Reporting, reflecting on and learning from adverse events in community pharmacy: development and evaluation of an incident reporting form

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Abstract

Aim
To develop and evaluate an incident reporting form for the collection of information on patient safety incidents that occur in community pharmacies.

Methods
Content analysis of nine existing incident reporting forms. Face validity and feasibility were explored in three focus groups with community pharmacists and support staff, and six telephone interviews with clinical governance leads within community pharmacy. The comprehensiveness of the form was examined by evaluating its ability to categorise 2,100 incidents reported to a national community pharmacy claims database, and its sensitivity assessed using incident scenarios with ten community pharmacists and two pharmacy technicians.

Results
The incident reporting form was judged to be acceptable, and was also found to be comprehensive and sensitive in terms of its ability to capture details of patient safety incidents that occur in community pharmacy, including no-harm or near-miss events. In contrast, the analysis of existing incident reporting forms found wide variation in content and complexity.

Conclusions
This study has produced an incident reporting form that is suitable for application in community pharmacies. The form not only facilitates the efficient reporting and analysis of patient safety incidents from a range of services, but also encourages staff to be more proactive in dealing, reflecting and learning from incidents.

Improving patient safety has become an international priority in health care following the publication of major policy documents in the UK and the US. Incident reporting has been repeatedly identified as one of the key factors to achieving an effective risk management culture within a range of high-risk industries, most notably in aviation. Recognising the success of such schemes, there has been growing awareness within the health service of the need to develop similar systems for reporting adverse incidents to ensure that lessons learnt from such events in one locality are shared across the health service as a whole. The National Reporting and Learning System (NRLS), a web-based incident reporting scheme, developed by the National Patient Safety Agency (NPSA) is currently being rolled out across NHS organisations in England and Wales and is intended to play a key role in meeting these strategic objectives.

In England and Wales, incident reporting and compliance with clinical governance arrangements are integrated components of essential services in the new national pharmacy contract. Specifically, contractors will be expected to maintain a log of patient safety incidents within the pharmacy. It is expected that the information collected will be used to complete the mandatory fields of the NRLS. At present, dispensing incident reporting schemes have been established in several localities and in some of the large pharmacy multiple chains. However, there has been a distinct lack of standardisation in the nature and quality of information that is gathered from such schemes.

Notably, there have been few reports that have systematically examined the causes and circumstances of incidents occurring in community pharmacies. It is likely that this partly reflects commercial sensitivities in publishing such data, but it is also the case that many of the existing incident report forms only capture free-text descriptions of the incidents, which restricts the level of analysis that can be undertaken with such data and can lead to difficulties in identifying error trends. In addition, almost all the existing forms focus exclusively on dispensing errors, and do not routinely capture data on incidents relating to other services operating in community pharmacy, such as over-the-counter medicine sales or near-miss events.

The aim of this study was to develop and evaluate a minimum dataset for the collection of information on patient safety incidents that occur in community pharmacies.

Methods
This study formed part of a wider programme of research into patient safety in community pharmacies. Relevant data for inclusion in the minimum dataset were derived by content analysis of nine existing incident reporting forms developed for community pharmacy that are either currently in use or have previously been used in research. The design and layout of the incident reporting form also took into account findings from 10 focus group discussions with community pharmacists and support staff, which indicated that any incident reporting form would need to be easy to use, be anonymous and complement the working practices of community pharmacy. Many of the existing forms required the reporter to identify individuals who were involved in the incident, either by providing their names or Royal Pharmaceutical Society registration numbers; these items were not included in the minimum dataset.

Once a draft reporting form had been developed, its face validity and feasibility were
explored in three focus groups with community pharmacists and support staff. Each focus group contained five to eight participants who were purposively selected to represent the wide variety of staff working within community pharmacy (pharmacy owners, employed pharmacists, locum pharmacists, technicians and pharmacy assistants). Telephone interviews about the form were also conducted with a purposive sample of three primary care trust community pharmacy clinical governance facilitators, two pharmacists responsible for clinical governance within national pharmacy chains and one independent pharmacist who was also a member of the local PCT professional executive committee.

The comprehensiveness of the incident reporting form was examined by comparing the ability of the form to capture and categorise 2,100 incidents reported to a national community pharmacy claims database between 1995 and 2003. Details of all incidents recorded in the claims database were categorised using the incident reporting form by one member of the research team, with a second member checking a 10 per cent random sample. Finally, we assessed the sensitivity of the form with a 10 community pharmacists and two pharmacy technicians. The participants were asked to complete a reporting form recording the details of each of 10 community pharmacy-based scenarios provided by the researchers. This exercise was repeated one week later.

An example of one of the scenarios used in the sensitivity test is shown in Panel 1. Descriptive statistics were used to describe the consistency of reporting. “Gold standard” ratings for the scenarios were also obtained from two pharmacists and two GPs who independently recorded the 10 scenarios using the incident reporting form.

The incident reporting form is available at www.cip.man.ac.uk.

Results

In contrast to many existing community pharmacy incident-reporting schemes, our data collection tool was designed to capture incidents that not only involve dispensing, but also over-the-counter sales and a number of other services provided from community pharmacies. Data are recorded via tick boxes and free-text entries, which facilitates the efficient reporting and analysis of incidents. Key fields on the form also map onto NRPSL categories making it easy to share information with the NRPSL if required. In addition, the form includes a prompt to facilitate the development of an action plan to negate similar incidents occurring in the future, thus encouraging staff to be more proactive in dealing, reflecting and learning from incidents.

Panel 1: Example scenario used in the sensitivity test

A patient, Jenny Cartwright (72 years of age), comes into your pharmacy and asks to speak to the pharmacist. She explains that while you were away, the locum had dispensed her usual NHS prescription for losartan 50mg. When she checked the package at home, she noted that she had been given Lustral 50mg. “Now picking the wrong medicine can happen to anyone,” she remarked. What was more upsetting, she noted, was that when she came back to the pharmacy to collect an outstanding balance from the prescription, the same thing had happened again. She confirms that she has not taken any of the wrongly supplied medicine.

I suppose you could use it for head office and for the national body as well.

Quicker to use at the time of incident than NPSA website, captures data quickly, which can be transferred to NPSA later, if thought relevant.

The participants thought that the form was a marked improvement on the way in which incidents were documented at present, particularly as it encouraged reflection on the incident and the development of an action plan:

I like the idea of reflecting upon a problem and encouraging them to think about future events.

You’re doing two things at once really, aren’t you? You’re reporting your incident but you’re saying what you could do to prevent this from happening again.

Others suggested that one of the key benefits was that the form covered the range of services that operate in community pharmacies, rather than focusing exclusively on dispensing incidents:

I like the idea that the form encompasses other services, other than dispensing, such as OTC, prescribing.

I think the fewer pieces of paper in the pharmacy the better, so the more services a form covers the more likely it will be used.

In addition, feedback from the clinical governance leads suggested that the use of tick-boxes was an effective means of capturing information rather than relying entirely on free-text entries that characterised most existing incident reporting forms:

Good form — plenty of boxes to tick. Our experience in pharmacy is that they don’t like too many blank spaces. Things need to be structured. Tick boxes tend to be filled in, whereas free-text doesn’t.

Very difficult to get anything written in free-text boxes, what is written is unusually uninformative — “spoke to the pharmacist”.

They also suggested that the details covered by the form would act as a guide to incident reporting, reducing the problem of memory recall and ultimately improving the accuracy of reports:

Gives their thinking structure, so instead of asking them what caused the incident, asking which of the following were involved.

Very user-friendly. Few boxes require free-text but the majority were tick-boxes, which act as a guide to incident reporting. There are mental prompts about the incident rather than relying on your memory for all the details.

Comprehensiveness of the incident reporting form The form was shown to be comprehensive with regard to its ability to
Sensitivity of the incident reporting form

Twelve raters (10 community pharmacists and two pharmacy technicians) assessed the sensitivity of the incident reporting form by recording details of 10 incident scenarios on the form on two separate occasions. In all, 238 ratings were made for the types of service (response rate = 99.2 per cent) and 233 ratings were made for the types of incidents (response rate = 97.1 per cent).

Across all 10 scenarios, the incidents were correctly recorded for type of service on 100 of 100 occasions (100 per cent) on the first rating exercise, and in 97 out of 98 ratings (99 per cent) one week later. The corresponding figures for rating the types of incidents were 93 out of 96 (97 per cent) on the first rating exercise, and 92 out of 97 (95 per cent) one week later.

Discussion

This study has produced an incident reporting form that is suitable for application in community pharmacies. The form proved to be acceptable, and was found to be comprehensive and sensitive in terms of its ability to capture details of incidents that occur in this setting, including no-harm or near-miss events. In contrast, analysis of existing incident reporting forms found wide variation in content and complexity.

Although our goal was to produce a minimum dataset for recording incidents that occur in community pharmacies, several important issues will need to be addressed in order to maximise its adoption and usefulness in practice. The qualitative data highlight some problems with incident reporting in community pharmacy. In addition, empirical evidence from other parts of this programme of research and experience from other healthcare sectors would suggest that under-reporting of incidents is likely to be a significant problem.2,3

Problems with elicitation and participation bias have previously been shown to affect the reliability of data generated from incident reporting schemes operating within health care.10 No matter how straightforward a reporting form is, staff will only use it if they see that the benefits that emerge from reporting outweigh the inconvenience of reporting and, specifically, that blame will not be attached to the reporter. Anonymous reporting, as used in this incident reporting form, is known to reduce fear of reprimand and is likely to improve reporting levels.1

However, the key to success will be to develop a reporting culture in community pharmacy, in which staff understand the benefits of a dataset that can uncover trends, identify issues and lead to solutions. Staff must also feel able to report incidents without fear of retribution.

The main aim was to develop a minimum dataset for the routine collection of information about incidents occurring in community pharmacies. However, the incident reporting form may also have other uses, for instance, as a research tool to measure outcomes from interventions aimed at improving patient safety in community pharmacy.

We believe that this form is an improvement over the variety of ad-hoc data collection tools currently in use in community pharmacy because it encourages standardisation of data collection and thereby improves the subsequent analysis of incident trends. In line with the requirements for the new national contract for community pharmacy, the incident reporting form will allow pharmacies to maintain a log of patient safety incidents that occur in their pharmacy, which could subsequently populate the mandatory fields in the NRLS.

Importantly, the incident reporting form not only facilitates the efficient reporting and analysis of incidents from a range of services, but also encourages staff to be more proactive in dealing, reflecting and learning from future incidents. This will be an important part of the landscape for developing an effective safety culture within community pharmacy.

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References