Title

Integrating data from the UK National Reporting and Learning System with work domain analysis to understand patient safety incidents in community pharmacy

Authors

Denham L. Phipps, Ph.D.^{1,2}
W. Vanessa Tam, M.Pharm.¹
Darren M. Ashcroft, Ph.D.^{1,2}

1. Centre for Pharmacoepidemiology and Drug Safety, Manchester Pharmacy School, The University of Manchester
2. NIHR Greater Manchester Patient Safety Translational Research Centre, The University of Manchester

Corresponding author's contact details:

Room 1.134 Stopford Building, Oxford Road, Manchester M13 9PT, United Kingdom. Email: Denham.Phipps@manchester.ac.uk

Acknowledgements:

The authors would like to thank the pharmacists who participated in the observations and focus groups. They would also like to thank the National Patient Safety Agency for its assistance in data collection for the study, and Drs Bruce Warner and David Gerrett of NHS England, for their comments on the manuscript.

Keywords:

Incident analysis; Incident reporting; National reporting and learning system; Cognitive work analysis; Sociotechnical system; Community pharmacy.

NOTE: The final published version of this article appears in Journal of Patient Safety, doi: 10.1097/PTS.0000000000000090

ABSTRACT

Objectives. To explore the combined use of a critical incident database and work domain analysis to understand patient safety issues in a healthcare setting

Method. A retrospective review was conducted of incidents reported to the UK National Reporting and Learning System (NRLS) that involved community pharmacy from April 2005 to August 2010. A work domain analysis of community pharmacy was constructed using observational data from five community pharmacies, technical documentation and a focus group with six pharmacists. Reports from the NRLS were mapped onto the model generated by the work domain analysis.

Results. 14,709 incident reports meeting the selection criteria were retrieved from the NRLS. Descriptive statistical analysis of these reports found that almost all of the incidents involved medication, and that the most frequently occurring error types were dose/strength errors, incorrect medication and incorrect formulation. The work domain analysis identified four overall purposes for community pharmacy: business viability; health promotion and clinical services; provision of medication; and use of medication. These purposes were served by “lower order” characteristics of the work system (such as the functions, processes and objects). The tasks most frequently implicated in the incident reports were those involving medication storage, assembly, or patient medication records.

Conclusions. Combining the insights from different analytical methods improves understanding of patient safety problems. Incident reporting data can be used to identify general patterns, while the work domain analysis can generate information about the contextual factors that surround a critical task.

1. BACKGROUND

Healthcare has been characterised as a sociotechnical system; that is, one containing both technical and social elements, which interact to create the work environment and outputs.[1-2] Studies of several healthcare tasks, for example intensive care [3-4] and medicines administration [5-7], suggest that they should be understood as multifaceted processes that involve different groupings of people and technology, and within the context of organisational goals and activities. However, few studies have provided adequate coverage of the healthcare “system”, and there is a need for improved understanding of how systems approaches can be applied in healthcare to improve patient safety.[8]

One patient safety activity in which cognisance of the system context is important is the analysis of critical incidents. In their discussion of healthcare incident investigation, Taylor-Adams and colleagues [9] identified a need for qualitative assessment methods that were grounded in an understanding of human and organisational factors. However, a study of incident reporting in one British teaching hospital [10] found that the reports did not give due consideration to such issues, and therefore were of limited value in supporting organisational learning from the incidents. The authors echoed Taylor-Adams et al. in suggesting that more guidance about the systems context of healthcare is needed for those who seek to make use of incident reports. Vincent [11] and Benn et al. [12] have further argued that the value of incident reporting is, to a large extent, its ability to facilitate healthcare improvement by improving understanding of the context in which patient safety concerns occur.

Cognitive work analysis (CWA) [13] provides a methodology for analysing sociotechnical systems. The basic premise of CWA is that a work setting should be understood in terms of its “constraints” – that is, the limitations and demands that it places on behaviour due to its physical, social and psychological characteristics. Several methods have been proposed as part of CWA; one of these is work domain analysis (WDA), which focuses on creating a functional model of the work setting. In doing so, WDA can be used as the basis for understanding the purpose(s) of work activities, and the contribution made by the processes and objects that are present.

More recently, it has also been applied to the analysis of critical incidents. Xu [14] found that a WDA of an automated aircraft system assisted in the interpretation of laboratory and field data concerning problems with aircraft automation, and generated design recommendations for improving the design. Lim [15] adopted a similar approach in her investigation of medication errors in nursing homes. Using WDA allowed Lim to demonstrate how these errors could be placed in the context of the medication system in its entirety [16-17].

Given the potential for WDA to facilitate the understanding of a work system, and in particular the problems that can occur within the system, it appears to lend itself well to use in the support of incident analysis and learning. The aim of the study reported in this paper was to examine how WDA might be applied to community (a.k.a. retail) pharmacy. Phipps et al. [18] noted that medication safety in community pharmacies can be affected by both technical factors (such as workload, staffing and human-computer interaction) and social and organisational factors (such as the relationship between pharmacy staff, prescribers and service users). Therefore, while many studies of medication errors point legitimately to immediate technical concerns [19], there is a need to consider how these fit into the broader context of pharmacy practice. In the current study, WDA was used alongside an existing national critical incident reporting system to determine the insights that each is able to provide about patient safety in community pharmacy.

2. Analysis one: Critical incident record review

2.1 Method

The source of critical incident data was the United Kingdom's National Reporting and Learning System (NRLS). This is an electronic database of patient safety incidents in the NHS, to which staff can make a confidential report either directly or via the NHS trust.[20] The NRLS was interrogated for all incidents between April 2005 and August 2010 (the point at which data collection took place) that were recorded as having taken place in a community pharmacy setting. As well as containing a brief description of the circumstances of the incident, each record within the NRLS is coded under the following headings:

- Severity of outcome;
- Error category.

The subcategories of severity of outcome and error category are listed in Table 1.

2.2 Results

The NRLS search resulted in the retrieval of 14,709 records. These were entered into version 16 of SPSS for descriptive statistical analysis. Table 1 provides the frequency with which a record is assigned to each coding category.

INSERT TABLE 1 HERE

Of the incidents reviewed, 13,573 (92.3%) were reported to result in no harm, 1,102 (7.4%) in low to moderate harm and 29 (0.2%) in severe harm or death. Within the *incident category*, 14,675 (99.8%) were classified as a medication incident, with much fewer classified under the other incident types (such as documentation or patient abuse). In terms of *error category*, most cases were classified as being due to a dose or strength error (4454, 30.3%), or to the wrong drug or medicine (4119, 28.0%). The least frequently occurring classifications included patient-medication mismatch (787, 5.4%) and adverse drug reaction (10, < 0.1%). However, while 14 of the wrong drug errors and 8 of the dose errors were reported as resulting in severe harm or death, 3 of the patient-medication mismatch errors and 1 of the adverse drug reaction errors also had the same outcome despite these errors occurring much less frequently overall.

3. Analysis 2: Work domain analysis

3.1 Method

A WDA of community pharmacy was carried out using the guidelines provided by Vicente [13] and by Naikar, Hopcroft & Moylan [21]. For the purposes of the analysis, “community pharmacy” was defined as the activities that take place under the auspices of pharmacy staff.

Work domain analysis uses the abstraction hierarchy [22] to document its findings. The abstraction hierarchy describes the work setting in terms of five levels:

- Purposes – reasons for the work system to exist within the wider environment (e.g. aims; regulations);

- Values and measures – ways in which one can judge whether the work system is achieving its purposes (e.g. criteria; policies);
- Functions – things that are done by teams and individuals within the system in pursuit of its purposes (e.g. roles; tasks);
- Processes – things that can be achieved using the objects within the system (e.g. applications; utilities);
- Objects – resources within the system, both material and human (e.g. equipment; staff).

Elements of the system identified by the analyst are assigned to one of the levels. Each element is connected to some or all of the elements at the adjacent levels; the criterion for there being a connection between particular elements is that the element at the lower level provides a means of achieving the element at the higher level – in other words, there is a *functional* (means-end) relationship between them.[13] An example of an abstraction hierarchy is shown in Figure 1.

INSERT FIGURE 1 HERE

The abstraction hierarchy for this study was compiled using the “CWA Tool” computer application.[23] The data used to compile the WDA came from three sources:

- i) *Literature.* We examined literature describing the context and processes of pharmacy practice. These included training texts [24-25] and pharmacy design guidelines [26];
- ii) *Observation.* Researcher DLP observed dispensary activities at five community pharmacies in the North West of England. These included two branches of a national pharmacy chain, one from a large regional chain, one from a small regional chain and one independent pharmacy. Approximately 32 hours of observation were carried out. The observations were approved by the University of Manchester Senate Ethics Committee, with the pharmacist at each location giving informed consent before data collection;
- iii) *Workshop.* Having compiled the first draft of the abstraction hierarchy, a workshop was convened with six pharmacists, all of whom were working in

community pharmacies. During this workshop, the participants were invited to comment on the content of the abstraction hierarchy, in terms both of the coverage and labelling of elements at each level and of the means-ends links between them.

During the compilation of the analysis, early drafts were reviewed by DMA, an academic pharmacist specialising in pharmacy practice. The final version was reviewed by another academic-practitioner working in community pharmacy, who commented on the accuracy and coverage of the model.

Having created the abstraction hierarchy, we sought to determine whether the hierarchy accounted for critical incidents that have occurred in pharmacy practice. We did so by mapping NRLS data onto the abstraction hierarchy; our starting point was the “functions” level of the hierarchy, as this corresponded to discrete tasks in the pharmacy.

Because of the large number of records retrieved from the NRLS, we selected a subset of them (incidents that been classified in NRLS as involving a “primary care or community” specialty and that had sufficient detail to be compared against the abstraction hierarchy; N = 30) for detailed examination. Researcher WVT examined the contents of each record and assigned one or more of the functions, and relevant lower-order elements (processes and objects linked to the chosen function), to the record based on the information provided. Researcher DLP examined a cross-section of the records to provide observer triangulation. Table 2 shows the definitions provided for each function and Figure 2 shows how different levels of the hierarchy (from the function level downwards) were applied to one of the incidents in the dataset.

INSERT TABLE 2 HERE

INSERT FIGURE 2 HERE

3.2 Results

The highest three levels of the hierarchy (purposes; values and measures; functions) generated for community pharmacy are shown in Figure 3. Space precludes the inclusion in this paper of the remaining levels in their entirety; instead, selected elements are discussed here by way of illustration, and the entire hierarchy is available on request from the first author.

INSERT FIGURE 3 HERE

As Figure 3 shows, four purposes were identified for the pharmacy: *business viability* (maintaining existence as a business concern); *health promotion and clinical services* (activities to enhance the health of customers); *provision of medication* (supplying medication to customers); *use of medication* (advising customers on, or assisting them with, the use of medication). It is interesting to note how these purposes are served by the values and measures at the next level down: while *quality and safety* (maximising quality and minimising harm) was considered to serve all four purposes, *cost effectiveness* (maximising the ratio of profit to cost) served only business viability and provision of medication. Meanwhile, *professional standards* (acting in accordance with professional and ethical standards of conduct) served all purposes except business viability. Not only did the participants in the workshop (who held different levels of managerial responsibility in their respective pharmacies) disagree about which purpose was most important from their perspective, but, as the different means-end patterns suggest, there was potential for a conflict between purposes. This was most notable between business viability and the other purposes, where one participant in the workshop raised the example of pharmacists selling clinical services to customers that they did not believe the customers actually required. Doing so generates a profit for the employer but does not, in the view of the pharmacist, necessarily benefit the patient.

At the next level down are eight functions for the pharmacy. Each of these contributes to all four of the higher-level values. Again, potential sources of conflict can be identified from these means-end relationships. Pharmacy staff described how they are required to execute the functions in such a way as to maximise “quality and safety”, but also to maximise “cost effectiveness”. If the latter is framed in terms of productivity (that is, the volume of items processed) then staff may come under

pressure to work at speed, potentially at the expense of accuracy in processing or checking orders. In effect, community pharmacies can demonstrate what Hollnagel [27] refers to as the “efficiency-thoroughness trade-off”: as it is difficult for an individual or an organisation to be both maximally efficient and maximally thorough at the same time, a compromise between the two often occurs. How they are traded off is dictated by a number of factors, including the available material and human resources, organisational priorities (implicit and explicit), and individual or group preferences for working in a particular manner. These factors can vary between pharmacies, and can affect the perceived level of safety in a given pharmacy.[28-29]

Table 3 shows the frequency with which particular functions, processes and objects were identified as being relevant to an incident. Of the functions included in the hierarchy, the ones that were most frequently implied in an incident report were the dispensing and checking of medication orders. This pattern is repeated at the next level down, with medication assembly, maintaining patient medication records and medication storage being the most frequently implicated processes. However, it is interesting to note how frequently the “maintaining competence” function was also assigned to an incident. It was originally included in the hierarchy to describe activities that are primarily concerned with ensuring the competence of pharmacy staff. When the hierarchy was applied to the current incident data, this function was assigned whenever an incident record implied that the cause was staff carelessness or lack of knowledge, or the remedial actions included an exhortation to staff to be more diligent in their work. Often, though, there was insufficient detail in the reports of these incidents to determine whether they were actually due to staff members lack of competence, or to contextual factors such as poor workspace layout, or to both.

INSERT TABLE 3 HERE

At the lowest level of the hierarchy are the objects. As one might expect, the pharmacist and pharmacy technician are the most frequent “objects” associated with an incident, with pharmacy assistants and managers also being frequently implicated. In contrast, prescribers were only mentioned once. This pattern is likely due to the way in which incidents were categorised in the NRLS – that is, those incidents that are associated primarily with prescriber activity are not categorised as

community pharmacy incidents. However, the presence of prescribers in the abstraction hierarchy suggests that their interaction with pharmacy staff (for example, the quality of communication, coordination or cooperation) is also important when investigating an incident.

Also included in the list of objects are inanimate tools, with the dispensing counter, patient medication records, standard operating procedures and shelving and cupboards being most frequently identified. Again, while some objects appear to have been implicated more often than others, it is useful to consider the work system in its entirety. For example, while the pharmacy staff or the dispensing counter might be obvious factors to consider, other contributions to errors could be from drug packaging that does not allow easy discrimination between names or dosages [30], or standard operating procedures that are in some way unworkable[31].

4. DISCUSSION AND CONCLUSIONS

In this study, two sources of information were used to understand patient safety problems in community pharmacy: critical incident data from a reporting database; and WDA. The incident report data revealed some basic patterns in the occurrence of incidents in community pharmacies, most notably with regard to the relationship between the type of error involved and the severity of the outcome. Interestingly, some types of errors were relatively infrequent but appeared to account for a disproportionately large number of those incidents reported as resulting in serious harm or death, insofar as the proportions can be determined given overall the low frequency of such incidents.

Meanwhile, the WDA illustrated the relationships within the pharmacy work system. At the highest levels of abstraction (the purposes and values), it showed elements of the system that have common subordinate elements (the functions, processes and objects) but also the potential to conflict with each other. For example, appeals to ensure accurate dispensing, which would fulfil the “quality and safety” value, might in practice be traded off against appeals to maximise productivity, which would fulfil the “cost effectiveness” value. At the lower levels, the hierarchy showed how a given activity within the pharmacy – for example, dispensing – involves a range of actors, processes and objects. Hence, the WDA points to issues that might not be identified

as immediate causal factors in an incident report but that are also worth considering as lines of inquiry or matters for remediation.

There are several methodological points to be made about this study. Firstly, it was grounded in a range of data from pharmacy practice. Initial data for the WDA came from observations of, and workshops with, community pharmacists. The triangulation of these sources, both with each other and with a critical incident database, supports the validity of the WDA model in particular.[21] As a more general point, some authors [32-33] have observed that a “toolkit” of different methods may be more appropriate for understanding incidents than relying on a single method in all circumstances. In the current study, the retrospective, quantitative record review and the prospective, qualitative WDA are quite complementary.

Lipczak et al. [32] though, also remind us of the need to recognize the limitations of different analytical methods as well as their strengths. In the current study, we encountered some potential problems with our methods. Revisiting Table 1, the information available from the categories applied to the dataset was limited. It is possible that there is actually overlap between some of the sub-categories or that more than one sub-category applies to a particular incident (and, in the second case, that the sub-category that was applied to the incident is not the most “important” one from a causal point of view, even if it was the most salient). Also, the account of each incident was typically quite brief with – as in Armitage’s [10] study – few if any allusions to systems factors. Hence, while it was relatively straightforward to map incidents onto the WDA at the “functions” level, the assignment of some lower-level elements was often a matter of inference. Crucially, the nature of the data collection meant that it was not possible to seek clarification or further details of the incidents, to independently verify the details and categorisations that were provided, or to establish whether the dataset was subject to any reporting biases (for example, whether there are any systematic differences between those pharmacies that report to the NRLS and those that do not). Similar problems have been encountered in previous studies [34-35], and Vincent [11] notes that the NRLS, as one of (as yet) only a few nationwide healthcare incident databases in the world, is pioneering but also technically challenging due to its scale. However, he argues that the data from

the NRLS can be usefully integrated with other sources of data to broaden our understanding of patient safety problems – and, in any case, it helps to establish general patterns across incidents [34-35]. One useful feature of the NRLS is that it addresses itself to low- and no-harm incidents as well as ones with more serious outcomes, thus (as shown in the current study) reducing the potential for analysts to be misled due to focusing only on mortality cases [35-36].

Meanwhile, with regard to the WDA, considerable effort was required upfront to construct the abstraction hierarchy. While this effort is repaid in the relatively straightforward application of the hierarchy once constructed, there is as yet little guidance for users of the method as to how they should then use the findings.[15] As a key reason for applying WDA (or any analytical method, for that matter) to incident analysis is ostensibly to make reporting a more worthwhile exercise to those that participate in it [37-40], further work is needed to establish how WDA might be integrated into an organisation's portfolio of analysis methods, and indeed the situations to which it is well- or ill-suited. A previous review of retrospective methods [33] suggests that amongst other techniques, root cause analysis, significant event auditing, the critical incident technique and the London Protocol all lend themselves to the qualitative examination of critical incidents in healthcare, and so could join WDA in a portfolio. These methods likely have relative strengths and weaknesses; for example, a comparison of the London Protocol with WDA [17] found that the former provided better representation of generic error- and violation-provoking factors, but a more limited representation of the work system in which the incident occurred.

Finally, we suggest some practical implications of our work. It demonstrates the value of using complementary methods to understand patient safety concerns in a healthcare setting. Specifically, we recommend that WDA (and possibly, other stages of cognitive work analysis) be considered as a means of articulating the system within which healthcare tasks take place. We also recommend that, as more knowledge is gained about the issues surrounding patient safety problems, the questions that need to be asked of incidents in order to understand these issues, and the optimal amount and depth of data to allow a useful analysis, such knowledge informs the future development of incident reporting schemes as far as possible.

REFERENCES

1. Department of Health, Design Council. Design for Patient Safety: A system-wide design-led approach to tackling patient safety in the NHS. London: Department of Health 2003.
2. Wiegmann DA, Eggman AA, Elbardissi AW et al. Improving cardiac care: a work systems approach. *Appl Ergon* 2010;41:701-712.
3. Monroe K, Wang, D, Vincent C et al. Patient safety factors in children dying in a paediatric intensive care unit (PICU): a case notes review study. *BMJ Qual Saf* 2011;20:863-8.
4. Goodman PS, Ramanujam R, Carroll JS et al. Organizational errors: directions for future research. *Res Org Beh* 2011;21:151-76.
5. Garfield S, Barber N, Walley P et al. Quality of medication use in primary care – mapping the problem, working to a solution: a systematic review of the literature. *BMC Med* 2009;7:50.
6. Howard R, Avery A, Bissell P. Causes of preventable drug-related hospital admissions: a qualitative study. *Qual Saf Health Care* 2008;17:109-16.
7. Sauer BC, Hepler CD. Application of system-level root cause analysis for drug quality and safety problems: a case study. *Res Soc Adm Pharm* 2013;9:49-59.
8. Waterson P. A critical review of the systems approach within patient safety research. *Ergonomics* 2009;52:1185-95.
9. Taylor-Adams S, Vincent C, Stanhope N. Applying human factors methods to the investigation and analysis of clinical adverse events. *Saf Sci* 1999;31:143-59.
10. Armitage GA, Newell R, Wright J. Improving the quality of drug error reporting. *J Eval Clin Pract* 2010;16:1189-97.
11. Vincent C. *Patient Safety* (2nd ed.). Oxford: BMJ Books, 2010.
12. Benn J, Koutantji M, Wallace L et al. Feedback from incident reporting: information and action to improve patient safety. *Qual Saf Health Care* 2009;18:11-21.
13. Vicente KJ. *Cognitive Work Analysis*. New Jersey: Lawrence Erlbaum, 1999.

14. Xu W. Identifying problems and generating recommendations for enhancing complex systems: applying the abstraction hierarchy framework as an analytical tool. *Hum Factors* 2007;49:975-94.
15. Lim RHM. A systems approach to medication safety in care homes: understanding the medication system, investigating medication errors and identifying the requirements of a safe medication system. PhD thesis, University of Surrey, 2008.
16. Lim R, Anderson J, Buckle P. Analysing care home medication errors using work domain analysis. Presented at the Improving Patient Safety Conference, Cambridge, 16-18 July 2008.
17. Lim R, Anderson J, Buckle P. Analysing care home medication errors: a comparison of the London Protocol and work domain analysis. Presented at the 52nd Human Factors and Ergonomics Society Annual Meeting, New York, September 22-26 2008.
18. Phipps DL, Noyce PR, Parker D et al. Medication safety in community pharmacy: a qualitative study of the sociotechnical context. *BMC Health Serv Res* 2009;9:158.
19. James KL, Barlow D, McARTney R et al. Incidence, type and causes of dispensing errors: a review of the literature. *Int J Pharm Pract* 2009;17:9-30.
20. Williams SK, Osborn SS. The development of the National Reporting and Learning System in England and Wales, 2001-2005. *Med J Aust* 2006;184:S65-S68.
21. Naikar N, Hopcroft R, Moylan A. Work domain analysis: theoretical concepts and methodology. Report DSTO-TR-1665, Defence Science and Technology Organisation, 2005.
22. Rasmussen J. The role of hierarchical knowledge representation in decisionmaking and system management. *IEEE Trans Sys Man Cybernetics* 1985;SMC-12:234-43.
23. Farmilo A, Hone G, Whitworth I. *The CWA Tool version 0.95 beta* [Computer program]. Shrivenham: Human Factors Integration Defence Technology Centre, 2006.
24. Langley C, Belcher D. *Pharmaceutical Compounding and Dispensing*, 2nd ed. London: Pharmaceutical Press, 2008.

25. Stone P, Curtis SJ. *Pharmacy Practice*, 3rd ed. London: Pharmaceutical Press, 2002.
26. National Patient Safety Agency. *Design for Patient Safety: a guide to the design of the dispensing environment*. London: NPSA, 2007.
27. Hollnagel E. *The ETTO Principle: Efficiency-thoroughness trade-off*. Farnham: Ashgate, 2009.
28. Jacobs S, Hassell K, Ashcroft DM. Culture in community pharmacy organisations: what can we glean from the literature? *J Health Organ Manag* 2011;25:420-54.
29. Phipps DL, Ashcroft DM. An investigation of occupational subgroups with respect to patient safety culture. *Saf Sci* 2012;50:1290-8.
30. Irwin A, Mearns K, Watson M et al. The effect of proximity, tall-man lettering and time pressure on accurate visual perception of drug names. *Hum Fact* 2013;55:253-66.
31. Phipps DL, Parker D, Pals EJM et al. Identifying violation-provoking conditions in a healthcare setting. *Ergonomics* 2008;51:1625-42.
32. Lipczak H, Knudsen JL, Nissen A. Safety hazards in cancer care: findings using three different methods. *BMJ Qual Saf* 2011;20:1052-6.
33. Woloshynowych M, Rogers S, Taylor-Adams S et al. The investigation and analysis of critical incidents and adverse events in healthcare. *Health Technol Assess* 2005;9.
34. Martinez EA, Shore A, Colantuoni E et al. Cardiac surgery errors: results from the UK National Reporting and Learning System. *Int J Qual Health Care* 2011;23:151-8.
35. Catchpole K, Bell MDD, Johnson S. Safety in anaesthesia: a study of 12606 reported incidents from the UK National Reporting and Learning System. *Anaesthesia* 2008;63:340-6.
36. Hogan H, Healey F, Neale G et al. Preventable deaths due to problems in care in English acute hospitals: a retrospective case record review study. *BMJ Qual Saf* 2012;21:737-45.
37. Boyle TA, Scobie AC, MacKinnon NJ et al. Implications of process characteristics on quality-related event reporting in community pharmacy. *Res Soc Adm Pharm* 2012;8:76-86.

38. Williams SD, Phipps DL, Ashcroft DM. Understanding the attitudes of hospital pharmacists to reporting medication incidents: a qualitative study. *Res Soc Adm Pharm* 2013;9:80-89.
39. Anderson JE, Kodate N, Walters R et al. Can incident reporting improve safety? Healthcare practitioners' views of the effectiveness of incident reporting. *Int J Qual Health Care* 2013;25:141-50.
40. Waring J, Currie G. The politics of learning: the dilemma for patient safety. In: Rowley E, Waring J, eds. *A socio-cultural perspective on patient safety*. Farnham: Ashgate, 2011:133-150.

POST-PRINT DRAFT

Table 1. Frequency of incidents in each reporting category. Percentage of the total sample is provided in square brackets.

	Reported severity of outcome ¹			
	No harm (N = 13573)	Low-Moderate (N = 1102)	Severe-Death (N = 29)	Total (N = 14704)
Incident category				
Medication	13546 [92.1]	1100 [7.4]	29 [0.1]	14675 [99.8]
Medical device / equipment	10 [< 0.1]	1 [< 0.1]		11 [< 0.1]
Documentation	4 [< 0.1]			4 [< 0.1]
Patient accident	1 [< 0.1]			1 [< 0.1]
Treatment / procedure	2 [< 0.1]			2 [< 0.1]
Patient abuse (by staff / third party)		1 [< 0.1]		1 [< 0.1]
Other or not specified	10 [< 0.1]			10 [< 0.1]
Error category				
Adverse drug reaction	7 [< 0.1]	2 [< 0.1]	1 [< 0.1]	10 [< 0.1]
Mismatch between patient and medication	752 [5.1]	32 [0.2]	3 [< 0.1]	787 [5.4]
Contra-indicated medication	11 [< 0.1]	3 [< 0.1]		14 [< 0.1]
Omitted medicine / ingredient	181 [1.2]	12 [< 0.1]		193 [1.3]
Patient allergic to treatment	5 [< 0.1]	1 [< 0.1]		6 [< 0.1]
Wrong / omitted / passed expiry date	266 [1.8]	21 [0.1]		287 [2.0]
Wrong / omitted patient information leaflet	11 [< 0.1]	4 [< 0.1]		15 [0.1]
Wrong / omitted verbal directions	807 [0.5]	44 [0.3]	1 [< 0.1]	852 [5.8]
Wrong / omitted / transposed medicine label	506 [3.4]	26 [0.1]		532 [3.6]
Wrong / unclear dose or strength	4145 [28.1]	301 [2.0]	8 [< 0.1]	4454 [30.3]
Wrong drug / medicine	3572 [24.3]	533 [3.6]	14 [< 0.1]	4119 [28.0]
Wrong formulation	1702 [11.6]	65 [0.4]	2 [< 0.1]	1769 [12.0]
Wrong frequency	162 [1.1]	20 [0.1]		182 [1.2]
Wrong method of preparation or supply	98 [0.7]	8 [< 0.1]		106 [0.7]
Wrong quantity	1304 [8.9]	26 [0.2]		1330 [9.0]
Wrong route	11 [< 0.1]	3 [< 0.1]		14 [< 0.1]
Wrong storage	33 [0.2]	1 [< 0.1]		34 [0.2]

¹The five severity levels in the NRLS were reduced to three in this study due to the small number of cases in some cells

Table 2. Definitions of the functions within the abstraction hierarchy

Function	Definition
Dispensing	Dispensing medication to customers, or assisting customers to take prescribed medication
Medicine check	Ensuring that the medication dispensed matches that prescribed
Maintaining competence	Ensuring pharmacy staff remain competent to carry out functions
Clinical check	Ensuring that the prescribed medicine is appropriate for the patient
Managing people	Providing leadership, supervision or line management to pharmacy staff
Managing stock	Ensuring stock lines and levels are appropriate
Monitoring and audit	Recording and reviewing activities in the pharmacy
Supply of products	Selling, or advising customers on the use of, pharmacy products

Table 3. Frequency of functions, processes and objects from the hierarchy
being suggested for an incident

<u>Element from the hierarchy</u>	<u>Number of incidents</u>
<i>Functions</i>	
Dispensing	27
Medicine (dispensed order) check	26
Maintaining competence	12
Clinical (prescription) check	12
Managing people	9
Managing stock	7
Monitoring and audit	5
Supply of products	2
<i>Processes</i>	
Medication assembly	22
Maintaining patient medication records	16
Medication storage and stock management	14
Managing performance	12
Housekeeping	9
Queries and orders (issuing or receiving)	4
Providing extended (specialist) services	3
Waste management	3
Endorsement and prescription filling	1
Consultation	1
Managing controlled drugs	1
<i>Objects</i>	
Pharmacist	30
Pharmacy technician	28
Dispensing desk	19
Patient medication records	18
Reference text / standard operating procedures	18

Pharmacy assistant	17
Shelving and cupboards	17
Manager	17
Out tray	12
Label	11
Computer	7
Checking tray	7
Notice board	6
Telephone	6
Pre-packaged medication	6
Stock room	4
Medication container	4
Fridge	4
In tray / query shelf	4
Wastage bin	4
Pharmacy user	2
Serving hatch / front desk	1
Non pre-packaged medication	1
Storage basket	1
Controlled drugs register	1
Prescriber	1
<u>Leaflets</u>	1

Note: total number of incidents reviewed = 30

Figure 1. An example of an abstraction hierarchy

Figure 2. An example of how the abstraction hierarchy was applied to a single critical incident

One of the incidents reported to the NRLS involved a dispensing error, whereby 10mg of Ramipril was dispensed instead of the 5mg that had been prescribed. The patient informed the GP, but not the pharmacist. The incident was ultimately attributed to “pharmacy error”.

Within the abstraction hierarchy, the functions that are potentially implicated in this incident are:

- *Dispensing*: because the incident occurred with a dispensed medicine;
- *Medicine checking*: because the incident was not prevented by a medicine check.

These functions involve the execution of processes from the next level down. Of the processes that link to these functions, the following are potentially relevant to this incident:

- *Medication storage and stock management*: was the medication stored in such a way as to make an error of selection likely?
- *Maintaining patient medication records*: was it a repeat prescription and if so, had there been a change in the prescription that went unnoticed?
- *Medication assembly or preparation*: was the procedure used to assemble medication one that was likely to introduce errors?

In executing the identified processes, several objects from the next level down are used. Of the objects that link to these processes, the following are potentially relevant:

- *Shelving and cupboards*: are these accessible and well organised?
- *Telephone*: is this accessible if required (in this case, to contact the prescriber)? Is it a source of distraction during dispensing?
- *Checking tray*: if this is in use, is it well organised?
- *Dispensing desk*: is this accessible and well organised?
- *Pre-packaged medications*: are these easily distinguished from each other?
- *Patient medication record*: is this easily accessed, readable and kept up to date?
- *Pharmacist*: was the pharmacist sufficiently knowledgeable (for example, about the pharmacy layout and procedures)? Was he or she subject to performance influencing factors (such as fatigue, high workload or distractions)?
- *Pharmacy technician*: was the pharmacy technician sufficiently knowledgeable? Was he or she subject to performance influencing factors?

Figure 3. The purposes, values and measures, and functions for community pharmacy