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Reporting errors: can a "fair blame" culture really work for pharmacists?

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In recent years the Government has become increasingly aware of, and concerned about, the level of errors made by health professional staff in the NHS. To tackle the problem it has set up the National Patient Safety Agency. Its aim is to create a "fair blame" culture and to encourage health professionals to report errors and "near misses" anonymously and without fear of disciplinary or legal consequences, to help in the process of eliminating them. But escaping blame when reporting errors may not be so straightforward for pharmacists, since they are bound by criminal law in relation to dispensing. A recent meeting of the Pharmacy Law and Ethics Association looked at this issue and also heard how one primary care trust is dealing with it.

Any dispensing error can amount to a criminal offence under section 64 of the Medicines Act 1968. The offence is absolute and involves strict liability, which means that merely making a dispensing error is a criminal act, even though there is no intention to do anything unlawful and even if no harm results. Furthermore, following the Bristol paediatric heart surgery scandal it was established that exemption from NHS discipline does not apply if a criminal offence has been committed. The law places pharmacists in a unique position among health professionals, and it is much more difficult to charge doctors and nurses with an offence as the result of an error. They are only criminally liable if what they do amounts to assault, ie, carrying out actions without a patient's consent, or, if they cause the death of a patient through gross negligence, they can be charged with manslaughter.

With regard to self-reporting of errors, it is a basic principle of English law that a person cannot incriminate him- or herself through disclosure of information. In addition, the Department of Heath has accepted the recommendation of Ian Kennedy, who carried out the Bristol inquiry, that immunity from disciplinary action should apply to the reporting of errors — unless a criminal offence has been committed. But this calls into doubt whether protection would apply to pharmacists for the criminal offence under the Medicines Act of making a dispensing mistake.

There are also contractual issues between pharmacists and their employers to be considered in reporting errors. If agreements are put into contracts of employment not to discipline or to regard contracts as repudiated if errors are reported, what happens if a pharmacist reports making many errors? If the employer is not allowed to discipline or dismiss such an employee, the employer could be accused of failing to protect the public. Also, although contracts of employment could include agreements not to pursue criminal proceedings if errors are reported, this would not bind prosecuting authorities. "Fair blame" agreements in contracts of employment cannot therefore be regarded as "comfort clauses" for employees.

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There are also questions around protecting confidentiality for a pharmacist who reports making an error. The NPSA is looking for mechanisms to ensure this, but public interest considerations may override its intention to maintain the anonymity of those reporting in all cases, and health authorities have been successfully sued in the past for failing to breach confidences when harm has resulted through maintaining them.

To resolve these issues and ensure an environment in which pharmacists will feel encouraged and secure in reporting dispensing errors, a change in the law may be necessary.

In spite of the difficulties surrounding the legal situation, some local health trusts are implementing medication error reporting schemes. One such is the SafeMed scheme for reporting incidents (the less judgemental term given to errors), potential incidents and near misses, which has been set up by the East Kent Community Health Trust. Introduced for primary care staff from 2001, it was rolled out first to community pharmacies, then to GPs and their practice staff and it is being extended to dentists and opticians from this year. Half the community pharmacies in the trust are already involved in the scheme.

SafeMed operates a fair blame culture, with anonymous reporting in primary care if desired. It also forms part of the community pharmacy clinical governance accreditation scheme. A crucial part of the process has been regular feedback to participants: summary reports are issued every eight to 12 weeks to stimulate practitioners to look at their own practice, and there is a "lesson of the month". Project-based work is also being carried out and recent projects have covered problems with methotrexate, for which there is currently no national guidance, and errors arising through packaging and labelling. Training on analysis of errors is also offered.

There have been some snags and several lessons have been learnt from the operation of the scheme. For example, reports made represent only the tip of the iceberg, with many events not being reported because they seem to pharmacists too mundane to record. Participation in the scheme has been variable and some pharmacy multiples have been reluctant to take part. Most larger multiples have their own internal error reporting systems and having to submit two forms, one to the PCT and another to the company, for the same incident acts as a deterrent to participation. It has also proved difficult to maintain the profile of the scheme, since it requires significant investment in terms of time and money, both of which are scarce. Other issues raised have been how to balance confidentiality against the responsibility for patient safety and the need to provide support to staff following an incident.

Experience from SafeMed has raised several questions about a national scheme of error reporting. Can a scheme really be mandatory? Can it really be confidential? How can data be presented? Will honest and full reporting be interpreted by the public and media as revealing poor, even dangerous, practice? Can national reporting address local issues? Will the NPSA be too slow in gathering information and formulating and disseminating error reduction strategies?

East Kent's SafeMed has been a pioneering scheme that has shown that a local initiative can work, although there have been no direct outcomes yet and overall benefits for patient safety are unclear. But it has demonstrated that health professionals broadly welcome such schemes and that they develop their own momentum since, when one group starts reporting, others follow. It has also shown that integrated, multiprofessional reporting is powerful and must be the way ahead for reducing error rates in health care and improving patient safety.

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