospital, Fulham Road, London SW3 6JJ.