Baker's report.

Summary

Following Harold Shipman's conviction for the murder of fifteen of his patients, an audit of his clinical practice from 1974 to 1998 was commissioned by the Chief Medical Officer for England. The aims of the audit were to identify:

(a) the pattern of observed to expected deaths in particular age group

(b) deaths showing unusual clusters in time

(c) deaths showing unusual clusters by place of death

(d) the relationship between certified cause of death and medical history

(e) the integrity of records

(f) the prescribing of restricted drugs.

In investigating the pattern of deaths, two sources of information were used. In the first, all medical certificates of cause of death (MCCDs) issued by Shipman from 1974 were identified. In order to estimate the number of deaths that would have been expected, those MCCDs issued by a comparison group of local general practitioners who worked during a similar period to Shipman were also identified. Information about the numbers of patients registered with each practitioner was used to calculate the death rates in different age groups of male and female patients.

In the second method of investigating patterns of deaths, a prospective audit was undertaken of the deaths of all patients who were registered with Shipman for any period from 1987. Patients of Shipman were identified from the Health Authority register, and deaths from the National Health Service Central Register. The expected number of deaths among Shipman's patients was estimated from the numbers of deaths in equivalent patient populations based on figures from the local district (Tameside), a group of districts sharing similar population socio-economic characteristics, and figures for England and Wales.

The relationship between certified cause of death and medical history was investigated by review of surviving clinical records and cremation forms. The analysis was strengthened by comparing cremation forms completed by Shipman with those completed by the group of comparison practitioners. The record review was also used to assess the integrity of records, supported by review of the audit trail on a duplicate copy of Shipman's practice computer system.

The prescribing of restricted drugs was investigated through review of data provided by the Prescription Pricing Authority and inspection of the controlled drugs registers at pharmacies in Hyde.

Several methods were used to investigate the pattern of deaths. The findings of review of MCCDs showed that:

- Shipman issued a total of 521 MCCDs, 499 whilst he worked in Hyde. The highest number issued by any of the six comparison practitioners in Hyde was 210

- The comparison of the numbers of MCCDs issued by Shipman and general practitioners in the same locality with similar patients indicated that he issued an excess total number of MCCDs of 297 (95% confidence interval 254 to 345) and an excess related to deaths occurring at home (including practice premises) of 236 (95% confidence interval 198 to 277)
- The excess was greatest among females aged 75 or above, second highest among females aged 65–74, and third highest among males aged 75 or above
- The excess numbers were evident from the first few years of Shipman's career as a general practitioner
- Six deaths certified by Shipman occurred on practice premises, one in the group practice and five in the single-handed practice.

The prospective audit that included all patients registered with Shipman from 1987 indicated a lower number of excess deaths. The excess was 98 among females 1987–1998, with 12 less than expected among males. Since all patients were included in this analysis, whether or not their illnesses were being directly managed by Shipman, it was probably less sensitive to variations in the annual numbers of MCCDs issued by Shipman.

The review of clinical records and cremation forms suggests that the excess related to deaths at home (236) is most likely to reflect the true number of deaths about which there should be concern. Between 1985 and 1998, information from records and/or cremation forms was available for 288 (88.9%) of the 324 deaths for which Shipman issued MCCDs. 166 (57.6%) of these were classified as highly suspicious and 43 (14.9%) as moderately suspicious on the basis of the relationship between cause of death as certified by Shipman and medical history, and other features typical of the convictions (Shipman present at or shortly before death, death at home, cause of death). The total excess number of deaths between 1985 and 1998 as estimated from the excess among deaths at home was similar – 199.

The review of the audit trail disclosed a small number of records that contained back-dated entries, but it was not possible to judge the integrity of records made on paper. Shipman's standard of record keeping was poor.

The review of cremation forms indicated that in comparison with the other local practitioners:

- Death was more likely to occur in the afternoon
- Be certified as due to heart conditions, stroke or old age
- More likely to occur within 30 minutes and the mode of death being described as syncope or collapse
- Shipman was more likely to be present at the death of his patients, and relatives or carers were less likely to be present.

It was not possible to identify abnormal prescribing of restricted drugs, other than the irregularities already identified by Greater Manchester Police. It is not clear, therefore, how Shipman obtained all the diamorphine necessary.

The findings from the various components of the audit have dreadful implications, and give rise to grave concerns about the activities of Harold Shipman during his career as a general practitioner. It is the duty of health services and health professionals to protect patients from individuals such as Shipman. Therefore, recommendations have been made about arrangements to monitor the death rates of patients of general practitioners, the information collected for death certification, the regular review of general practice records and recording of information about restricted drugs.

One: Introduction

1.1 Aims of the audit

In January 2000 Harold Shipman was convicted of the murder of fifteen patients in his care, and of forging the will of one. The day following the pronouncement of the verdict, the Secretary of State for Health announced arrangements for an Inquiry in order to identify factors that may have enabled these events to occur. The House of Commons was informed that the Crown Prosecution Service was considering further charges and that the police had, at that stage, investigated a total of 136 cases.

In addition to the Inquiry, several other steps were announced. These included:

(i) plans to require doctors to disclose criminal convictions and steps taken against them by a professional regulatory body, whether in the UK or abroad, before they could be appointed to medical lists;

(ii) plans to require general practitioners to report deaths in their surgeries and other serious incidents to Health Authorities;

(iii) a review of death certification procedures and the checks undertaken before cremation and burial;

(iv) a clinical audit of Shipman's past practice, commissioned by the Chief Medical Officer.

This report describes the methods of the audit, and details the findings and principal implications.

The key aims of the audit were to identify:

(a) the pattern of observed compared to expected deaths in particular age groups

(b) deaths showing unusual clusters in time

(c) deaths showing unusual clusters by place of death

(d) the relationship between certified cause of death and medical history

(e) the integrity of records

(e) the prescribing of restricted drugs.

1.2 Shipman's professional career

Shipman graduated from Leeds University Medical School in 1970 (an outline of his career is included in Appendix 1). Following pre-registration hospital posts, he worked in junior hospital posts until 1974, when he became a GP assistant in Todmorden, West Yorkshire. After one month as an assistant, he was invited to become a principal.

1 | Terms of reference and process of investigation

1.1 During the summer of 2001, concerns were raised with CHI about the use of some medicines, particularly analgesia and levels of sedation, and the culture in which care was provided for older people at the Gosport War Memorial Hospital. These concerns were also about the responsibility for clinical care and transfer arrangements with other hospitals.

1.2 On 22 October 2001, CHI launched an investigation into the management, provision and quality of healthcare for which Portsmouth Healthcare NHS Trust was responsible at the Gosport War Memorial Hospital. CHI's decision was based on evidence of high risk activity and the likelihood that the possible findings of a CHI investigation would result in lessons for the whole of the NHS.

Terms of reference

1.3 The investigation terms of reference were informed by a chronology of events provided by the trust surrounding the death of one patient. Discussions were also held with the trust, the Isle of Wight, Portsmouth and South East Hampshire Health Authority and the NHS south east regional office to ensure maximum learning locally and for the NHS.

1.4 The terms of reference agreed on 9 October 2001 are as follows:

The investigation will look at whether, since 1998, there had been a failure of trust systems to ensure good quality patient care. The investigation will focus on the following elements within services for older people (inpatient, continuing and rehabilitative care) at Gosport War Memorial Hospital.

Investigation focuses on the following Elements

i) staffing and accountability arrangements, including out of hours

ii) the guidelines and practices in place at the trust to ensure good quality care and effective performance management

iii) arrangements for the prescription, administration, review and recording of drugs

iv) communication and collaboration between the trust and patients, their relatives and carers and with partner organisations

v) arrangements to support patients and their relatives and carers towards the end of the patient's life

vi) supervision and training arrangements in place to enable staff to provide effective care

4 | Arrangements for the prescription, administration, review and recording of medicines

Police inquiry and expert witness reports

4.1 CHI's terms of reference for its investigation in part reflected those of the earlier preliminary inquiry by the police, whose reports were made available to CHI.

4.2 Police expert witnesses reviewed the care of five patients who died in 1998 and made general comments in the reports about the systems in place at the trust to ensure effective clinical leadership and patient management on the wards. The experts' examination of the use of medicines in Daedalus, Dryad and Sultan wards led to significant concern about three medicines, the amounts which had been prescribed, the combinations in which they were used and the method of their delivery. In summary:

Evidence from Police Expert-witness

- **there was no evidence of trust policy to ensure the appropriate prescription and dose escalation of strong opiate analgesia as the initial response** to pain. It was the view of the police expert witnesses that a more reasonable response would have been the prescription of mild to moderate medicine initially with appropriate review in the event of further pain followed up
- **there was inappropriate combined subcutaneous administration of diamorphine, midazolam and haloperidol,** which could carry a risk of excessive sedation and respiratory depression in older patients, leading to death
- **there were no clear guidelines available to staff to prevent assumptions being made by clinical staff that patients had been admitted for palliative, rather than rehabilitative care**
- there was a failure to recognise potential adverse effects of prescribed medicines by clinical staff
- clinical managers failed to routinely monitor and supervise care on the ward

It is important to emphasise that these reports were not produced for this CHI investigation and CHI cannot take any responsibility for their accuracy. Whilst the reports provided CHI with very useful information, CHI has relied on its own independent scrutiny of data and information gathered during the investigation to reach the conclusions in this chapter.

Executive summary

CHI has undertaken this investigation as a result of concerns expressed by the police and others around the care and treatment of frail older people provided by Portsmouth Healthcare NHS Trust at Gosport War Memorial Hospital. This follows police investigations between 1998 and 2001 into the potential unlawful killing of a patient in 1998. As part of their investigations, the police commissioned expert medical opinion, which was made available to CHI, relating to a total of five patient deaths in 1998. In February 2002, the police decided not to proceed with further investigations.

Based on information gathered during their investigations, the police were sufficiently concerned about the care of older people at Gosport War Memorial Hospital to share their concerns with CHI in August 2001. CHI is grateful to the Hampshire Constabulary for sharing information with us which contributed towards the local and national recommendations CHI makes to improve the care of this vulnerable group of NHS patients.

CHI has conducted a detailed review of the systems in place to ensure good quality patient care. CHI does not have a statutory remit to investigate either the circumstances around any particular death or the conduct of any individual.

Key conclusions

CHI concludes that a number of factors, detailed in the report, contributed to a failure of trust systems to ensure good quality patient care:

- there were insufficient local prescribing guidelines in place governing the prescription of powerful pain relieving and sedative medicines
- the lack of a rigorous, routine review of pharmacy data led to high levels of prescribing on wards caring for older people not being questioned
- the absence of adequate trust wide supervision and appraisal systems meant that poor prescribing practice was not identified
- there was a lack of thorough multidisciplinary total patient assessment to determine care needs on admission

CHI also concludes that the trust now has adequate policies and guidelines in place which are being adhered to governing the prescription and administration of pain relieving medicines to older patients.