ORIGINAL ARTICLE

Likelihood of reporting adverse events in community pharmacy: an experimental study

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Background: In the UK the National Reporting and Learning System (NRLS) is designed to coordinate the reporting of patient safety incidents nationally and to improve the ability of the health service to learn from the analysis of these events. Little is known about levels of engagement with the NRLS.

Objective: To examine the likelihood of community pharmacists and support staff reporting patient safety incidents which occur in community pharmacies.

Methods: Questionnaire survey containing nine incident scenarios. In the scenarios two factors were orthogonally manipulated: the outcome for the patient was reported as good, bad or poor, and the behaviour of the pharmacist was described as either complying with a protocol, not being aware of a protocol (error), or violating a protocol. Respondents were asked to rate whether they would report the incident (1) locally within the pharmacy and (2) nationally to the National Patient Safety Agency (NPSA).

Results: 275 questionnaires were returned (79% response rate) from 223 community pharmacists and 52 members of support staff. There were significant main effects for both patient outcome ($F(2,520) = 18.19$, $p < 0.001$) and behaviour type ($F(2,520) = 93.98$, $p < 0.001$), indicating that pharmacists and support staff would take into account both the outcome of the behaviour and whether or not it follows a protocol when considering to report an incident within the pharmacy. Likewise, both pharmacists and support staff considered patient outcome ($F(2,524) = 12.59$, $p < 0.001$) and behaviour type ($F(2,524) = 34.82$, $p < 0.001$) when considering to report to the NPSA. Both locally and nationally, the likelihood of reporting any incident was low, and judgements on whether to report were more affected by the behaviour of the pharmacist in relation to protocols than the resulting outcome for the patient.

Conclusions: Community pharmacists and their support staff would be unlikely to report adverse incidents if they witnessed them occurring in a community pharmacy. They remain to be convinced that the advantages to them and their patients outweigh the consequences of blame.

Improving the safety record of health care has become an international priority in recent years. Increasingly, it is acknowledged that learning from mistakes is key to improving the quality of health care.^{1,2} National incident reporting schemes have been developed in a number of countries such as Australia, Denmark and the US, and are currently being planned for Canada and the Netherlands.³ In 2004 the National Patient Safety Agency (NPSA) launched the National Reporting and Learning System (NRLS) in England and Wales, designed to coordinate the reporting of patient safety incidents nationally and to improve the ability of the health service to learn from the analysis of these events.

However, if these benefits are to be realised, then local incident reporting schemes and the NRLS will need to be adopted and used by health professionals. Successful reporting systems have previously been identified as sharing a set of common characteristics—namely, that they are confidential, non-punitive, independent, systems orientated, and responsive.⁴ In addition, it is increasingly being recognised that, for a system to work, it needs to be embedded in an open and fair reporting culture.⁵ Lessons from other high risk industries indicate that, under these circumstances, significant improvements in safety performance can be achieved.⁶

A number of voluntary schemes have been established in the UK in which community pharmacists can report medication errors, and some of the large community pharmacy chains have also established mandatory in-house dispensing error reporting schemes. Despite this, there has been a distinct lack of standardisation in the nature and quality of information that is gathered from such schemes.⁷

In addition, there are no published data available on dispensing error rates from these in-house reporting systems. More recently, requirements for reporting medication related patient safety incidents have been identified as an essential service to be undertaken by all community pharmacy contractors as part of the new national pharmacy contract in England and Wales.⁸ Incident reporting forms part of the minimum standards against which community pharmacies will be performance managed by primary care trusts (PCTs). Initially, error logs will need to be maintained in all community pharmacies with only serious incidents being reported to the NPSA. In the longer term it is expected that all patient safety incidents will be reported directly to the NPSA. Despite this, very little is known about levels of community pharmacy staff engagement with incident reporting schemes generally and the NPSA scheme specifically.

The aim of this study was to explore the likelihood of community pharmacists and their support staff reporting incidents that occur in community pharmacies.

METHODS

The community pharmacists and support staff were recruited on a volunteer basis with invitation letters sent to all community pharmacies located in 14 PCTs in England, nine of which were based in the Midlands and the remaining five in the North West. In total, 347 questionnaires were distributed during April 2004. After 1 month a reminder letter was sent to any non-responders.

Ethical approval for the study was obtained from the University of Manchester Senate Committee on the Ethics of Research on Human Beings.

Development of the questionnaire

Each questionnaire contained nine short scenarios describing the behaviour of a pharmacist whilst dispensing a prescription or supplying an over the counter (OTC) medicine. The development of the scenarios was informed by two focus group discussions with community pharmacists designed to generate realistic scenarios for use in the survey. During each focus group, participants were asked to consider situations they had previously encountered and describe the rule related behaviour of a community pharmacist. Two factors were included in each scenario: (1) the outcome for the patient was categorised as good, poor or bad; and (2) the behaviour of the pharmacist was described as either in line with a protocol (compliance), not being aware of a protocol (error), or a deliberate deviation from a protocol (violation).⁹ For the purpose of this study, the operational definition of a poor outcome included avoidable and short term discomfort for the patient, while a bad outcome included more prolonged and serious harm. The example shown in box 1 describes a violation of a protocol that results in a bad patient outcome.

Nine versions of the questionnaire were produced in which the two factors (behaviour type and patient outcome) were orthogonally manipulated. The scenarios were also randomly ordered in the different versions to control for the effects of order of presentation. For each respondent the nine scenarios in their version of the questionnaire covered all possible combinations of behaviour and patient outcome (full factorial design). Respondents were asked to read each scenario and imagine that they had witnessed the situation described. They were then asked to rate the likelihood that they would report the incident locally within the pharmacy, and that they would report the incident nationally to the NPSA. Responses were indicated on a 5-point scale with end points labelled “very unlikely” (1) to “very likely” (5).

Data analysis

The data were analysed using repeated measures analysis of variance (ANOVA).¹⁰ The analysis had two within participant factors each with three levels—namely, behaviour type (compliance, error, violation) and patient outcome (good, poor, bad)—and one between participants factor with two levels—namely, staff group (pharmacist, support staff). Comparison of the mean scores by staff group allowed us to investigate the ratings of each group. The analysis also allowed us to compare ratings of the three types of behaviour independent of patient outcome, to compare ratings of patient outcome independent of behaviour, and to examine the interaction of behaviour, patient outcome, and staff

group. All calculations were performed with SPSS version 11.5.

In addition to the quantitative survey results, we also examined the free text comments provided by the survey respondents in order to explore further the opinions and views of community pharmacists and their support staff towards incident reporting. The comments were read independently by two members of the research team (DMA and CM) and key themes were identified using content analysis techniques and constant comparative methods.¹¹ QSR NVivo software (Version 2.0) was used to apply codes to the data.

RESULTS

In all, 275 questionnaires were returned (79% response rate) from 223 community pharmacists (pharmacy owner (n = 22), employed pharmacist (n = 67), locum pharmacist (n = 134)) and 52 members of support staff (pharmacy assistant (n = 14), preregistration pharmacist (n = 25), pharmacy technician (n = 13)).

Likelihood of reporting an incident locally within the pharmacy

Figure 1 shows that overall the pharmacists and support staff would be unlikely to report adverse incidents if they witnessed them occurring in a community pharmacy. There were significant main effects for both patient outcome ($F(2,520) = 18.19$, $p < 0.001$) and behaviour type ($F(2,520) = 93.98$, $p < 0.001$), indicating that the pharmacists and support staff would take into account both the outcome of the behaviour and whether or not it follows a protocol when considering to report an incident. The two way interaction of behaviour type by staff group was also significant ($F(2,520) = 3.64$, $p = 0.03$), highlighting that the distinctions made between behaviour types were significantly more striking for support staff than those made by the pharmacists.

Figure 1 Likelihood of reporting an incident locally within the pharmacy by behaviour type and patient outcome by (A) community pharmacists and (B) support staff.

Box 1 Example scenario used in the questionnaire

Violation with a bad patient outcome

A pharmacist receives a prescription for diclofenac and methotrexate for a patient with rheumatoid arthritis. She notices from the records on the pharmacy computer that the patient had been dispensed these two drugs last month. The pharmacy computer highlights that there is a potentially serious drug interaction when these two drugs are taken together. The protocol in the pharmacy states that the pharmacist should contact the doctor to discuss all potentially serious drug interactions. Given that the patient had received the drugs before, the pharmacist decides to ignore the protocol and dispenses the prescription. The patient takes the tablets and is admitted to hospital due to methotrexate toxicity.

Figure 2 Likelihood of reporting an incident nationally to the NPSA by behaviour type and patient outcome by (A) community pharmacists and (B) support staff.

As might be expected, there were linear trends showing that when the behaviour led to a good patient outcome (mean = 1.77), it was far less likely to be reported than a poor (mean = 1.96) or bad outcome (mean = 2.20). This trend applied across all three behaviour types. Likewise, compliance with a protocol (mean = 1.40) was far less likely to be reported than either a violation (mean = 2.23) or an error (mean = 2.30). Inspection of the means associated with the interaction effect indicated that, even when the scenario depicted a poor or bad outcome and there had been a violation or an error, ratings of the likelihood of reporting were below the mid point of the scale, as shown in fig 1. In other words, overall the chance of reporting an incident was low, even when the pharmacist's behaviour was suboptimal and there was a negative outcome for the patient.

Not surprisingly, the comments from respondents indicated that the prevailing safety culture within community pharmacy had a profound impact on the likelihood of reporting.

"Reporting incidents within the pharmacy would depend on which pharmacy! If I was aware of a 'learn from mistakes' culture then I would be more likely to report. If it was a 'fault-led' attitude I would be more likely to speak privately to the pharmacist."

Rather than focusing on a systems approach, the comments indicate that fault was readily assigned to individuals but, despite this, there was still a reluctance to report incidents.

"I would only report a person who was making continual mistakes."

"One-off situations, I would not report the pharmacist, would discuss with individual. I would not be happy to 'whistle blow' unless I felt that the same person was doing errors or [they] were potentially life threatening."

This reluctance was often driven by feelings of loyalty and sympathy towards colleagues, or tensions within the workplace that had resulted from previous incident reports.

"I would never report another pharmacist for making a misjudgement as it destroys loyalty. We are all only human and mistakes do occur everywhere."

"I can understand all the arguments for reporting to Head Office but there are now pharmacists who feel angry about other pharmacists and support staff reporting incidents."

Needless to say, anonymity emerged as an important factor in facilitating reporting within a community pharmacy.

"I would feel uncomfortable reporting incidents to [the] company unless they could be done anonymously."

Likelihood of reporting an incident nationally to the NPSA

Overall, the results indicate that the community pharmacists and support staff were very unlikely to report incidents to the NPSA, regardless of the action of the pharmacist or the nature of the patient outcome (fig 2). Nonetheless, there were significant main effects for both patient outcome ($F(2,524) = 12.59$, $p < 0.001$) and behaviour type ($F(2,524) = 34.82$, $p < 0.001$), indicating that pharmacists and support staff would take into account both the outcome of the behaviour and whether or not it followed a protocol when considering whether to report an incident to the NPSA.

Errors (mean = 1.59) and violations (mean = 1.57) were more likely to be reported than compliance with a protocol (mean = 1.20). Predictably, good patient outcomes (mean = 1.32) were less likely to be reported than when the pharmacist's behaviour led to poor (mean = 1.46) or bad patient outcomes (mean = 1.56). In this case there were no significant differences between pharmacists and support staff; in other words, there was no two-way behaviour or patient outcome $\times$ staff group interaction effects.

Some of the respondents did not know about mechanisms for reporting incidents to the NPSA:

"Reporting to the NPSA is something I have never considered and would be interested to know more about."

Nonetheless, others had strong feelings about their level of engagement with such schemes:

"NPSA does not appear to be well thought out and due to possible duplication of incident reporting, with PCT reports also being referred to the NPSA, any results are statistically meaningless. Until this is resolved, I have no confidence in the NPSA and I am unlikely to report."

"I don't see the need for another body for reporting pharmacists to. There are more than enough already. In every case, I would speak to the pharmacist face to face."

DISCUSSION

In the UK a major policy commitment is to establish a national incident reporting system to ensure that lessons learnt from adverse events in one locality are shared across the health service as a whole. This approach is at odds with the prevailing culture in community pharmacy manifest in this study. Adverse incidents in community pharmacies are associated with less than satisfactory performance, and reporting incidents is associated with the attribution of blame. There is also little established tradition of organisational learning from mistakes.

Each year over 645 million prescription items are dispensed in 10 462 community pharmacies in England and Wales.¹² It has previously been estimated that, on average, for every 10 000 items dispensed there are around 22 near misses and four dispensing errors.¹³ However, these figures are likely to underestimate the true extent of medication errors occurring in community pharmacies as incidents may not be noticed by the patient and/or may not be reported. The results from the questionnaire in the current study suggest that under-reporting of incidents is likely to be a significant problem. In deciding on whether to report, community pharmacists and support staff take into account both the actions of a pharmacist and the resulting patient outcome. However, judgements on whether to report an incident were more

affected by the behaviour of the pharmacist in relation to protocols than the resulting outcome for the patient. Reliance on existing reporting schemes is therefore likely to provide an incomplete picture of the extent and nature of incidents that occur in this setting.

Other studies that have examined the likelihood of reporting patient safety incidents have focused on other sectors of health care.^{14–17} Lawton and Parker¹⁵ found significantly different ratings of reporting likelihood between doctors, nurses and midwives, with doctors generally being less likely to make a report than either nurses or midwives. Qualitative findings suggest that cultural differences between doctors and nurses underpin attitudes to incident reporting, whereby nurses report more habitually due to a prevailing culture that provides more directives, protocols and the notion of security, whereas the medical culture appears to be less forthcoming, favours dealing with incidents “in house”, and is less reliant on directives.¹⁶ More recently, a survey of 2575 UK doctors found that, although approximately 80% of respondents had witnessed a colleague making a mistake, few would be willing to report the incident, citing a lack of trust with available incident reporting schemes as a major barrier.¹⁸

In practice, there will be a need to ensure that innovations introduced to improve patient safety actually achieve their potential. Without local engagement, national initiatives are unlikely to be implemented.¹⁹ In particular, the roll out of national incident reporting schemes will not overcome problems with chronic underreporting resulting from a prevailing “blame” culture.²⁰ Clearly, the key to success will be to develop a reporting culture in which staff feel able to report incidents without fear of retribution. To tackle the problem the NPSA is working to develop an “open and fair” culture towards reporting, in which health professionals can report incidents anonymously, without fear of unreasonable disciplinary or legal action.⁵ However, escaping blame may not be so straightforward for pharmacists, given that in the UK any dispensing error can potentially amount to a criminal offence under section 64 of the Medicines Act 1968.²¹

Several limitations to this study need to be taken into account in interpreting the findings. Firstly, the use of scenarios within the questionnaire could be criticised on the grounds that they may lack realism. To avoid this, we developed the scenarios in collaboration with practising community pharmacists and they were based on situations that had previously been encountered. Secondly, it was not possible to survey a random sample of community pharmacists and support staff and it is likely that those who responded were individuals with a particular interest in patient safety. One potential limitation is that there was a greater degree of uptake of the questionnaire with locum community pharmacists than with other sectors of community pharmacy. Although locum community pharmacists account for a large proportion of pharmacists working in community pharmacy, it is important to note that the proportion of locum pharmacists within this sample is higher than that present in the profession.²² Nonetheless, the types of community pharmacies in which the pharmacists predominantly worked broadly reflect the national distribution of community pharmacies.¹² In order to minimise any bias we also analysed the results by type of pharmacist (pharmacy owner, employed pharmacist, locum pharmacist) and found that there were no discernable differences in ratings between the three groups.

Learning from incidents requires that the reporting of such events is reliable. The findings from this study suggest that underreporting of incidents occurring in community pharmacies is likely to be a significant problem. Reliance on existing reporting systems in community pharmacy will

therefore provide incomplete feedback on levels of safety and rule breaking behaviour. Based on the findings of this study it appears that, so far at least, there is a very low level of engagement with national reporting schemes which suggests that, in practice, opportunities for capturing and sharing learning from incidents that occur in community pharmacies will be limited. Recent findings suggest that this reluctance relates in part to a lack of trust.⁷ Community pharmacy staff need to be convinced of the benefits that accrue to them and to patients through reporting adverse incidents, particularly nationally. They also need to be reassured that such benefits are not outweighed by adverse managerial scrutiny or threats to promotion and employment.

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