Attitudes to Reporting Medication Errors by Hospital Pharmacists

A thesis submitted to the University of Manchester for degree of Master of Philosophy in the Faculty of Medical and Human Sciences

2010

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School of Pharmacy and Pharmaceutical Sciences
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Abstract

Attitudes to Reporting Medication Errors by Hospital Pharmacists

Master of Philosophy, University of Manchester.

Steven David Williams September 2010

There is a clear need for the NHS hospitals to learn from medication errors to prevent future patient harm but this is hindered by an incomplete picture of the level and type of errors. The literature illustrates that the attitudes of health professionals to reporting incidents *per se* seem to be driven by negative attitudes about why they do not report (barriers) as opposed to positive attitudes about why they should report (benefits). The views of pharmacists are, currently, extremely poorly understood. A two part study was conducted with hospital pharmacists in the North West NHS region of England, including 4 focus groups (17 pharmacists) and 270 completed Theory of Planned Behaviour questionnaires about the attitudes of hospital pharmacists to reporting medication errors. The study found that UK hospital pharmacists fully understood that it is part of their professional role to report medication errors and hold very strong intentions to report medication errors for the ultimate benefit of improved patient safety. They agreed with the four perceived barriers to the reporting of incidents by Health Professionals: **Knowledge** i.e. what to report, with the severity of the error most strongly influencing decisions to report or not; **Effort** i.e. difficulty in reporting, due to cumbersome forms and time/workload pressures; **Fears**, with the culture of blame still very much recognised by pharmacists and anxieties about reporting other health professionals due to close working relationships with medical and nursing staff; **Outcomes** i.e. lack of positive changes to prevent repetition of the error, with beliefs about the positive effects of reporting (increased awareness and reduced risk of similar harm) significantly predicting pharmacists’ intention to report. Hospital pharmacists however also appear to have an additional fifth barrier to reporting, that is **Size** (of the problem). The “endemic” nature of medication errors means that hospital pharmacists, although resolving the errors, just do not report them as often as they would like, and know they should. Hospital pharmacists’ intention to report medication errors was more likely if they were senior, or if they were female with strong beliefs that other pharmacists would similarly report the error.

The key to improved reporting appears to be threefold: 1 **Confidence** - personal confidence to report health professional colleagues and overall confidence that positive outcomes will be seen from reporting. Though such cultural changes may be improved by greater hospital confidence in the benefits of reporting, and the introduction of measures to reduce harm, it is most likely this would require longer term organisational and professional cultural change; 2 **Clarity** - greater clarity about which medication errors should and should not be reported. Targeted reporting strategies could be introduced locally (e.g. cyclical reporting of one type of high risk medicine for 3 months) but might be more effective if implemented nationally, with a medication error reporting hierarchy comparable to the MHRA yellow card reporting scheme; 3 **Simplicity** - simpler drug specific reporting forms and assistance with the completion of the form by others e.g. a dedicated medication safety pharmacist. A national drive to allow hospital pharmacists to use a national medication specific, electronic error reporting form may further improve reporting.
Declaration

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

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For Wendy, Megan and Thomas, who will give a collective sigh of relief that it is over, thanks for putting up with me whilst I was writing this thesis.

Special thanks to Darren Ashcroft (my supervisor), Denham Phipps and Jonathan Cooke for their guidance and loyal support.

My gratitude to all the pharmacists who took part in the focus groups and completed the questionnaire.

Finally this study further endorses my work mantra: “Don’t find fault, find a remedy. Anyone can complain” Henry Ford.
General introduction

The worldwide interest in adverse events in healthcare is really a 21st Century phenomenon following the publication of the Institute of Medicine’s (IOM) “To err is human” report in the USA\(^1\), an “Organisation with a Memory” in the UK\(^2\) and similar reports in other developed countries.\(^3,4\)

Many terms are used interchangeably to describe errors or adverse incidents/events, so for the purposes of this report the following definitions are used:

Adverse event- any injury that was caused by medical management (rather than underlying disease) and that prolonged the hospitalisation, produced a disability at the time of discharge, or both.\(^5\)

Patient safety incident- any unintended or unexpected incident which could have or did lead to harm for one or more patients.\(^6\)

Medication error- any incident where there has been an error in the process of prescribing, dispensing, preparing, administering, monitoring or providing medicine advice, regardless of whether any harm has occurred\(^7\)

Near misses- incidents that do not cause harm but are judged to have had the potential to cause harm.\(^7\)

According to the IOM report more than one million preventable adverse events occur each year in the United States yet it is estimated that underreporting of adverse events ranges from 50 to 96% annually.\(^8\) Likewise in the UK, 974,000 patient safety incidents and near misses were recorded on NHS trusts’ reporting systems in 2004-05 but trusts estimated that on average 22% of incidents and 39% of near misses go unreported.\(^9\)

For more accurate information about the incidence of adverse events a recent systematic review found that for eight retrospective case record reviews carried out worldwide the median incidence of in-hospital adverse events was 9.2% (43.5% preventable), 15.1% medication related, and 7.4% of all events were fatal.\(^10\) Bates et al studied adverse drug events using a similar methodology and discovered 6.5 adverse drug events and 5.5 potential adverse drug events occurred per 100 hospital admissions, with 28% judged as being preventable.\(^11\)

The number of medication incidents voluntarily reported to the UK’s National Reporting and Learning System (NRLS) has increased every year since its inception in 2005.
72,482 medication incidents were reported between 1 January 2007 and 31 December 2007 (9% of all incidents reported) which was the third largest group of incidents after patient accidents (34%) and problems with treatments/procedures (9%).

The majority of medication incidents (96%) were reported to have resulted in no or low harm, but there were one hundred reports of death or severe harm. For serious medication errors drug administration and prescribing errors accounted for 41% and 32% respectively and errors involving injectable medicines represented 62% of all reported incidents leading to death or severe harm.

Studies comparing incident reporting with prospective and retrospective case note review however have shown the incomplete picture of adverse events, when relying on voluntary reporting alone, with incident reporting rates ranging from just 4% to 23% of all adverse events discovered. Similarly only 6% of adverse drug events (including adverse drug reactions) were detected through voluntary reporting when compared with retrospective case note review. In a recent study investigating the prevalence of prescribing errors in UK hospitals only 1 out of the 868 prescribing errors, detected by ward pharmacists in the researcher’s base hospital, had been voluntarily reported via the hospital’s incident reporting system. Direct observation of medication administration in another study revealed an 11.7% error rate compared with just 0.04% for errors detected through the incident reporting scheme.

So, although large numbers of medication errors are reported to the NRLS each year the numbers and types of error are not a true reflection of the medication errors that are occurring in UK hospitals. This may be inhibiting the ability of the NHS, and more importantly individual hospitals, to learn from medication errors and to take steps to prevent future patients from repetitive harm. At the same time there is emerging evidence that better voluntary incident reporting per se is associated with a more positive patient safety culture in UK hospitals and so there is also potentially a broader benefit to researching this subject for the advancement of the patient safety agenda.
The content of this thesis is structured into five chapters, the content of which is outlined below:

Chapter 1 provides an in-depth evaluation of the published literature and draws overall conclusions about the attitudes of health professionals to reporting errors and demonstrates the paucity of data regarding pharmacists’ attitudes.

Chapter 2 explains the research methodology that was used in this programme of research including: consideration of different qualitative data collection methods; an explanation of a Theory of Planned Behaviour (TPB) and why it was used; details of sampling and recruitment strategies; design of the interview schedule and the TPB questionnaire; data analysis and issues regarding reliability and validity.

Chapter 3 discusses the ethical issues of the research including: the principles of preventing harm, informed consent, privacy and deception; and the approvals required for the study at local ethics committee, university and local NHS hospital level.

Chapter 4 presents the results of both the Focus Groups and the TPB questionnaire.

Chapter 5 discusses the study strengths and limitations, the overall findings, recommendations for how to improve reporting by hospital pharmacists and possible future research.
Chapter 1: The attitudes of Health Professionals to incident reporting

1.1 Introduction

A comprehensive literature search was undertaken to confirm the originality of the research study. The literature was identified through in-depth searching of online databases (MEDLINE, EMBASE, CINHAL, International Pharmaceutical Abstracts, PsycINFO), the Internet and hand searches of bibliographies from relevant articles.

The following keywords were used and relevant MESH terms and “Boolean” searches were adopted using different combinations of the keywords to maximise the retrieval of relevant references.

Keywords used:
Adverse events, errors, medical errors, incidents, human errors, errors, risk, medication safety, patient safety
Adverse event reporting, incident reporting, error reporting, reporting, attitudes, barriers, disclosure, organisational culture, guideline adherence

The review of the primary literature is purposely presented in sections depending on the subjects studied: nurses only, doctors only, pharmacists only and mixed health professional groups. It is also presented in chronological order of the publication year given the ever increasing focus on patient safety culture since the turn of the century, and the effect this may have had on the cultural outlook of the participants.

Note: There is a wealth of literature regarding the concept of “medical error disclosure” by doctors which is a pre-requisite for the success of incident reporting systems. Although the factors encouraging and preventing error disclosure are wholly relevant to the attitudes of health professionals to incident reporting the literature is much broader and often includes informing patients and their families about errors. This literature review therefore concentrates on studies that specifically investigated attitudes of health professionals to incident reporting. Kaldjian et al have published a structured literature review on medical error disclosure by physicians and concluded that the three most common goals of disclosure were to improve patient safety, enhance learning and inform patients. However they highlight the diversity of factors cited in the literature about
impeding (41 factors including professional repercussion, legal liability and blame) and facilitating (35 factors including accountability, honesty and restitution) disclosure.18

1.2 Nurses’ attitudes to reporting errors

Most of the studies (70%) that primarily involved nurses were conducted in the US (14/20), with two in the UK20,30, two in Australia25,27 and one each in Turkey31 and Taiwan24, both of which were based on studies previously performed in the US, as shown in table 1.

Fifty percent were published after 2000 and all were carried out in hospital settings, two specifically in paediatric hospitals29,34 and three in community hospitals.26,28,38 Sixty percent of studies (12/20) were carried out in a single site with the remaining studies performed over multiple sites.

Eighteen of the studies used quantitative survey methodology, three of which also used qualitative focus groups27,28 or semi-structured interviews in addition.20 Two of the studies used qualitative methods with one lone researcher using observational methods25, and one using purely semi-structured interviews.30

Half of the studies were exploring all types of medication errors, with another six specifically studying medication administration errors. Three studies were investigating all types of hospital error26,37,38, with one comparing medication error reporting to the reporting of patient falls.32

1.2.1 Nursing attitudes to reporting medication administration errors

Walters investigated nurses’ perceptions of reporting medication errors in a tertiary care hospital in the United States in the early 1990s.19 237 nurses who had attended a study day on medication administration completed a 33 item questionnaire (71% response rate). The mean number of medication errors volunteered as having been made in the previous 12 months was 0.95 (standard deviation 1.5), with approximately equal numbers of respondents stating that they had made no errors versus any errors. The mean number of errors that the nurses said they had reported was lower, mean 0.6 (standard deviation 1.1). Statistically fewer errors were made and reported by respondents nursing for more than one year (p<0.05) and significantly fewer errors were reported in respondents greater than 35 years of age (p<0.05). The participants varied in their likelihood of reporting, depending on the type of incident, and only 13% of respondents suggested that they would
complete an incident report for all the late, omission or incorrect medication type errors in the questionnaire. 97.1% claimed they would report the error if an incorrect medication caused a life-threatening reaction and 95% if an omitted drug was vital to the patient; 88.7% and 82.4% respectively would report the error if it was an incorrect Intra Venous medicine given or the wrong route; 61.8% would report if a medicine was omitted, and 62.6% if a patient was given an under dose.

Table 1: Summary of studies involving nurse attitudes to reporting errors

<table>
<thead>
<tr>
<th>Study</th>
<th>Date published</th>
<th>Research methodology</th>
<th>Study size</th>
<th>Type of incidents</th>
<th>Setting</th>
<th>Key findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walters (US)</td>
<td>1992</td>
<td>Survey</td>
<td>237 nurses</td>
<td>Medication administration errors</td>
<td>One hospital</td>
<td>Likelihood of reporting varied depending on severity of error e.g. &gt;95% if life threatening versus 60% if patient was given an under dose. Fewer reported errors if &gt; 1yr qualified and &gt; 35 years old</td>
</tr>
<tr>
<td>Gladstone (UK)</td>
<td>1995</td>
<td>Survey and Semi-structured interviews</td>
<td>81 nurses (14 interviewed)</td>
<td>Medication administration errors</td>
<td>One hospital</td>
<td>More likely to tell a doctor than report an error. 63% unsure what or when to report and fear/uncertainty of management reaction affected reporting</td>
</tr>
<tr>
<td>Wakefield DS et al (US)</td>
<td>1996</td>
<td>Survey</td>
<td>1300 nurses</td>
<td>Medication administration errors</td>
<td>Multiple acute hospitals</td>
<td>Average scores indicated that fear, lack of administrative response, effort needed and knowledge of what to report were barriers to reporting</td>
</tr>
<tr>
<td>Wakefield DS et al (US)</td>
<td>1996</td>
<td>Survey</td>
<td>1300 nurses</td>
<td>Medication administration errors</td>
<td>Multiple acute hospitals</td>
<td>Average scores indicated that fear, lack of administrative response, effort needed and knowledge of what to report were barriers to reporting</td>
</tr>
<tr>
<td>Wakefield DS et al (US)</td>
<td>1999</td>
<td>Survey</td>
<td>1428 nurses</td>
<td>Medication administration errors</td>
<td>Multiple acute hospitals</td>
<td>Similar to 1996 findings plus supervisors were more likely to consider error definition and reporting effort, and less likely to consider</td>
</tr>
<tr>
<td>Year</td>
<td>Study</td>
<td>Country</td>
<td>Setting</td>
<td>Type</td>
<td>Participants</td>
<td>Medication</td>
</tr>
<tr>
<td>------</td>
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<td>---------</td>
<td>---------</td>
<td>------</td>
<td>--------------</td>
<td>-----------</td>
</tr>
<tr>
<td>2000</td>
<td>Hand et al. (US)</td>
<td>2000</td>
<td>Survey</td>
<td>Semi-structured interviews</td>
<td>17 nurses</td>
<td>Medication errors</td>
</tr>
<tr>
<td>1999</td>
<td>Osborn et al. (US)</td>
<td>1998</td>
<td>Survey</td>
<td></td>
<td>57 nurses</td>
<td>Medication errors</td>
</tr>
<tr>
<td>1998</td>
<td>Walker et al. (Australia)</td>
<td></td>
<td></td>
<td></td>
<td>43 nurses</td>
<td>Medication errors</td>
</tr>
<tr>
<td>1997</td>
<td>Elmsley et al. (US)</td>
<td>1997</td>
<td>Survey</td>
<td></td>
<td>24 nurses</td>
<td>Medication errors</td>
</tr>
<tr>
<td>1997</td>
<td>Baker (Australia)</td>
<td>1997</td>
<td>Observation study</td>
<td></td>
<td>18 week study</td>
<td></td>
</tr>
<tr>
<td>2006</td>
<td>Chuang et al. (Taiwan)</td>
<td>2006</td>
<td>Survey</td>
<td></td>
<td>727 nurses</td>
<td>Medication errors</td>
</tr>
<tr>
<td>1997</td>
<td>Elnitsky et al. (US)</td>
<td>1997</td>
<td>Survey</td>
<td></td>
<td>242 nurses</td>
<td>Medication errors</td>
</tr>
<tr>
<td>1999</td>
<td>Walker et al. (Taiwan)</td>
<td>1999</td>
<td>Survey</td>
<td></td>
<td>57 nurses</td>
<td>Medication errors</td>
</tr>
<tr>
<td>2000</td>
<td>Antonow et al. (US)</td>
<td>2000</td>
<td>Survey</td>
<td></td>
<td>72 nurses</td>
<td>Medication errors</td>
</tr>
</tbody>
</table>

**Note:** The table above summarizes the findings of various studies examining barriers to medication error reporting in different healthcare settings. The studies varied in terms of methodology, setting, and findings, highlighting the complexity and multifaceted nature of barriers to reporting errors.
identified as barriers. Benefit of highlighting a problem to staff arose as a benefit of reporting

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Method</th>
<th>Sample Size</th>
<th>Case</th>
<th>Greatest barrier to reporting was afraid of manager or co-worker response. Only 26% not reported an error that was not serious</th>
</tr>
</thead>
<tbody>
<tr>
<td>Karadeniz et al (^31) (Turkey)</td>
<td>2002</td>
<td>Survey</td>
<td>27 nurses</td>
<td>Medication errors</td>
<td>One hospital</td>
</tr>
<tr>
<td>Blegen et al (^32) (US)</td>
<td>2004</td>
<td>Survey</td>
<td>1105 nurses</td>
<td>Medication administration errors and patient falls</td>
<td>25 acute hospitals</td>
</tr>
<tr>
<td>Mayo et al (^33) (US)</td>
<td>2004</td>
<td>Survey</td>
<td>983 nurses</td>
<td>Medication errors</td>
<td>Multiple hospitals</td>
</tr>
<tr>
<td>Stratton et al (^34) (US)</td>
<td>2004</td>
<td>Survey</td>
<td>57 nurses</td>
<td>Medication errors</td>
<td>One paediatric hospital</td>
</tr>
<tr>
<td>Potylycki et al (^35) (US)</td>
<td>2006</td>
<td>Survey</td>
<td>650 nurses</td>
<td>Medication errors</td>
<td>One hospital</td>
</tr>
<tr>
<td>Ulanimo et al (^36) (US)</td>
<td>2007</td>
<td>Survey</td>
<td>25 nurses</td>
<td>Medication errors</td>
<td>One hospital</td>
</tr>
</tbody>
</table>

Estimated reporting rate was 47% for all medication errors compared with 77% for falls. Personal fears and concerns about administrative response identified as strongest barriers. Quality management programme positively related to reporting and negatively reported to reasons for not reporting

91.3% knew when to report. 52.9% did not report if not serious. Fear of manager and co-worker responses reported

Barriers to reporting included personal fear and poor administrative response to errors

Comparison before and after introduction of a patient safety programme showed minor non statistical improvement in the likelihood of reporting and minor improvement in staff feeling supported when reporting \((p<.001)\) Strong agreement that need to report depended on severity of incident, and some agreement that staff felt supported but that errors might not be reported due to excessive paperwork

Perceived 28.9% of medication errors were reported. Medication errors not reported as afraid of reactions of managers (60%) or
Co-workers (64%). 36% admitted not reporting if error was not serious.

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Methodology</th>
<th>Sample Size</th>
<th>Errors Reported</th>
<th>Setting</th>
<th>Report Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Throckmorton et al  37 (US)</td>
<td>2007</td>
<td>Survey</td>
<td>435 nurses</td>
<td>All errors</td>
<td>Multiple hospitals</td>
<td>&gt;94% would report if outcome minor, moderate or serious compared with 55.5% if no harm occurred</td>
</tr>
<tr>
<td>Elder et al 38 (US)</td>
<td>2008</td>
<td>Survey + Focus Groups</td>
<td>92 nurses (33 focus groups)</td>
<td>All errors</td>
<td>4 intensive care units</td>
<td>Difference between what nurses say would report in survey versus in focus groups. Barriers included being too busy, fears of blame or punishment and a lack of feedback. Level of “emotional conflict” about reporting increased with greater seniority of health professional involved in the error. No nurse admitted ever reporting an error made by a doctor due to the power differential</td>
</tr>
</tbody>
</table>

Gladstone studied medication administration errors in one British hospital pre-1995 using a questionnaire and a small number of interviews with trained nurses that included reporting issues. A total of 81 nurses (14 interviewed) were asked about the likely reporting of four scenarios. There was great variation between whether respondents thought an error had occurred and if they would report it to their nurse manager, or tell the doctor about it. Where nurses thought an error had occurred they were more likely to tell the doctor than report it formally to their nurse manager. 63% of respondents said they were not sure what constituted a drug error or when an error should be reported, and 74% considered that some errors were not reported because of fears of management reaction. Comments made by nurses identified fears and uncertainty as to when reports should be made and the belief that historically management had reacted poorly to errors reported.

Wakefield DS et al published the results of two identical surveys carried out first in 1994 and then again in 1996 to explore reasons why nurses did not report medication administration errors in acute hospitals in the United States. Using a non-randomised convenience sampling technique 1428 surveys were returned in the 1996 study (1300 in
Participants were asked 15 questions about why they thought medication administration errors were not reported, using a six point continuum scale (one=strongly disagree, six=strongly agree). Confirmatory factor analysis was used to confirm a four factor model of reasons for not reporting. There was no particularly strong agreement or disagreement with the four major factors for not reporting, however fear and administrative responses both had the highest level of agreement each with a mean score of 3.4 (SD 1.2 and 1.1 respectively). The other two major factors, namely reporting effort and disagreement over whether an error had occurred and needed reporting, both had means ≥ 3 and all the results were broadly the same as for the 1994 sample. Additional analysis from the 1996 sample revealed there were differences in responses between supervisors and nurses working on the same unit. Supervisors were more likely to view disagreement over error definition and reporting effort as more important reasons why errors were not reported, and less likely to view administrative response as an important reason why errors were not reported, compared with the staff nurses on the unit.

Wakefield BJ et al used a convenience sample of nurses from six hospitals in the USA to investigate whether the reason why nurses do not report medication administration errors was in part a function of the organisational culture and an extent of the implementation of continuous quality improvement (CQI) philosophy. (CQI is a programme that aims to drive out fear and make organisations look at systems rather than individuals) The hypothesis was that supportive, risk-taking culture enhances great adoption and implementation of CQI principles which in turn would mean fewer barriers to reporting medication administration errors. A convenience sample of 297 nurses was selected from a mix of specialities across six hospitals. Larger hospitals were found to have more hierarchical cultures whereas smaller hospitals had group orientated cultures. (Group orientated cultures involved trust and a people orientated supportive management style, Hierarchical cultures involved rational and controlling type management) As hospital sizes increased the extent of CQI implementation and the perceived role of medication administration error reporting decreased. The barriers to reporting were the same as in the research group’s earlier study. Participants were also asked their perception of the percentage of administration errors reported for 11 different types of administration error plus an estimate of the total percentage of medication administration errors reported. When the relationship between reasons for not reporting and estimated percentage of errors reported was examined higher barriers to reporting scores were associated with statistically significant decreased reporting. The study found no statistically significant relationship
between the different reasons why nurses do not report and the estimated percentage of the total number of errors being reported. The authors speculated that this may mean that the different reasons are of equal importance, when deciding whether or not to report, but conceded that this needed confirmation in larger studies. The presence of a group orientated culture ($r = .72$) and high levels of CQI implementation ($r = .56$) were positively (but not significantly) associated with the improved reporting of medication administration errors whilst hierarchical culture was associated with reduced perceived reports.

Chiang et al carried out a study following the same methodology as Wakefield\textsuperscript{22} and utilised questionnaires returned by 727 nurses in one Taiwanese hospital post 2000 (90% response rate).\textsuperscript{24} 57% of the respondents thought that medication administration error reporting rates in their hospital were an underestimate and found that fear (mean 3.92) was the strongest perceived barrier to reporting errors, with administrative barriers also having a mean just above the midpoint of the scale at 3.5. The most striking difference was the moderate positive correlation between power hierarchy and face-saving concern and barriers that the nurses perceived. The authors noted that in Chinese culture people are more likely to respect authority and worry about offending co-workers concerns so this seemed a plausible explanation. There was a weak negative correlation between better work environment, quality management and peer relations and the perceived barriers but no significant differences were found in barriers according to years of nursing experience.

Conclusions

Personal fears and a perceived lack of administrative response appear to be the strongest barriers to reporting a medication administration error in a hospital, with the majority of the studies being conducted before the year 2000. The presence of a quality/ safety improvement programme seems to improve the likelihood of reporting medication administration errors and reduce the strength of the feeling about barriers to reporting.

1.2.2 Nursing attitudes to reporting medication errors and general errors

Baker carried out an 18 week qualitative study in one hospital in Australia before 1995 and observed the views of nurses about reporting medication errors.\textsuperscript{25} The nurses explained how they re-defined errors in such a way that if they can make it feel like a “non-error” then it does not need to be reported. The examples given included shifting administration
times from those prescribed to fit in with the patient's daily routine and changing the incorrect name on an IV drug before being given to the patient. The author described the nursing staff behaviour as "if you can put it right, it is not an error" and suggested that it may be commonplace and affecting incident reporting rates.

Elnitsky et al studied nurses working in community hospitals in the United States in 1995.\textsuperscript{28} The 424 respondents selected via a “snowball” sample were asked about their own reporting behaviours, and their perception of their supervisor’s views regarding all types of incidents, not just medication. 87.7% of participants agreed that it was important to report all incidents (75% for all medication errors) whilst 36% agreed that some incidents do not need reporting. 19.1% believed that their supervisor would use an incident against them and a similar number that incidents would be used against them in their job evaluations.

Walker et al considered nurses’ views on reporting medication incidents in one Australian hospital pre-1997.\textsuperscript{27} Forty three self-selected nurses were involved in a quantitative questionnaire and qualitative focus groups. The questionnaire results identified that the majority of nurses agreed that administration errors such as Metoprolol given to the wrong patient (100%), wrong dose of diuretic (97%), wrong intravenous fluid (83%) or incorrect route (95%) were technically reportable but only 53% agreed that IV Digoxin given 1 hour late was reportable. The focus groups identified two main themes. The first "self-preservation" included fears of reporting depending on their working relationships with peers or seniors. The second "it depends" nurses described as an individual assessment of the clinical situation i.e. if there was a near miss or the action seemed reasonable then they were less likely to report the error. Other issues included time taken to report and clear definitions of errors and management inaction with previous reports.

Osborne et al studied nursing perceptions of medication errors using a convenience sample of 57 nurses (61.9% response rate) at a community hospital in the United States pre-1999.\textsuperscript{28} 43.9% of respondents thought that only 25% of errors were reported whilst 5.3% thought all errors were reported. The responses to the possible reporting of five scenarios varied from 14% for a missed dose of an antibiotic to 91.2% for an infusion given at twice the prescribed rate. More than 80% of nurses said that they knew when a medication error had occurred and when it should be reported. Regarding barriers to reporting 86% of nurses said errors were not reported as nurses were afraid of manager or co-worker
response but only 25% said they had failed to report an error due to fear of repercussions. 57.9% said that they had not reported a medication error as they thought it was not serious enough.

Antonow et al published a survey of nursing staff attitudes to medication error reporting which was carried out in 1998 on 1 paediatric hospital unit in the USA. The survey was included in an annual mandatory test for 72 nurses, but was completed anonymously. Participants were asked to report if they had observed a medication error and then asked to describe it, and include whether an incident form was completed. 15.3% of participants said they had never seen a medication error whilst 30.5% said that the error they described was not formally reported. Errors that did not reach the patient were least likely to have been reported (odds ratio (OR) 0.18 95%CI 0.07-0.47). Clearly this type of study relies on memory recall and may have been biased by participants favouring incidents that they could remember most clearly and so may have underestimated error frequency and overestimated formal reporting.

Hand et al studied the attitudes of nurses towards medication errors in one UK hospital pre-2000. Semi structured interviews were used with a purposive sample of 17 nurses from general and specialty wards. Most nurses thought that all errors should be reported but were aware that they were not, whilst others believed that all errors were reported. The benefits of reporting by raising staff awareness of a problem were highlighted. Fears of disciplinary action and a belief that you could get away with it were the commonest reasons that nurses said they did not report errors.

Karadeniz and Cakmakci used the same methodology as Osborne to establish nurses’ perceptions of medication errors in a group of 27 Turkish hospital nurses post 2000. The responses to the possible reporting of five clinical errors were around 50% for all scenarios, ranging from a missed dose of an antibiotic to an infusion given at twice the prescribed rate. 88% of nurses said that they knew when a medication error had occurred and 70% when it should be reported. Regarding barriers to reporting 63% of nurses said errors were not reported as nurses were afraid of manager or co-worker response and 53% said they had failed to report an error due to fear of repercussions. Only 26% of respondents said that they had not reported a medication error as they thought it was not serious enough. These perceptions of reporting medication errors were different to the findings of Osborne, with the Turkish cohort of nurses appearing less fearful of
managerial and peer response to reporting, and much less likely to not report a less serious error. It is unclear if cultural differences played any part in these contrasting results.

Blegen et al carried out a much larger study (using the same questionnaire survey as Stratton et al) with 1105 nurses responding from 25 acute hospitals across the United States in 2001. Nurses were asked which of the ten examples of medication administration errors should be reported and to estimate what proportion of medication administration errors and patient falls that occurred on their unit were actually reported. The majority of respondents felt that they would report all 10 types of medication administration errors in the questionnaire except the near misses. Only 36% thought that near misses should have been reported. The average estimated reporting rate for all medication incidents was 47%, in comparison to 77% for patient falls. Using the five point Likert scale (one=least agreement, five=most agreement) the reasons for not reporting were presented as mean scores of 3.17 (SD 0.87) for concern about administrative response and 3.41 (SD 0.81) for personal fears. Substantial analysis including work environment and nurse demographics revealed very little significant levels of correlation to the proportion of patient incidents reported. A quality management process occurring in a unit was however positively related to the reporting of medication administration errors, and negatively related to the reasons for not reporting.

Mayo et al performed a study following the same methodology as Osborne but with a 20% response rate, had 983 responses from nurses working in different acute hospitals in the United States post 2000. On average 45.6% of participants reported that all drug errors were reported using an incident reporting system (5.3% in Osborne study). Similar numbers however (91.3% of nurses) said that they knew when to be report and 52.9% said they had not reported a medication error as they did not think it was serious enough. Regarding barriers to reporting 76.9% of nurses were afraid of their manager’s, and 61.4% of their co-workers’ reactions, but only 19.6% said they had failed to report an error due to fear of disciplinary action.

Stratton et al published a pilot study looking at medication error reporting by paediatric hospital nurses carried out in the United States in 2000. Using a convenience sampling technique 57 paediatric nurses responded to the self administered questionnaire, of which 67% estimated all the types of medication error included in the questionnaire were reported on their unit. Participants were then asked to agree or disagree with seven
personal and four management related reasons for not reporting medication errors using a five point Likert scale (one=lowest, five= highest). The mean score for personal reasons for non-reporting was 3.4 (SD +/- 0.82) and these included fear of blame, fear of peer views, the fear of losing license and/or bad publicity, reprimand from doctor and fear that patients would have a negative attitude. The mean score for management related reasons was just above the midpoint at 3.13 (SD +/-0.85). These reasons included no positive feedback; the process still focused on the person who made the mistake; the administrative response did not match the severity of the error and the incorrect emphasis of errors as a measure of the quality of care. There was a negative correlation between agreement with reasons for not reporting medication errors and the number of errors reported.

Potylycki et al published the results of a three-year study looking at medication error reporting following the introduction of patient safety improvement programme. 

Around 650 nurses from one hospital in the United States took part in the baseline survey in 2002 and a repeat survey in 2004. In this study respondents were asked to use a five point Likert scale (one = strongly disagree, five = strongly agree) for questions regarding causes of errors, likelihood of reporting and barriers to reporting. Mean awareness of the patient safety programme amongst respondents was 3.9 +/-1.25 (one=strongly disagree, five=strongly agree) and though some comparisons were statistically significant the mean differences pre-and post-programme appeared marginal. Agreement about the need to report varied from 2.37 (2.46 in 2004) for an error that did not reach the patient to 4.62 (4.61 in 2004) for an error where the patient needed to be transferred to a critical care unit, but these differences were not statistically significant. Mean scores for staff feeling supported when they had reported an error were statistically improved 3.31 and 3.55 (2002 and 2004 respectively p<.001) and in both years agreement that an error was not reported because of too much paperwork was below the midpoint. Respondents who had attended the safety programme workshops were only marginally more comfortable reporting without fear of reprisal, less likely to not report and believed that the primary objective of medication error reporting was improving patient safety.

Ulanimo et al utilised a questionnaire, based on the work of Gladstone, to identify the attitudes of 25 nurses, working in a US hospital with sophisticated IT systems for medicines (electronic patient records, barcoded medicines administration, prescriber order entry), to reporting medication errors post 2000. The convenience sample consisted of
medical and surgical nurses but excluded nurse managers or advanced practitioners. Nurses estimated that less than 30% of medication errors were reported, and like Gladstone, the authors found that there was wide variation between nurses about what constituted or when to report a drug error. Nurses agreed that some medication errors are not reported because nurses were afraid of the reactions of managers (60%) or co-workers (64%). In addition 36% of nurses admitted not reporting a medication error if they thought the error was not serious enough. In contrast to the work of Gladstone only 16% of nurses agreed they had not reported because of fears of disciplinary type actions. Cited barriers to reporting included lack of knowledge of what to report, workload pressures, personal negligence in reporting and personal attitudes to reporting. Empowering factors for reporting suggested by nurses in the sample included supportive doctors and senior nurses, active involvement of nurses in finding and reporting errors, time to report and consistent handling of disciplinary action by managers where appropriate.

Throckmorton et al studied a randomised sample of 435 nurses in the United States, the majority of whom worked in non-teaching, non-government institutions with a mean of 20.29 years registered as a nurse. The questionnaire included issues regarding the climate around reporting errors and intention to report errors. When asked to rate the climate for reporting errors, on a 10 point scale, approximately half of the 271 who answered the question indicated that the current environment was non-punitive, whilst a quarter suggested punitive perceptions. Reasons for not reporting were based on the tool devised by Wakefield 1999 and respondent scores ranged from 16 to 91 (mean 59.1, standard deviation 14.23), with the higher scores indicating greater barriers to reporting errors. Respondents were asked if they would complete a formal incident report if they had made an error in their daily practice but were asked to respond to the same question five times with a different outcome, varying between no injury and death (scale 0-5). Of the 418 nurses who responded to these questions 55.5% said they would report the error if no harm had occurred and greater than 94% responded that they would report the error if the outcome were minor, moderate, serious or fatal.

Elder et al looked indirectly at nurse perceptions about reporting errors in intensive care units in 4 US community hospitals post 2000. The study used the results from 92 AHRQ hospital patient safety culture surveys and the analysis of eight focus groups involving 33 nurses. The results showed the limitation of using culture surveys to establish incident
reporting behaviour. Survey responses suggested that 54% of nurses would report most of the time / always if a mistake had no potential for harm and 45% if the mistake was corrected before reaching the patient. However the focus groups suggested that for no harm/near miss errors it was unlikely that nurses would complete a report. Barriers to reporting identified from the focus groups included being too busy, fears of blame or punishment and a lack of feedback following an error, despite nurses agreeing that reporting can serve as a learning experience and improve clinical practice. The focus groups also revealed that the amount of “emotional conflict” about reporting errors varied depending on the health professional involved in the error. Telling a more junior nurse was considered as not causing any anxiety but telling a peer or a more senior nurse that they had made a mistake was perceived as an emotionally difficult process, which may result in a decision not to report. The focus group respondents additionally reported great difficulty discussing and reporting errors that involved doctors, due to the perceived power differential between doctors and nurses, and in fact no nurse in the focus groups had ever reported an error made by a doctor.

Conclusions
The fear of manager and co-worker response (in particular doctors) was identified as the biggest barrier to reporting medication errors in adult and paediatric hospitals, with no clear difference in studies published after the year 2000. In addition there is a clear perception that nurses are less likely to report a medication error if the harm to the patient was not serious, with perhaps a belief that if they can redefine the error they can get away with it and not report.

1.3 Doctors’ attitudes to reporting errors

Half of the studies that primarily involved doctors were conducted in the UK (5/10) with two authors publishing two similar papers each, with four in the US and one in New Zealand. (see table 2) All of the studies were performed in hospital settings and published from 2003 onwards, two specifically including surgical trainee doctors and two including paediatric doctors. Six of the studies were carried out on a single site with the remaining studies performed over multiple sites.

Eight of the studies used quantitative survey methodology, whilst the other two used qualitative semi-structured interviews. Ninety percent of the studies were investigating
attitudes to all types of errors/ incidents, one of which just involved anaesthetic errors but one study explored medication errors exclusively.

Table 2: Summary of studies involving medical attitudes to reporting errors

<table>
<thead>
<tr>
<th>Study</th>
<th>Date published</th>
<th>Research methodology</th>
<th>Study size</th>
<th>Type of incidents</th>
<th>Setting</th>
<th>Key findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mcardle et al 40 (UK)</td>
<td>2003</td>
<td>Semi-structured interviews</td>
<td>15 doctors</td>
<td>Medication errors</td>
<td>One hospital</td>
<td>Supportive of reporting to make it safer for patients but split on including Drs names on forms to “weed out” incompetent ones or prevent blame. Reporting took too long and never any positive feedback.</td>
</tr>
<tr>
<td>Yong et al 41 (New Zealand)</td>
<td>2003</td>
<td>Survey</td>
<td>136 doctors</td>
<td>All anaesthetic errors</td>
<td>Multiple hospitals</td>
<td>Nearly half admitted scheme had changed their practice but that system still needed simplifying and to stimulate positive change</td>
</tr>
<tr>
<td>Waring 2 (UK)</td>
<td>2004</td>
<td>Semi-structured interviews</td>
<td>28 consultant doctors and 13 senior managers</td>
<td>All errors</td>
<td>One hospital (different specialities)</td>
<td>Obstetricians were the most supportive of reporting due to positive change driven by increase litigation, followed by anaesthetists. Surgeons and physicians were wholly unsupportive and preferred internal reporting schemes.</td>
</tr>
<tr>
<td>Waring 3 (UK)</td>
<td>2005</td>
<td>Semi-structured interviews</td>
<td>28 consultant doctors</td>
<td>All errors</td>
<td>One hospital</td>
<td>Concerns about tarnishing careers and increased litigation were themes for not reporting. Sceptical about value of incident reporting and ability of managers to investigate properly or feedback. Reporting schemes do not suit medical style of clinical judgement and discretion.</td>
</tr>
<tr>
<td>Sharma et al 44 (UK)</td>
<td>2005</td>
<td>Survey</td>
<td>65 surgical trainee doctors</td>
<td>All errors</td>
<td>One hospital</td>
<td>Little feedback or change if reported. 52% were unclear what to report and 55% believed medical culture was biggest reason for not reporting. 42% claimed would report more if anonymous and 64% said accessibility was important</td>
</tr>
<tr>
<td>Schectman et al 45 (US)</td>
<td>2006</td>
<td>Survey</td>
<td>120 doctors</td>
<td>All errors</td>
<td>One hospital</td>
<td>The following barriers to reporting were agreed to be important by more then half of Drs: unfamiliar with reporting process, worried about reporting others, reporting made no difference, inadequate Dr involvement, time consuming form and why need to report if no patient harm. Similarly more than</td>
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</tbody>
</table>
half thought that clarification of reporting system, anonymous reporting and electronic reporting were very likely to increase reporting. The number and degree of barriers was inversely proportional to safety perception scale.

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Method</th>
<th>Sample</th>
<th>Errors</th>
<th>Setting</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Garbutt et al 46</td>
<td>2007</td>
<td>Survey</td>
<td>557 paediatric doctors</td>
<td>All errors</td>
<td>Multiple hospitals</td>
<td>97% agreed should report serious errors and 82% for near misses, to improve patient safety. Features selected to increase reporting were evidence of positive change, confidential and non-punitive forms, which took less than 2 minutes to complete.</td>
</tr>
<tr>
<td>Sharma et al 47</td>
<td>2008</td>
<td>Survey</td>
<td>81 surgical trainee doctors</td>
<td>All errors</td>
<td>One hospital</td>
<td>Only 4.5% unclear what to report and 27.3% believed medical culture was biggest reason for not reporting. Fact that “nothing would be achieved” was commonest reason for not reporting.</td>
</tr>
<tr>
<td>Kaldjian et al 48</td>
<td>2008</td>
<td>Survey</td>
<td>338 doctors (adult and paediatric)</td>
<td>All errors</td>
<td>Three teaching hospitals (65% outpatient practice only)</td>
<td>More likely to report hypothetical errors resulting in major harm (92%) compared with no harm (64%). 47.9% said would be more likely to report if had positive feedback and nearly 60% were concerned about discipline. Respondents more likely to report no or minor harm hypothetical errors if believed reporting improved quality of care and knew how to report.</td>
</tr>
<tr>
<td>Logio et al 49</td>
<td>2010</td>
<td>Survey</td>
<td>443 doctors</td>
<td>All errors</td>
<td>Five hospitals</td>
<td>Doctors did not know how to locate an incident form (22.3%-31.5%) or had ever completed an incident form in each hospital (6.2%-20%) but reporting was more likely when doctors knew how to find an incident form.</td>
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</table>

McArdle et al used semi-structured interviews to discover the attitudes of doctors about medication error reporting in one hospital in the UK post 2000. 40 A random sample of 15 doctors from medicine, neonatology and anaesthetics (six consultants, three registrars and six senior house officers) was used. All participants felt that reporting medication errors was very important due to litigation worries, and the fact that it helped to “weed out” incompetent doctors and made it safer for patients. Senior doctors noted the greater
importance of dealing with the error and preventing repetition than actually reporting and felt the medical notes were a better place to document such incidents. The doctors complained that the current hospital reporting system was cumbersome and took too long to complete and the majority complained that there was never any positive feedback. Some doctors were very concerned about the name of the individual doctor being on the form as they believed the culture of “no blame” did not exist either in the NHS or within society itself.

Yong et al used a postal survey to evaluate the attitudes of anaesthetists to anaesthetic incident reporting. The study carried out post 2000 in New Zealand included 136 replies (57% response rate). The participants showed good awareness of the anaesthetic incident monitoring scheme with nearly 50% saying the system had changed their practice. However there were still concerns that the system needed to simplify the reporting and to ensure that something useful happened following investigation of the incident. The authors concluded that the use of the reporting system may however be declining due to a feeling that it was becoming less effective at stimulating positive change.

Waring published two papers considering cultural barriers to incident reporting, carried out between 2001 and 2003, in the UK. The first study involved semi-structured interviews with five consultants from each of the five specialties, in addition to three senior consultants in management and thirteen senior managers from one district general hospital. The results showed that the views of consultants varied depending on the specialty in which they worked. Obstetricians were the most enthusiastic and supportive of incident reporting. The authors stated that this appeared to be due to the increasing litigation in that area over the last 10 years, meaning that reporting is accepted, and the belief of obstetricians that reporting had made a positive contribution to service development. Anaesthetists were also supportive of reporting as a means to improve quality but preferred to use a localised anonymous system which they had used for many years and following guidance from their Royal College. Surgeons were unfamiliar with the reporting scheme within hospitals and were hostile towards reporting errors to management. They felt that it was a waste of time as nothing would get done and they preferred the internal audit meetings and national confidential peri-operative death enquiries as a means to improve services. Physicians were also not supportive of the trust's reporting scheme as they felt it was nurse led and that other non-medical groups were involved. They also described an alternative system that they had implemented
themselves which had been anonymous and involved one consultant collecting and presenting the data to colleagues to help improve services in Medicine. Waring concluded the three broad themes that influenced medical attitudes to and participation in incident reporting systems were confidence in the scheme, a clear purpose and collegiality i.e. internal evaluation to the exclusion of non-professional groups. The author's suggestion that incident reporting needs to be introduced from within the medical profession is at variance with the general thrust of national reporting schemes and is based on a small sample of consultants from one hospital.

In the second paper Waring reviews the interviews about adverse incident reporting with just the 28 consultant doctors. Four major themes were described from the interviews. The issue of blame culture was described by all as a reason for unease about reporting. Consultants felt that the public, press and indeed their hospitals wanted to make doctors culpable for care that does not meet set standards, and that the increasing litigation in the UK was making the situation worse. The concern about colleagues’ careers being tarnished by competence issues was also raised. The doctors seemed sceptical and apprehensive about incident data with only the senior medical director aware that reporting could be used to prove and solve problems. The doctors also described the inevitability of medical error meaning that doctors tended to accept routine mistakes as the “norm” and therefore did not bother to report. They also thought that reporting was a managerial exercise and that reporting was a waste of time, as nothing ever seemed to happen for the benefit of patients. There was a perception that confidential enquiries e.g. peri-operative deaths were more useful for service review. The question of bureaucracy was also raised with consultants expressing a feeling that non clinical managers would not be able to truly evaluate errors as they had no understanding. The authors questioned whether this was because of a fear of general increased managerial scrutiny of medical practice over the last 10 years. Lastly the doctors felt that the reporting system suited the working style of nurses better as unlike doctors they followed a more rigid structured approach with less room for judgment and discretion.

Sharma et al surveyed 65 surgical trainee doctors from one UK hospital in 2003 about incident reporting. The questionnaire was completed anonymously and the mean NHS experience of the doctors involved was 4.5 years. 94% said they were aware of the trust’s reporting system but only 33% had actually ever reported an error. For those who had
reported an incident only 12% said they received feedback and none had received any information about change following the incident. 52% of respondents were unclear what incidents needed to be reported and medical culture was identified by 55% of respondents as being the biggest reason for not reporting incidents. Other reasons for not reporting included not wishing to get themselves (10%) or others into trouble (18%), thinking that nothing would change (27%) a lack of awareness of the issues or apathy for the whole process (18%). 42% of the doctors said they would report more if the reporting system was anonymous whilst 64% said that accessibility to the reporting system was an important factor for its use.

Schectman and Plews-Ogan studied doctors’ perceptions of barriers to incident reporting in one hospital, running a quality improvement programme, in the United States in 2005. 120 faculty and resident doctors from one department completed the anonymous questionnaire (56% response rate). Sixty percent said they had witnessed at least three adverse events or near misses in the previous year but only 8% had made more than one or two reports of the events. Responses indicated uncertainty about the reporting scheme with 41% not familiar with the reporting process and 33% not knowing how to report at all. Respondents were then asked about their overall perception of safety culture at the hospital, using the Agency for Healthcare Research and Quality (AHRQ) safety culture survey, barriers to reporting and suggestions for the improvement of reporting. Respondents were asked about possible barriers to reporting adverse events or near misses using a three point scale: not important, somewhat important and very important. 55% of respondents indicated (somewhat or very important) that reporting made no difference, with 56% having concerns about the consequence of reporting other people’s errors, however only 35% indicated concerns about being blamed for the error. Barriers such as inadequate physician participation in the system, reporting was too difficult or time-consuming and no actual harm came to the patient were rated somewhat or very important by around two thirds of physicians. Other questions reiterated physician uncertainty about what constituted an error, whose responsibility it was to report, and the actual reporting mechanism itself.

Open comments from physicians about the reporting system included: fears of professional retribution and litigation; professional beliefs about not needing to report if patients came to no harm and preferring to handle incidents themselves; the difficulty in finding paper reporting forms, the lack of anonymity and the insufficient training in the use of the reporting forms; and the lack of changes and feedback from the hospital following errors.
Respondents were asked about ways to increase reporting using a three point scale: unlikely, somewhat unlikely, very likely. Over half of physicians thought that clarifying the reporting system, and what constituted an error; and allowing anonymous reporting were very likely to increase reporting, with 71% thinking that electronic reporting was very likely to increase reporting. Around a third of respondents thought that providing individual feedback or providing summary feedback on a regular basis was very likely to increase reporting, and a similar number that making reporting mandatory would very likely increase overall reporting.

For the patient safety culture questionnaire 51% of respondents strongly agreed or agreed that “patient safety was never sacrificed to get more work done” and 58% that “procedures and systems are good at preventing errors from happening”. 37% agreed or strongly agreed that it was “just by chance that more serious mistakes don’t happen”. The overall perception of hospital safety was considered to be neutral with an overall score of 6.5 (standard deviation 2.6, normal range 0-12), with the higher the score the more positive the perception of hospital safety. The numbers of reported and witnessed adverse events were statistically inversely associated with safety perception. The mean safety culture score was lower for physicians having witnessed one to two (6.7) or more than 2 adverse events or near misses (6) compared with those witnessing no adverse events (7.9). Additionally the number and degree of barriers to reporting by respondents was also statistically inversely associated with their perception of safety (mean rating 5.8 for those in the highest tercile of barriers to reporting versus 7.0 for those in the lowest tercile). 58% of doctors said they were willing to participate in hospital’s quality improvement process and the authors hypothesise that “rank and file physician involvement in quality improvement processes, along with physician leadership are critical ingredients for a self-sustaining and culture-changing endeavour”.

Garbutt et al published a study investigating the attitudes of paediatric physicians and residents working in two different hospitals in the United States between 2003 and 2004.46 A paper or web-based questionnaire was circulated to 898 paediatricians to complete anonymously and explored attitudes to reporting errors both to the hospital and to their patients and families. With a 62% response rate the majority of the 557 respondents were senior paediatricians (21% paediatric residents) and 63% of all respondents spent less than 25% of their time caring for hospitalised patients. Only 7% of all participants reported that they had never been involved in an error and the vast majority of them believed that they should report errors to improve patient safety (serious errors 97%, minor errors 90%, near
misses 82%). 40% of respondents did not know if their institution had an error reporting system but 65% said that they had formally reported an error using an incident report of some description. Paediatricians appeared to be more likely to report errors if they believed them to be one of the most serious problems in health care and 86% said that their institution had changed systems after errors to improve patient safety. Participants were asked to select features of a reporting system that they believed would increase the likelihood of them reporting: 89% selected evidence that the data was used to improve systems, 88% that the information was confidential 89% that the system was not punitive, 73% that the report took less than two minutes to complete and 58% that the reporting system was local to their department.

Sharma repeated the study in 2007 and 81 surgical trainee doctors, who were approached personally, completed the questionnaire (95.3% response rate). The number of years experience of the sample was the same as for the 2004 sample (mean 4.5 years) and the number of doctors who had reported an error had increased from 33% to 46%. The most common reason quoted for not reporting had changed to a feeling that “nothing would be achieved”, whereas only 27.3% of respondents agreed that it was not within medical culture to report. There was the same support for anonymous reporting as last time (44% of respondents), particularly amongst the most junior doctors and 15.9% of doctors cited that they did not know how to access incident forms as a reason for not reporting. Only 4.5% of respondents said they did not know what needed to be reported.

Kaldjian et al investigated the reporting of medical errors reported using a self-administered paper-based questionnaire survey in three different teaching hospitals in the United States between 2004 and 2005. 338 faculty and resident physicians completed the questionnaire (response rate 74%) and the majority of physicians were Medicine based but included some paediatric physicians. 65% of the physicians were mainly involved in outpatient medical practice only. Respondents were asked if they had ever reported actual errors made by themselves and then to identify whether they would report a hypothetical error regarding a patient with an antibiotic allergy. Respondents were asked if they would report the error using a five point Likert scale (one=very likely, 5=very unlikely) but dependent on different outcomes for the patient i.e. no harm, minor harm and major harm. Respondents were also asked questions about their attitudes to reporting errors using a five point Likert scale. Overall 35.6% of respondents acknowledged having made at least one minor or one major error in their institution with 17.8% of respondents claiming to have
reported a minor error, 3.8% reporting a major error. 16.9% of respondents claimed they had not reported a minor error and 3.8% not reported a major error. Regarding the hypothetical errors 92% of respondents claimed they would be likely or very likely to report the error if it resulted in major harm, 73% for minor harm and 43% if no harm. The vast majority of respondents (84.3%) felt that reporting errors improved the quality of care for patients in the future, with 54.8% saying they knew how to report errors within their institution, but only 39.5% knew what sorts of errors should be reported. 47.9% said they would be more likely to report errors if they knew they would receive positive feedback with only 7.4% saying that reporting errors was not worth the effort. Concerns about professional discipline were acknowledged by 57.7% of physicians, with resident physicians more concerned than their more senior faculty colleagues. Multivariate regression analysis was used to identify any variables associated with the hypothetical reporting and actual reporting behaviour and respondents who had reported minor errors were statistically more likely to indicate that they would report the hypothetical error regardless of the severity. Respondents were also statistically more likely to report the no and minor harm hypothetical error if they believed reporting improved quality of care and knew how to report errors. Finally participants had been asked about their spiritual / religious beliefs and those who indicated that forgiveness was an important part of their spiritual / religious beliefs were significantly more likely to report the no and minor harm errors. The authors conclude that there was a distinct difference between doctors’ attitudes to reporting errors and what they actually did in practice.

Logio et al surveyed 443 junior doctors (residents and fellows), who rotated through five US hospitals during their medical training, and they did not know how to locate an incident form (22.3% -31.5%) or had ever completed an incident form in each hospital (6.2%-20%). Reporting was however more likely when doctors knew how to find an incident form.

Conclusions

A lack of positive feedback and the belief that reporting systems do not sit comfortably with medical culture are the strongest barriers to reporting errors in hospitals by doctors and there is support for reporting systems that are easier to use and that are anonymous. Doctors, like nurses, appear more likely to report more serious errors than no harm errors
or near misses. Obstetricians and anaesthetists emerge as the most supportive of reporting compared with surgeons and physicians.

1.4 Pharmacists’ attitudes to reporting medication errors

There is very limited literature considering pharmacist attitudes to reporting medication errors with three contrasting studies, one carried out in a US hospital using qualitative methodology and two performed in community pharmacies using a quantitative survey technique.

Tamuz et al’s research into the definition of medical error involved semi-structured interviews with 36 pharmacy staff from a tertiary referral teaching hospital in the United States in 2001. The key discovery was that some pharmacy staff made a conscious decision whether to formally report an incident via the hospital reporting system or document the incident as a “pharmacy intervention” as it affected their annual appraisal. Staff were formally rewarded at appraisal for interventions made but formally recorded incidents involving themselves were used in appraisals to compare staff with their peers. The pharmacy department promoted a non-punitive culture but staff perception of whether that was true varied and pharmacy managers confirmed that pharmacists never or rarely filed formal incident forms involving themselves or other pharmacy colleagues. Pharmacy staff also confirmed that dispensing errors noticed before leaving the department (ie near misses) were not recorded anywhere.

Ashcroft et al investigated the likelihood of reporting adverse events in community pharmacy in 2004 and included 223 British community pharmacists and 52 support staff. The questionnaire involved nine different scenarios involving dispensing or counter prescribing of a medicine, where the behaviour of the community pharmacist involved compliance (in line with protocol), violation (deliberate deviation from protocol) or error (not being aware of a protocol). Participants were asked how likely they were, on a 5 point Likert scale (1= very unlikely, 5= very likely), to have reported the event locally and nationally to the National Reporting and Learning Scheme (NRLS) if they had witnessed it. There were significant main effects for behaviour type and patient outcome but all mean scores were below the mid point indicating that pharmacists and their support staff were unlikely or very unlikely (mean scores below 2) to report any events to the local or national reporting scheme respectively. This study was performed after the introduction of
the NRLS but additional comments from participant’s seemed to reveal a lack of understanding about the NRLS and a deep resentment and mistrust about the need for reporting schemes due to fears of repercussions for the pharmacist involved.

Boyle at al considered attitudes to medication incident reporting in community pharmacies in Canada in 2008. Seventy two staff from thirteen different pharmacies (28 pharmacists, 18 pharmacy managers and 26 pharmacy technicians) completed a web based survey. Participants were asked to rate their current reporting systems on a 5 point Likert scale. (1=strongly disagree, 5= strongly agree). Its impact on day to day operations, the ease of completion and the personal support given to individuals involved in errors were rated the highest above the mid point (3.35, 3.26, and 3.34 respectively). The two most common complaints about the reporting systems were the lack of a formal medication incident process and feedback after an error.

Pharmacy staff were also asked to rate the importance of multiple characteristics of a new incident reporting and learning system and to consider actions that might improve incident reporting. In addition to education, training and cultural/technical support participants identified the need for time to use the system (3.75) , its impact on day to day activities (3.58) and a desire for anonymity (3.39) as desirable characteristics for a new reporting system using a 5 point Likert scale (1= would not, 5= most definitely). The sharing of learning from errors and ensuring anonymity for pharmacy staff were rated most highly (3.74 on a scale 1= would not, 5 = definitely) as factors that would likely increase reporting and learning. Further comments again echoed concerns about the anxiety of reporting others if not an anonymous system.

Conclusions

Apprehension and suspicion about reporting schemes, due to the fears of the consequences for the pharmacist involved in the error, is the overriding attitude of pharmacists to reporting medication errors. In the most recent study the lack of learning after errors and the impact of reporting on daily activities also appear important to community pharmacists.

1.5 Health Professionals’ attitudes to reporting errors

Half of the studies were conducted in the UK (9/18) with six in the US, two in Australia and one in Taiwan (see table 3)
Eighty nine percent (16/18) were published after 2000 and also carried out in hospital settings, one specifically in a paediatric hospital. Of the other two studies one involved postgraduate health professionals selected, from three UK universities, from hospital and community care settings, and one study investigated medication errors in US nursing homes.

Fifty six percent of studies (10/18) were carried out over multiple sites with 39% (7/18) involving a single hospital or just a single obstetric, intensive care, or surgical unit. Half of the studies used quantitative survey methodology, three used both qualitative and quantitative methods and a third used focus groups or interviews only. Fourteen of the studies (78%) were exploring all types of errors, with four investigating attitudes to medication errors only.

Table 3: Summary of studies involving health professionals’ attitudes to reporting errors

<table>
<thead>
<tr>
<th>Study</th>
<th>Date published</th>
<th>Research methodology</th>
<th>Study size</th>
<th>Type of incidents</th>
<th>Setting</th>
<th>Key findings</th>
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<tbody>
<tr>
<td>O’Connor53 (UK)</td>
<td>1996</td>
<td>Interviews</td>
<td>Unknown number of HPs</td>
<td>Any errors</td>
<td>One obstetric unit</td>
<td>Supportive of incident reporting to implement change and considered self reporting best way to reduce fear of reporting others</td>
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<tr>
<td>Vincent et al54 (UK)</td>
<td>1999</td>
<td>Survey</td>
<td>42 obstetricians , 56 midwives</td>
<td>Any errors</td>
<td>Two hospitals</td>
<td>HPs more likely to report a maternal death (96%) than the need for a transfusion (19.8%) Midwives more likely to report than doctors.</td>
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<tr>
<td>Coles et al55 (UK)</td>
<td>2001</td>
<td>Interviews with HPs (single, group and telephone interviews) plus survey of clinical risk managers</td>
<td>69 doctors , nurses, pharmacists radiographers</td>
<td>Any errors</td>
<td>Multiple hospitals</td>
<td>Clinicians sceptical about open and fair culture and concerned about litigation and damage to reputations. Time taken to report and investigate are practical barriers to reporting</td>
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<tr>
<td>Lawton and Parker56 (UK)</td>
<td>2002</td>
<td>Survey</td>
<td>315 doctors, nurses and midwives</td>
<td>Any errors</td>
<td>Three hospitals</td>
<td>All Health Professionals (HPs) were statistically more likely to report event to a supervisor if behaviour of an HP was a violation rather than an improvisation or a compliance with protocol, and if the outcome was bad rather than poor or good. Nurses and midwives were more likely than doctors to report violations with bad outcomes</td>
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<tr>
<td>Study</td>
<td>Year</td>
<td>Methodology</td>
<td>Participants</td>
<td>Event Reporting</td>
<td>Setting</td>
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<tr>
<td>Uribe et al&lt;sup&gt;37&lt;/sup&gt; (US)</td>
<td>2002</td>
<td>Nominal group technique and survey</td>
<td>56 doctors and 66 nurses</td>
<td>Any errors</td>
<td>One hospital</td>
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<td>Firth Couzens et al&lt;sup&gt;38&lt;/sup&gt; (UK)</td>
<td>2004</td>
<td>Focus groups</td>
<td>29 doctors and 15 nurses</td>
<td>Any errors</td>
<td>Multiple sites including hospitals and general practice</td>
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<tr>
<td>Kingston and Evans&lt;sup&gt;39&lt;/sup&gt; (Australia)</td>
<td>2004</td>
<td>Focus groups</td>
<td>14 doctors and 19 nurses</td>
<td>Any errors</td>
<td>Multiple hospitals</td>
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<tr>
<td>Jeffe et al&lt;sup&gt;40&lt;/sup&gt; (US)</td>
<td>2004</td>
<td>Focus groups</td>
<td>30 doctors and 49 nurses/ nurse manager</td>
<td>Any errors</td>
<td>Multiple hospitals</td>
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</table>

Most important barriers to reporting for doctors were not knowing what or how to report, extra time involved and perception that reports did not improve quality of care. For nurses extra time involved, the unnecessary need to report if the patient came to no harm but also the fear of lawsuits, no anonymity and hesitancy in reporting others were the most important barriers.

All HPs said would not report near misses and that minor errors where staff had insight did not need reporting but that errors needed to be discussed anonymously locally. GPs had highest threshold for reporting serious errors. Not knowing what to report, the time taken to report, fear of reporting more senior colleagues and fact that nothing changes after an incident were identified as barriers. Nurses identified difficulty in challenging Drs due to medical culture of using clinical judgement.

Nurses report as per hospital directives and to cover themselves if something goes wrong whilst doctors preferred to keep in house as believed whistle blowing was unethical and unsupportive. All groups had concerns about punitive and legal implications but could see the benefit of improving patient care if positive change followed incidents but reported that this did not currently happen.

Not knowing what to report, including severity and repetition of errors, was an issue for all, as well as how to report for doctors in particular. Fears of repercussions and confidentially, the time required to report and a lack of follow up after incidents were other barriers to reporting.
<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Type</th>
<th>Participants</th>
<th>Error Type</th>
<th>Site/Proportion</th>
<th>Challenges</th>
</tr>
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<tbody>
<tr>
<td>Taylor et al(^{61}) (US)</td>
<td>2004</td>
<td>Survey</td>
<td>74 doctors and 66 nurses</td>
<td>Any errors</td>
<td>One paediatric hospital</td>
<td>Unsure about what to report (40.7%) and concerns about implicating others (37%) greatest barriers to reporting. Better education about what constituted an error (65.4%), more feedback about reported errors (63.8%), evidence that reporting lead to systems changes (55.4%) and the use of electronic reporting (44.9%) identified as factors to improve reporting. Nurses more likely to report errors than doctors and all HPs more likely to report serious errors (99.3%) than trivial errors (36.4%) and less likely to report near misses (31.7%).</td>
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<tr>
<td>Wild et al(^{62}) (US)</td>
<td>2005</td>
<td>Survey</td>
<td>84 HPs (29% junior doctors, 71% nurses)</td>
<td>Any errors</td>
<td>One community hospital</td>
<td>Less doctors knew anything about the reporting system than nurses (54% versus 97% (p=0.001)) and fewer doctors had ever used the system (13% versus 22% (p=0.001)). Doctors were also more likely to rate the hospital atmosphere as non-supportive of error reporting (38% versus 0% (p=0.001)).</td>
</tr>
<tr>
<td>Evans et al(^{63}) (Australia)</td>
<td>2006</td>
<td>Survey</td>
<td>186 doctors and 587 nurses</td>
<td>Any errors</td>
<td>Multiple hospitals</td>
<td>Difference between what would report and should report and this in turn depended on severity of error. (100% of nurses and 35% doctors said do report if drug error needed corrective treatment). More than 50% of doctors reported lack of feedback, incidents too trivial and time needed to report as most likely barriers to reporting. No feedback was only barrier agreed by &gt; 50% of nurses.</td>
</tr>
<tr>
<td>Wilson et al(^{64}) (UK)</td>
<td>2008</td>
<td>Survey</td>
<td>201 HPs(^{#}) (37% doctors 61% nurses/mid-)</td>
<td>Any errors</td>
<td>Postgraduates from three universities</td>
<td>Nurses had a statistically more positive attitude to reporting errors than...</td>
</tr>
<tr>
<td>Study</td>
<td>Year</td>
<td>Methodology</td>
<td>Participants</td>
<td>Reason for Reporting</td>
<td>Findings</td>
<td></td>
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<tr>
<td>Wu et al&lt;sup&gt;65&lt;/sup&gt; (Taiwan)</td>
<td>2008</td>
<td>Survey</td>
<td>290 (49% nurses, 30% IT and 21% doctors or pharmacists)</td>
<td>Any errors</td>
<td>Multiple hospitals</td>
<td>Perceived usefulness, perceived ease of use, subjective norm and trust all had a statistically significant effect on the intention of individuals to use an electronic reporting system, using a technology acceptance model.</td>
</tr>
<tr>
<td>Kreckler et al&lt;sup&gt;67&lt;/sup&gt; (UK)</td>
<td>2009</td>
<td>Survey</td>
<td>55 doctors and 83 nurses</td>
<td>Any errors</td>
<td>Surgical unit in one hospital</td>
<td>Both HPs more likely to report incidents resulting in harm than no harm and near misses but 74% of doctors were not sure what types of incident to report. 47% of doctors and 29% of nurses were too busy to fill out forms with 51% and 29% agreeing that the form took too long to complete. 69% and 38% respectively reported that they never received any feedback.</td>
</tr>
<tr>
<td>Coley et al&lt;sup&gt;68&lt;/sup&gt; (US)</td>
<td>2006</td>
<td>Focus groups and telephone interviews (2)</td>
<td>14 HPs*</td>
<td>Medication errors</td>
<td>Eight hospitals including community, and paediatric</td>
<td>Inadequate staffing is a major barrier to reporting due to the time-consuming nature of confirming medication errors and then collecting the relevant details. Could improve reporting rates using a dedicated medication safety manager or increasing the use of pharmacy technicians.</td>
</tr>
<tr>
<td>Sanghera et al&lt;sup&gt;69&lt;/sup&gt; (UK)</td>
<td>2007</td>
<td>Semi-structured interviews</td>
<td>5 doctors and 8 nurses</td>
<td>Medication errors</td>
<td>Intensive care unit in one hospital</td>
<td>Barriers included not being aware of an error, the process of reporting being too difficult, the fact that no benefits are seen and fears of reporting (disciplinary /litigation).</td>
</tr>
<tr>
<td>Handler et al&lt;sup&gt;70&lt;/sup&gt; (US)</td>
<td>2007</td>
<td>Nominal group technique and survey</td>
<td>13 doctors, 8 pharmacists, 78 nurses, 4 other practitioners</td>
<td>Medication errors</td>
<td>Four nursing homes</td>
<td>Lack of feedback, lack of knowledge about when errors occurred and need reporting, lack of available reporting form and the extra time involved in reporting identified as most likely barriers to reporting.</td>
</tr>
<tr>
<td>Sarvadikar et al&lt;sup&gt;71&lt;/sup&gt; (UK)</td>
<td>2010</td>
<td>Survey</td>
<td>56 health professionals</td>
<td>Medication errors</td>
<td>One hospital</td>
<td>Doctors were more likely to report if patient</td>
</tr>
</tbody>
</table>
(32% doctors
39% nurses,
29% pharmacists)

harm was serious whilst pharmacists and then nurses were most likely to report all errors. The nurses followed by the pharmacists were more likely than their medical colleagues to think they would be blamed or disciplined for involvement in a medication error with such fears increasing for all the greater the patient harm.

# A second smaller questionnaire was distributed to 102 HPs (60% nurses) for test-retest reliability
* Profession unclassified but participants had to be involved with one aspect of the MEDMARX reporting system (e.g. data collection, report distribution) so may have included pharmacists, pharmacy technicians, and clinical risk staff

1.5.1 Health Professionals’ attitudes to reporting general errors

O’Connor also studied general attitudes of obstetric staff to clinical risk management in a single obstetric unit in the UK at a similar time.\(^\text{53}\) Supportive of incident reporting and its need to implement change staff were concerned about inefficient feedback following incidents and felt that self reporting was the best way to allay fears of reporting others.

Vincent et al carried out a questionnaire study involving 42 obstetricians and 56 midwives from two British hospitals in the late 1990s.\(^\text{54}\) Even before national reporting was introduced more than 70% knew that an incident reporting scheme existed, where to find the incident form and how to report it. Staff views on the need to report 10 different types of incidents, which did not include drug errors, found that on average 67.4% of participants would always report. This varied from 96% for maternal deaths to 19.8% for transfusion need and illustrates a very strong reporting culture in obstetric units due to the risk of litigation. Midwives were more likely than doctors to report and junior staff were more likely than senior staff to report. Participants were asked to score on a five point Likert scale (1=strongly disagree, 5=strongly agree) twelve reasons for not reporting adverse incidents. For both professions all mean ratings were below the midpoint suggesting they did not agree that any of these were barriers to reporting. However the paper reports that 31% of participants felt the circumstances often made reporting unnecessary, 36% felt that junior staff could be unfairly blamed, 29% felt that it increased workload, 30% agreed that they were too busy to report and 23% that they were worried about litigation. A one-way analysis of variance was used to compare mean scores across
grades and professions and the most important differences were between senior and junior staff. For those that were statistically significant junior medical staff were more likely to be worried about increased workload, too busy and forget to report than senior medical staff. For midwifery staff juniors were more likely to not know which incident should be reported, nor whose responsibility it was to report it to their senior colleagues. The participants were personally approached and had previously taken part in another study about incident reporting so these results could have been unduly biased.

Coles at al published a report, commissioned by the NPSA, which was carried out between August and October 2001 in the UK, prior to the launch of the NPSA’s National Reporting and Learning System (NRLS). It involved a literature review and discussion with international experts in patient safety, a survey of 171 risk managers in English acute NHS about current reporting systems and interviews with 69 clinicians across 23 specialties and departments. The clinicians included doctors, nurses, pharmacists, radiographers and risk managers. 43 clinicians were interviewed on a one-to-one basis whilst 23 medical specialist registrars and consultants were interviewed in two focus groups and three risk managers were interviewed over the telephone. Interviewees were broadly asked about four central themes: acceptance of central reporting, identification of the need to report, barriers to reporting and incentives to reporting. The major concern of clinicians about reporting was the possibility of unjust exposure, criticism, litigation and personal damage to reputation and career. Clinicians felt this meant the need for clear rules about the need for anonymity and confidentiality. In addition they shared concerns about whether the reporting would actually benefit patient care or not, if no changes were made. Clinicians also voiced the need for clear guidance about definitions of what constitutes an incident and believed that resources would be needed for time to report, providing input into root cause analysis and resources required to rectify the deficiencies identified by the report (i.e. retraining, new equipment or staff, capital spending). Finally clinicians were concerned about an additional reporting route when incidents are reported to a wide range of bodies already, for example the National Confidential Enquiry into Patient Outcome and Death (NCEPOD)

They summarized:

- Barriers to reporting incidents as: fears of litigation, publicity and lack of trust; professional scepticism and workload; fear of litigation; loss of reputation
Incentives to report incidents as: confidentiality and professional protection; professional integrity, education and saving lives; demonstrating compliance with standards; safety saves money.

The overriding conclusions of the report were:
1- The need for an open and fair culture which most clinicians remained sceptical about.
2- Practical barriers to reporting were needed which involve time of clinicians to report and to investigate.
3- There are still major concerns about the risk of unnecessary personal damage of litigation.

Lawton and Parker studied barriers to incident reporting in three British hospitals in 1998. A convenience sample of 315 doctors, nurses and midwives working in obstetrics, anaesthetics or surgery were asked to complete a questionnaire which included nine different clinical scenarios, where the behaviour of a health professional involved compliance (in line with protocol), violation (deliberate deviation from protocol) or improvisation (use of clinical judgment where no protocol existed). At least one of the scenarios was medication related and the actual outcome for the patient varied between good, bad or poor. Participants were asked how likely they were, on a 5 point Likert scale (1=very unlikely, 5= very likely), to have reported the event to a supervisor if they had witnessed it. All health professionals were significantly more likely to report scenarios involving violation than improvisation and least likely to report scenarios involving compliance, however the only mean scores above the mid point on the scale were from nurses and midwives for violations. All health professionals were significantly more likely to report scenarios involving bad outcomes rather than poor outcomes and least likely to report scenarios involving good outcomes. However the only mean scores above the mid point on the scale were from nurses and midwives for improvisations and violations. Doctors were the least likely to report overall with a mean score of 2.97 (SE 0.18) for reporting a violation where the outcome for the patient was bad. Mean scores for nurses and midwives were 4.15 (SE 0.12) and 3.85 (SE 0.16) respectively. The sampling technique for medical staff involved personal approaches by researchers.

Uribe et al studied 56 doctors and 66 nurses (17.3% response rate) in a large academic medical centre in United States post 2000 regarding likely barriers to error reporting. The questionnaire was developed using a nominal group technique and required participants to use a five point Likert scale (1=very likely, 5=very unlikely).
The six most likely barriers to reporting were time taken, extra work reporting, not anonymous, hesitancy about telling on someone else, fear of lawsuits and unnecessary to report due to no negative outcome for patient. The mean scores for the six factors were between 2.44 (SD 1.18) and 2.74 (SD 1.46). Not knowing whose responsibility it was to report (mean 3.45) and fear of losing one's job (mean 3.53) were the least likely reported barriers. When the results were studied for individual professions 14 out of 17 factors were considered barriers by doctors whilst for nurses only six factors had mean scores of less than 3. The most important barriers for doctors were not knowing what or how to report, the extra work and time involved in reporting and the perception that reporting the error did not contribute to improved quality of care. For nurses the extra work and time involved, the unnecessary need to report if the patient came to no harm but also the fear of lawsuits, no anonymity and hesitancy in reporting others were the most important barriers. There was no specific mention about medication errors and there appeared to have been no effect of years of experience, age or gender within the cohort.

Firth-Cozens et al used focus groups involving hospital and community doctors and nurses from two different NHS regions in the United Kingdom to study experiences with errors post 2000. The convenience sample of 44 participants (29 doctors of different grades and a mix of 15 student and senior nurses) reported that minor common place “genuine” type errors need not be reported particularly if the person involved appeared to have insight into the error. Regarding serious errors, GPs had the highest threshold for reporting as they felt that it was so difficult to replace people who may be dismissed. Nobody said that they would report near misses and the participants made the point that dealing with reported errors was easier than challenging professionals about personal behaviours or attitudes. Participants universally accepted the need for errors to be locally discussed anonymously and nurses and junior doctors felt they had a greater need to record things that had gone wrong in order to protect themselves. Barriers to reporting poor care included a lack of clarity about what to report, difficulty in reporting those more senior because of the need to maintain professional relationships and the time taken to fill out the reports. A number of themes emerged around culture including juniors’ fears that they would not be supported following an error; medical and senior nursing beliefs that “good” professionals would be punished; and the difficulty of anonymity in the NHS. The nurses also reported that there was a particular medical culture issue which meant it was difficult to challenge doctors as medical staff do not always follow strict rules and tend to rely more on clinical judgement.
Finally senior doctors and nurses in particular felt that the fact that “nothing ever changes” after an error was a serious barrier to why people did not bother to report.

Kingston and Evans conducted a study in Australia in 2002 investigating the attitudes of medical and nursing staff towards reporting incidents using uni-disciplinary focus groups with a purposive sample of 14 doctors and 19 nurses from Australian tertiary referral hospitals. The nurses but not the doctors seemed to report out of habit as per hospital directives e.g. reporting medication errors and falls and to cover themselves if something had gone wrong. The doctors had a preference for keeping incidents “in house” stating that professional loyalty was important and that whistle blowing was unethical and unsupportive. Emotionally both groups felt a distrust of the reporting system surrounding data security and had concerns about the likely punitive and medico-legal implications of reporting. Both groups could see the potential benefit of identifying problems and improving patient care if positive change followed incidents, but reported that this did not currently happen.

Jeffe et al used nine focus groups with doctors and nurses who worked across different specialties, and in different types of hospitals, across the United States in 2002 to understand perspectives on error reporting. 60 30 doctors and 49 nurses / nurse managers were recruited using convenience sampling and the groups were uni-disciplinary. Six barriers to reporting were established and not knowing what to report was a major issue for both doctors and nurses. Both types of health professionals said that they were aware that serious harm errors should be reported but that they were unlikely to report low risk errors. The likelihood of reoccurrence was also considered to be an important factor when deciding to report. Not knowing how to report appeared to be more of an issue for the medical staff, who said that they were not “trained like the nurses”. The fear of repercussions was also identified as a barrier with nurses concerned about being told off by doctors or nurse managers. The lack of confidentiality was noted by all and doctors feared medical malpractice or a “besmirched” personal record, whilst staff shortages, work demands and the lack of a simple reporting form were identified as time efficiency barriers. Doctors said they wanted to spend only two minutes reporting whilst nurse managers felt that up to 10 minutes was a reasonable time to report an incident electronically. The lack of feedback was identified as one of the most frustrating barriers, though nurses realised that this may take time if root cause analysis was needed. Participants discussed the educational needs for reporting and admitted that sometimes
reporting was needed for self protection. Suggestions for improved reporting revolved around anonymous reporting on simple forms with critical feedback, perhaps delivered by practice educators or pharmacists. Doctors wanted feedback to only be pertinent to their practice.

Taylor et al randomly selected 100 nurses and 100 physicians (residents and faculty members) at a large children’s hospital in the US (post 2000) to participate in a survey exploring attitudes and experiences of the incident reporting system for medical errors. 74 physicians (81% senior) and 66 nurses completed the survey giving a response rate of 70%. Participants were asked about their use of the current reporting system, about reasons for underreporting and to give suggestions for improving reporting. A selection of clinical scenarios was presented and participants were asked how likely they were to report them, using a six point Likert scale (1=very likely, 6=very unlikely). Nurses were statistically more likely to have used the reporting system with 63.6% reporting two to five reports in the last 12 months, compared with 21.6% of physicians. Similarly 45.9% of physicians compared with 10.5% of nurses had not reported any errors on the system in the last 12 months. More than half of the nurses (56.9%) indicated that they reported more than 80% of their own errors whilst 52.2% of physicians indicated that they reported less than 20% of theirs.

When asked to indicate applicable potential barriers to reporting medical errors 40.7% of all participants agreed they were unsure what was considered to be a medical error and 37% agreed that they were concerned about implicating others. Around a quarter of respondents also agreed that it was not important to report errors that did not reach the patient and that they were unsure whose responsibility it was to report errors, this being statistically higher for doctors than nurses (34% versus 12.7%). No direct statement considered the fear of litigation and none of the 47 respondents who wrote additional reasons for underreporting commented about the risk of possible litigation.

When asked about potential improvements to increase reporting more than 50% indicated that better education about what constituted an error, more feedback about reported errors and evidence that reporting led to systems changes would lead to better reporting. The use of electronic reporting to increase reporting was supported by 44.9% of respondents but only 21.3% supported the idea that making reporting mandatory would increase reporting. 20% of respondents thought that a confidential reporting system, where supervisory staff were not directly informed, would increase their likelihood of reporting errors and 30.7% thought that an anonymous reporting system would increase their reporting.
For the nine clinical scenarios nurses were significantly more likely to report all but two of the scenarios and all respondents were more likely to report serious rather than trivial errors, and those that had happened rather than those that were near misses. 99.3% of respondents indicated they would be likely or very likely to report a tenfold morphine dosing error that had happened but only around a third of respondents said they were likely or very likely to report a near miss regarding the wrong route of administration for a drug or a missed drug allergy.

Wild et al surveyed 84 health professionals (24 junior doctors, 60 nurses) in one community hospital in the US regarding the hospital’s error reporting system. Fewer doctors knew anything about the reporting system than nurses (54% versus 97% p=0.001) and less doctors had ever used the system (13% versus 22% p=0.001). Doctors were also more likely to rate the hospital atmosphere as non-supportive of error reporting (38% versus 0% p=0.001).

Evans et al studied attitudes and barriers to hospital incident reporting in Australia during 2001-03 using an anonymous cross sectional survey. In total 186 medical and 587 nursing staff were recruited through personal approaches from metropolitan and rural hospitals across different specialities. Presented with 11 types of incident, including medication errors, falls, hospital acquired infection, incorrect treatment and breach of confidentiality participants were then asked how often they reported such examples, and how often they thought they should be reported, using a 4 point Likert scale (1=never, 2=<50% of occasions, 3=>50% of occasions, 4=always). The correlation between what professionals did compared with what they thought was assessed using intra-class correlation coefficients (ICC). Both professional groups reported they completed incident forms most often for patient falls and least often for pressure sores. For drug errors in particular the percentage of staff who would report depended on whether the patient received the treatment and if they needed corrective treatment. 100% of nurses but only about 35% of doctors said they always reported drug errors requiring corrective treatment but more than 90% of nurses and about 70% of doctors said that they should report them. These percentages fell when no corrective treatment was required and fell to around 15% for both professional groups who reported drug errors which were not given to the patient. Agreement between what professionals did and what they thought was only reported for certain types of incidents but varied for doctors from between an ICC of 0.44 for incidents where patients received wrong treatment generally to an ICC of 0.17 for pressure sores.
For nurses the ICC ranged from 0.78 for patient falls to 0.27 for deep vein thrombosis due to inadequate prophylaxis. (No ICCs were given for drug treatment scenarios) Junior doctors seemed more likely than senior ones to always report wrong treatment or procedure (54.1% versus 39.5%; RR 0.73 [95% CI .63 to .84]). There appeared to be no significant difference for doctors or nurses according to whether they worked in metropolitan or rural hospitals. Finally participants were asked to rate on a five point Likert scale potential reasons for not reporting incidents (one=strongly agree, five=strongly disagree). More than 50% of doctors agreed that a lack of feedback, the incident was too trivial or that the incident form took too long to complete were barriers to reporting incidents. 20.7% perceived litigation worries and 8.3% disciplinary worries as possible barriers to reporting. For nurses the lack of feedback (61.8%), no point in reporting near misses and forgetting to report when the ward was busy were the major barriers reported. More than 40% also agreed with doctors that the length taken to fill out an incident form and an incident being too trivial were barriers to not reporting. Fears about litigation were identified by a similar proportion to doctors (20.6%) but fears about disciplinary procedures were identified by more nurses (18.1%). There were no significant differences for any barriers according to experience or rural/metropolitan location.

Wilson et al aimed to develop a validated measure of health professionals’ attitudes towards Clinical Adverse Event Reporting (CAER). Nurses/midwives and doctors undergoing postgraduate training at three universities in the UK were asked to voluntarily participate in 2003. A 73 item questionnaire assessed behaviour to reporting adverse events and attitudes using a four point Likert scale (1=strongly agree, 4= strongly disagree). 201 health professionals anonymously completed the questionnaire (61% nurses/midwives, 37% doctors) and the mean years since qualification was 14 (SD 7.5). 85% of respondents said they had witnessed an adverse event, with no significant difference between nurses/midwives and doctors, and the majority (89%) said they had also reported it. Nurses/midwives were statistically more likely to report than doctors (95% versus 80% p=0.001). A second smaller questionnaire was distributed six weeks later to 102 participants to evaluate test retest reliability and this was returned by 37% of the original 201 participants (60% nurses).

Through factor analysis and removal of redundant items only 25 statements were included in the second questionnaire with five broad dimensions: blame as a consequence of reporting, criteria for reporting, colleagues’ expectations, perceived benefits and clarity of
reporting procedures. These were tested for internal and external reliability with retest reliability moderate (Spearman’s correlation 0.65).

On both questionnaires nurses/midwives were found to have a more positive attitude towards reporting than doctors, in all five dimensions (p< .05). The authors hypothesised that their validated questionnaire could be used in the training and assessment of NHS staff regarding culture and behaviour of adverse event reporting.

Wu et al studied a technology acceptance model to investigate different health professionals’ intentions to use an adverse event reporting system in Taiwan after 2004.65 Questionnaires were sent using snowball, and then convenience sampling, technique to 940 health professionals in 144 hospitals in Taiwan who were actually or partially implementing the National web-based voluntary reporting system. The 290 returned questionnaires (31% return rate) represented 49% nurses and 30% non health professionals (i.e. administrative and IT) with the remainder made up of pharmacists and doctors. The sample was 81% female reflecting the female nursing culture in Taiwan. Respondents were asked to record, using a five point Likert scale (-2=strongly disagree, -1=disagree, 0=uncertain, 1=agree, 2=strongly agree), their perception of each variable in a technology acceptance model based on the theory of reasoned action.66

In this model acceptance was based on perceived usefulness (PU) i.e. the degree to which a person thought that using the system would enhance their job performance, perceived ease (PE) i.e. system free from effort, attitude towards using , behavioural intention to use , and actual system use:

-Perceived usefulness questions included: using the system would be helpful for medical quality, would allow me to learn from my mistakes and would improve my performance.
-Perceived ease-of-use questions included: learning the system is easy, operating the system is not hard, it would be easy for me to become skilful at using the system.
Trust questions included: I feel assured that legal structures protect me from problems and I feel comfortable using the reporting system.
-Intention to use questions included: When I encounter an accident due to my, or another’s mistake I would report it and I intend to use the system as often as needed.
-Subjective norm questions included: My boss or my colleagues or my subordinates think I should use the system.
-Management support questions included: Management are aware of the benefits of the system, management support / encourages the use of the system and management is really keen to see that people are happy using the system.
The questions were analyzed using structural equation modelling and assessed for reliability using composite reliability and average variances. Perceived usefulness had a significant effect on the behavioural intention of respondents to use the reporting system. Perceived ease of use had a direct effect on behavioural intention and perceived usefulness suggesting that health professionals’ perception of usefulness and ease of use of the reporting system are important factors dictating whether a health professional is prepared to use a reporting system or not. In addition this perception of the ease of use influenced the professionals’ perception of usefulness of the reporting system. Subjective norm (i.e. the influence of others) made the biggest contribution to intention to use implying that it was the most important factor for success of the system, but this could reflect Taiwanese culture.

Perceived usefulness, perceived ease of use, subjective norm and trust all had a significant effect on the intention of individuals to use the reporting system. Perceived ease of use and subjective norm both had a direct effect on perceived usefulness and trust respectively. Management support had a direct effect on perceived usefulness, perceived ease of use and subjective norm and suggests management support is important to produce an environment where staff do not fear punishment. The authors conclude that however supportive an environment exists to report, you cannot overcome the barriers of time and energy as reporting incidents is not an integral part of patient care and so health professionals will not be naturally motivated to always use it.

Kreckler et al investigated factors influencing surgical staff reporting incidents in a UK hospital in 2007. A questionnaire based on the Vincent and Evans studies was completed exclusively online by 55 doctors and 83 nurses. The overall response rate was 67.5% with a good distribution of different grades of staff. (26% ward sisters and 33% consultants) Doctors were significantly less likely to have ever filled in a form compared with nurses (15% versus 65%) and 69% of doctors had not completed any incident reports. 45% of nurses had completed two to four incidents in the preceding year. Doctors were also significantly less likely to know where to find an incident report form (43% versus 19%). Respondents were presented with three clinical scenarios including a patient fall, a patient with a documented penicillin allergy and a patient not cross matched for blood before an operation. Each of the three questions was then randomly presented with three different outcomes, including harm, no harm or harm prevented. Participants were asked to indicate how likely they were to report the incidents on a four point Likert scale (always, more than 50% of the time, less than 50% of the time or never).
Health professionals were most likely to report an error where harm occurred. For the allergy incident 88% of nurses and 84% of doctors said they would always report if harm had occurred (55% and 27% if no harm and 21% and 11% respectively for a near miss). Nurses were nearly three times more likely to always report no harm incidents compared with doctors and both professionals claimed the allergic reaction incidents were likely to be reported more frequently than both the fall and the blood incidents.

Participants were also asked how often they would report five surgical complications including DVT, postoperative wound infection and pressure sores and overall they were less likely to report than the three main clinical scenarios. Respondents were asked to rate the importance of barriers to reporting incidents on a five point Likert scale (1=strongly agree, 5 = strongly disagree). 47% of doctors and 29% of nurses agreed or strongly agreed that they were too busy to fill out forms with 51% and 29% respectively agreeing or strongly agreeing that the form took too long to complete. Only 15% of doctors and 11% of nurses agreed or strongly agreed about litigation fears and 9% & 8% respectively feared incidents being discussed in meetings. 69% of doctors and 38% of nurses reported that they never received any feedback about incidents and 43% of doctors and 20% of nurses reported that they were unlikely to complete an incident form because it made little contribution to the quality of patient care. 74% of doctors and 30% of nurses agreed or strongly agreed that they were not sure what types of incident to report with 77% and 35% respectively stating that they did not report because the incident was too trivial or that the incident did not result in any harm (54% of doctors and 23% nurses).

Overall doctors were more likely to agree with any of the barriers compared with nurses but the barriers of fear were significantly less important for both staff groups than the other barriers. The authors thought that staff may be slightly reluctant to report incidents where human error is likely to be blamed e.g. a medication error, compared with an incident such as a fall when nobody might be held directly responsible.

The results regarding barriers to reporting confirmed that the problem was multifactorial and were interesting because the fear factors seemed to be significantly less than in the studies carried out in the past, which may indicate an improving culture of acceptance of errors and the need to report them since the start of the century.

Conclusions

Nurses and midwives are clearly better informed about error reporting and less negative than doctors about the barriers to reporting, with all obstetric health professionals wholly
supportive of the process. All health professionals seem more likely to report serious errors than those causing minor or no harm. The lack of positive feedback and the practical time / workload issues of reporting are consistently acknowledged as major barriers and although reporting fears are cited in smaller qualitative studies less than one fifth of health professionals identified litigation and disciplinary fears in the largest quantitative study.  

1.5.2 Health Professionals’ attitudes to reporting medication errors

Coley et al performed focus groups to study perceived barriers of a regional wide medication error reporting system in one region in the United States post 2000. Theoretical sampling was used to target individuals in hospitals actively involved with the national database for medication errors (MEDMARX). 14 participants from 17 hospitals were invited to take part with 8 agreeing (equal split between teaching/non-teaching and urban/suburban settings). Two focus groups were held for six participants and two participants had one-to-one telephone interviews. It was unclear what types of staff were involved exactly e.g. pharmacists, technicians or others. One part of the focus group was actually about the collection of medication error data and groups identified inadequate staffing as a major barrier to reporting due to the time-consuming nature of confirming medication errors and then collecting the relevant details. Some hospitals had dedicated staff to aid the reporting process but few agreed that they had sufficient staff for this. There was great variation in the process for the identification of medication errors with most hospitals only having paper patient records, with details then being re-entered onto databases for internal purposes as well as the MEDMARX system. Suggestions for improving reporting rates included dedicated medication safety managers or increasing the use of pharmacy technicians.

Sanghera et al used semi structured interviews to assess the attitudes of health professionals to the reporting of medication errors in an intensive care unit in the UK hospital between 2003 and 2004. Barriers reported from the purposive sample of 13 (eight nurses, five doctors) included not being aware of an error, the process of reporting being too difficult, the fact that no benefits are seen, and fears of reporting (disciplinary /litigation). Interestingly overseas qualified staff raised cultural differences as they stated the culture of reporting others seemed “strange”. The perceived benefits of reporting mentioned were improving or reflection on practice, learning from mistakes and preventing future errors, accountability and reduced chance of litigation.
Handler et al utilized the nominal group technique to establish modifiable barriers to medication error reporting in four independent non-profit nursing homes in the United States in 2005. Four sessions took place involving 28 participants (physicians, pharmacists, nurses and advanced practitioners). In each of the sessions an average of 19.3 barriers to reporting were identified (range 12 to 26). The barriers identified were used to create a 20 item questionnaire following the same methodology as Uribe et al. 104 surveys (67.5% response rate) were returned by nursing home health professionals with 75% of all the questionnaires from nurses, with a majority of female full-time employees. Participants were asked to use a five point Likert scale to rate how likely they thought each factor would act as a barrier to medication error reporting (1= very likely, 5=very unlikely). Participants were also asked to indicate how modifiable each factor was (1=very modifiable, 5=not modifiable). A least-squares mean for both the likelihood and modifiability rating was calculated for each question in the survey and 14 factors had mean scores of < 3 on both the likelihood and modifiability scales. Barriers were classified as being at an individual or organisational level and the lack of feedback, lack of knowledge about when errors occurred and needed reporting, lack of available reporting form and the extra time involved in reporting were identified as the most likely barriers to reporting (mean scores for between 2.42[SE 0.13] and 2.69 [SE 0.24]).

The three factors considered being most modifiable, and in line with most likely barriers, were a lack of any usable reporting system, a lack of information on how to report medication error and lack of feedback to the reporter and healthcare organisation. Other barriers included the time involved in documenting errors and fears of blame / disciplinary action.

The questionnaire results contrasted with the original Uribe study, which was about medical errors in general, where the most likely barriers to reporting were time taken, extra work reporting, not anonymous, hesitancy about telling on someone else, fear of lawsuits and unnecessary reporting due to no negative outcome for patient.

Sarvadikar et al surveyed 56 health professionals in one large UK hospital (32% doctors, 39% nurses, 29% pharmacists) regarding two medication error scenarios with four different patient outcomes, ranging from a near miss to a fatality. Participants were asked to use a five point Likert scale (one = unlikely, five = likely) to indicate their likelihood of reporting the error and the perceived likelihood of; blame/criticism, disciplinary action and job dismissal if they had been the health professional involved in the error. Doctors were only likely to report if the patient harm was serious whilst
pharmacists and then nurses were most likely to report all errors. The nurses, followed by pharmacists, were more likely than their medical colleagues to think that they would be blamed or disciplined for involvement in a medication error, with such fears increasing for all health professionals the greater the patient harm. Fears of job dismissal were only expressed when the medication error outcome was fatal. The authors suggested that healthcare organisations needed to consider different approaches for different health professionals to encourage medication error reporting.

Conclusions
Despite the contrast between groups a lack of awareness about medication error reporting, the time involved in their collection, the absence of feedback and the fears of reporting have all been identified as barriers to reporting medication errors by doctors, nurses and pharmacy staff. Doctors appear less likely than nurses or pharmacists to report medication errors or be concerned about blame or disciplinary consequences, if personally involved in the medication error.

1.6 Conclusions about the reporting of errors by Health Professionals

1.6.1 Hypothetical versus actual reporting of errors

The literature illustrates the difference between what incidents healthcare professionals think they should, and would, hypothetically or actually report. 70 to 90% of nurses said they knew which medication errors should be reported but estimates of whether medication errors would be reported varied widely between 5.3 -67%. Nurses are more likely to report a witnessed error and have a more positive attitude to reporting than doctors dealing with adult and paediatric patients. Nurses admit they tend to report out of habit, to cover themselves, whilst doctors appear to keep things “in-house” due to feelings of loyalty to colleagues.

The type of incident also dictates likely reporting with 70% of doctors and more than 90% of nurses suggesting they should report all errors that needed corrective action. However 35% of those doctors and 100% of those nurses said they would always report such errors, falling to only 15% if the errors did not reach the patient i.e. near miss. Similarly 26-57.9% of nurses reported that they do not need to report medication errors if it was a near miss or if the error is not serious enough with 54-77% of doctors disclosing they did not report no harm or trivial errors.
Two studies using the same methodology for nurses, midwives and doctors, and later community pharmacists found that pharmacists and doctors were very unlikely to report incidents even if the patient had a bad outcome or if the error involved violation of a protocol. Only nurses and midwives appeared moderately likely to report for bad patient outcomes or protocol violations. Hospital pharmacists also admit that they do not report near miss medication dispensing errors that do not leave the department.

The likelihood of study participants claiming they would report an error varied greatly depending on the severity of the examples given e.g. 1. 15% of nurses for a patient 1 hour late with an antibiotic compared with 100% of nurses for a beta-blocker given to the wrong patient. 2. 99.3% of paediatric doctors and nurses for a tenfold morphine dosing error that has happened falling to 31.7% for a near miss regarding the wrong route of administration for a drug.

1.6.2 Knowledge of which errors should be reported

The controversy around what constitutes an error that needs to be reported has been explored further with both nurses and hospital pharmacists. Nurses may re-define the error so that if they can make it feel like a “non-error” that can be easily rectified then they will not report it and admit they do not report if they can “get away with it”. Hospital pharmacists have admitted that they may make a conscious decision whether to formally report an incident via the hospital reporting system or document the incident as a “pharmacy intervention” as it affects their annual appraisal. Doctors also seem uncertain about which errors to report, varying from 4.5–60.5% and are more unaware about their own organisation’s reporting systems than nurses.

1.6.3 Barriers to reporting errors

In all, the quantitative studies involving nurses and medication errors (pre-and post-2000) the most important barriers to reporting appear to be personal fear (litigation/disciplinary) and concern about inadequate management response/change. The only qualitative study adds the interesting concept that “if you can get away with it” may be a barrier to reporting.

In the small qualitative studies involving doctors or mixed health professional groups post-2000 barriers to reporting were also fears/distrust of the reporting
scheme due to concerns about management’s, and even society’s unfair blame culture, and a dislike of “whistle blowing” on colleagues, coupled with the belief that positive change is rarely seen after investigation of an error. General practitioners in the UK appear to have a high reporting threshold due to fear of colleagues’ dismissal and subsequent difficulty in recruiting new staff 58 and UK hospital clinicians have major concerns about the unnecessary personal damage of litigation.55 Community pharmacists also highlighted the apprehension about reporting systems and the fear of repercussions for the perpetrator as reasons for not reporting. 51,52

Doctors also believe that errors are inevitable as doctors need to use clinical judgment and discretion rather than the more rigid patient care decisions made by nursing staff 42,43 but they do believe that reporting is important to prevent further errors, improve practice and to ease litigation worries.40,46,59,69 Both the qualitative studies 55,60,68,70 and the quantitative studies 57,63,67 in mixed health professional groups identified time and the extra work involved in completing forms as a significant barriers to reporting, especially the unnecessary effort if the error was trivial.63 These time and effort issues involved in reporting errors are similar to the barriers identified by doctors to the voluntary reporting of adverse drug reaction reporting schemes72 and Wu and colleagues, evaluating a national web based reporting system, believe that however supportive an environment exists to report, you cannot overcome the barriers of time and energy as reporting incidents is not an integral part of patient care and so health professionals will not be naturally motivated to always do it.65

1.6.4 Effect of health professionals’ experience, culture or area of work on reporting

None of the primary literature showed any significant differences in reporting rates or in barriers to reporting between professionals from different working environments e.g. rural versus metropolitan, educational backgrounds or personal demographics e.g. age, sex. Obstetric health professionals appear to be very comfortable with reporting and are supportive of reporting schemes due to positive changes in services and possible high levels of litigation in that field43,46 and anaesthetists also seem to be more comfortable with reporting systems compared with their surgical and medical colleagues.41,43 Three studies, 1 carried out in the UK 69, 1 in Taiwan24 and 1 in Turkey 31 highlight the possibility of cultural differences regarding nurses’ fears of reporting.

The issue about the seniority of healthcare professionals reporting appears equivocal. Vincent et al found that overall junior midwives and doctors were more likely to report
errors than senior staff. Junior midwives were less likely to know what should be reported and junior doctors worried most about the time taken to report, whereas senior doctors worried most about litigation. Other studies published have shown that older nurses admit reporting significantly fewer errors and that nurses in supervisory roles were more likely to cite “disagreement if a medication error had occurred” and the effort required to report, rather than the administrative response when compared with staff nurses on their units. A much larger quantitative study agreed that senior doctors were less likely to report but found that senior nurses were more likely to report than their junior colleagues whilst another study reported that junior doctors were more worried about disciplinary action than seniors.

The presence of a quality management/improvement process in a hospital department has been reported as negatively associated with reasons for not reporting and positively associated with a level of reporting and greater barriers to reporting by doctors was associated with worse hospital safety culture scores.

1.6.5 How to improve reporting

Some studies have reported that there is a link between less error reporting and greater perceived barriers to reporting and so possible ways, identified in these studies, to increase the reporting of errors were simpler forms, including electronic reporting, clarification of what and how to report and positive feedback. There was also support for a dedicated medication safety manager and feedback by pharmacists. Support for anonymous reporting as a means to increase reporting was supported by community pharmacists but varied between 42-80% of doctors.

1.6.6 Overall conclusions

In summary the attitudes of health professionals, across a wide range of specialties (including medicine, surgery, paediatrics, intensive care and in nursing homes) to reporting incidents appear to be driven by negative attitudes about why don’t report (barriers) as opposed to positive attitudes about why should report (benefits), with the possible exception of obstetricians and midwives.

The barriers to incident reporting by all healthcare professionals appear to be fourfold: (adapted from Wakefield)
1. Knowledge (what and when to report)
2. Effort (simplicity of reporting form)
3. Fears (personal)
4. Outcomes (perceived lack of feedback and positive change)

Personal fears and the lack of positive change after an incident seem to be the greatest barriers for all health professionals. There is no consistent difference between studies conducted before and after the publication of reports highlighting that it was good to admit to making errors and to report for the benefit of patients (i.e. pre and post 2000), but the two most recently published surveys in surgical staff do appear to show fear factors as being less prominent.\textsuperscript{37,67}

1.6.7 Relevance to research study

With only three published studies exploring pharmacists’ attitudes to reporting medication errors there is clearly a research need to gain further insight into pharmacists’ attitudes. Pharmacists as “medicines experts” probably have a unique view on reporting medication errors but it remains to be seen if their attitudes/barriers to reporting resonate with those identified in the literature for other healthcare professionals. The literature does suggest that different health professionals do have different attitudes e.g. obstetric staff appear culturally happier to report errors than other types of health professionals and nurses seem more likely to report errors than doctors, so this research study is necessary to substantially improve the knowledge base about hospital pharmacists in this internationally important subject.

In addition the question of whether seniority affects attitudes to reporting also needs to be included in the research as the results for nurses and/or doctors are inconsistent.
Aims and Objectives

Aim of the study: To determine the attitudes of hospital pharmacists in the north-west NHS region of England to reporting medication errors and identify barriers and drivers to reporting.

Objectives of the study:

a) To use qualitative focus group discussions with hospital pharmacists to identify the attitudes and barriers to reporting medication errors

b) To develop a questionnaire survey, based on the results of the qualitative data, to distribute to hospital pharmacists to explore their attitudes to reporting medication errors

c) To consider how under reporting of medication errors by hospital pharmacists might be reduced, through psychological or technological interventions, organisational or national policy changes
Chapter 2 : Research Methods

2.1 Introduction

Morgan’s paper on mixed research methods emphasises that “although the broad belief is that qualitative research relies on an inductive/subjective/contextual approach and that quantitative research relies on a deductive/objective/generalising approach they are neither absolute nor mutually exclusive”. Further, Bryman warns researchers against thinking about quantitative research as merely focusing on “behaviours” and qualitative research as just focusing on “means” as quantitative surveys often use attitude scales to try to understand meanings and qualitative techniques try to interpret behaviour within the norms, value and culture of a group. He describes a classic study about racial prejudice in the US in 1934 by La Piere to illustrate why relying on quantitative surveys about attitudes may not give you the same answer as observational methods, as there can be a stark difference between what people do and what they say they would do.

In other words there was thought to be benefit from considering the use of both qualitative and quantitative research methods to assess the attitudes of hospital pharmacists to reporting medication errors and the two different methodologies, and their individual merits, are detailed below.

2.2 Qualitative methodology

2.2.1 Introduction

Pope and Mays explain that “the goal of qualitative research is the development of concepts which help us to understand social phenomena in natural (rather than experimental) settings, giving due emphasis to the meanings, experiences and views of all the participants”. At the most basic level qualitative research tries to answer the question “what is X and how does X vary in different circumstances and why?” rather than the quantitative question of “how many Xs are there?”. This resonates with the idea of trying to establish why pharmacists do or do not report medication errors as it would allow opportunities to explore “how people really behave and what people actually mean when they describe their experiences, attitudes and behaviours”. Bryman and Burgess encourage the qualitative researcher to not have any preconceptions or hypotheses before data collection and "not to separate the stages of design, data collection and analysis, but to go
backwards and forwards between the raw data and the process of conceptualisation, thereby making sense of the data throughout the period of data collection”. 77
Ritchie and Spencer describe four broad categories of questions that need to be addressed through qualitative research78 and the question regarding attitudes of hospital pharmacists to reporting medication errors fit well with all these:
Contextual: identifying the form and nature of what exists e.g. what are the dimensions of attitudes or perceptions held by individuals
Diagnostic: examining the reasons for, or causes of, what exists e.g. what factors underlie individuals' particular attitudes
Evaluate: appraising the effectiveness of what exists e.g. what affects the successful delivery of a service, what barriers exist to systems working
Strategic: identifying new theories, policies, plans or actions e.g. what actions, systems need to be improved to make services more effective.

In qualitative research, there are a large number of different theories and techniques that could be used to research a particular topic, which can complement each other by considering different angles on a subject matter that may be very complex e.g. culture79 but can also be useful when dealing with a research question where minimal information exists.80

2.2.2 Observation

McCall asserts that, compared with interviews and questionnaires, observational methods provide more reliable information and greater detail about the timing, duration and frequency of events.81 Considering that the decision by a healthcare professional to report, or not report, errors is a complex decision, and there is a clear difference between what they say they should and actually do report.28,31,33 Observational methods appeared an attractive option. However observation is extremely time-consuming, subject to the possibility of a significant Hawthorne effect82, and most importantly does not allow researchers to get to the intentions behind any behaviour, as it is not possible to observe the decision-making process that is occurring in a person's mind.
2.2.3 In-depth Interviews

According to Ritchie and Lewis in-depth interviews allow “undiluted focus on an individual person” to understand their personal perspective in significant depth\(^\text{83}\) and semi-structured and telephone interviews have been used to explore the deep rooted and complicated issue of health professionals attitudes to reporting errors.\(^{43,69}\) The flexibility of using open and closed questions, with appropriate probing of an individual regarding sensitive issues, would be an advantage however the number of interviews needed would have been very time-consuming and impractical for a part-time researcher. One to one interviews are also at risk of reactive measurement effects, where the interviewee seeks to impress the interviewer by saying things that they believe the interviewer wishes to hear.\(^{84}\)

2.2.4 Consensus methods

Two studies considering the attitudes of health professionals to error reporting have used the nominal group technique to identify the most likely barriers and then ranked the most modifiable ones.\(^{57,70}\) The aim of consensus methods, such as the nominal group technique, is to generate and then to prioritise ideas by establishing how much “experts” agree or disagree about a single given issue.\(^{85}\) The technique is very structured, using a silent process for eliciting ideas about the stated issue and then anonymous voting for the most important, which is actually a good way of negating individuals with strong views from affecting the outcome. Though a valid methodology, the nominal group technique is really intended to identify a consensus on a well understood topic. There is less spontaneity and synergy between participants than in a focus group, which means that findings are likely to be less in-depth\(^{86}\), possibly not getting to the root of why something may act as a barrier. On a practical level the use of the nominal group technique requires commitment from group members and in particular would have involved expecting participants from different hospitals to travel to one central venue. It would also have meant that the influence of any individual hospital’s culture regarding attitudes to reporting errors might be lost.
2.2.5 Focus groups

Kitzinger asserts that focus groups “reach the parts that other methods cannot reach, revealing dimensions of understanding that often remain untapped by more conventional data collection techniques” and explains that they help identify not only what people think, but how they think and why they think that way. In particular she champions the group interaction and dynamics between participants in focus groups giving seven aims that should help enrich the information gathering.

1. Highlight the respondents’ attitudes, priorities, language and framework of understanding
2. Encourage research participants to generate and explore their own questions and develop their own analysis of common experiences
3. Encourage a variety of communication from participants, tapping into a wider range and form of understanding
4. Help to identify group norms and cultural values
5. Provide insight into the operation of group social processes in the articulation of knowledge (for example, through the examination of what information is censured or muted within the group)
6. Encourage open conversation about embarrassing subjects and to permit the expression of criticism
7. Facilitate the expression of ideas and experiences that might be left underdeveloped in an interview and to illuminate the research participants’ perspectives through the debate within the group

Focus groups are more naturalistic than one-to-one interviews allowing all participants to continually reflect on their own attitudes in light of what might be said during the discussions. The possibility of reactive effects are also less than with one-to-one interviews as “participants interview each other and the researcher just listens”. Therefore the biggest and most important issues are therefore more likely to come across as the participant interaction and exchange of viewpoints almost act as filtering method. The origins of focus groups are within market research but they are now widely utilised to explore attitudes of health professionals regarding safety culture and patient or patient and health professional beliefs about health matters and were therefore considered to be the qualitative research method of choice for this study.
2.3 Focus Group Methodology

2.3.1 Study setting

Study sites are usually selected so that participants reflect the range of the population being researched. There was therefore a desire to include both small, large and district, teaching hospitals to reflect the mixture of hospital pharmacy departments in England, which are all expected to voluntarily report medication errors to the National Reporting Learning System (NRLS), via their own internal reporting system.

The Northwest NHS region of England includes 29 hospital trusts (excluding mental health trusts) with a mix of small and large, district or teaching, and specialist hospitals e.g. paediatrics, cancer and so for geographical ease and to simplify ethics and research and development approvals, this area was chosen as the setting for this study.

2.3.2 Sampling

The literature considering other health professionals’ attitudes to reporting errors is complex and diverse with differences in opinions possibly depending on cultural issues such as the fear of litigation in obstetric units.53,54

One study undertaken in NHS Northwest pharmacy departments explored the attitudes of pharmacy staff to patient safety, assessed using a safety culture questionnaire.91 The questionnaire, a modified version of a survey used for the assessment of patient safety culture in hospitals in the United States of America39, consisted of forty questions, with a five point Likert scale, and focussed on employee perception of department safety ethos & systems, communication and feedback about errors. Respondents were asked whether there were any existing patient safety problems in their department and whether systems and procedures were good at preventing errors. Respondents were also asked whether staff worried that mistakes were kept on personal files and if they received feedback about errors or had seen positive change after an error had been reported. There was great variation in the responses between the different hospitals and though the setting of the hospital and the number and type of respondents may be relevant it was thought that an individual department’s unique safety culture may, in part, have shaped respondents’ views and may in part have explained the differences between the hospitals.

Purposive sampling allows researchers to actively include participants who might be at different ends of the spectrum with regard to the subject matter.92 So for this study the
proposal was to purposively invite different size and types of hospitals whose pharmacy staff had scored them positively, neutrally and negatively in the safety culture survey, rather than using a pure convenience sample or a more random sampling technique. Focus group size and numbers are not considered to be critical and interviews should continue until no new information is presented, described as “data saturation”. Smith states that five to seven participants is considered to be the optimum number but warns that although a larger group may include a wider range of views it can also restrict the depth of any discussion or the number of active participants.93 In contrast Lederman contends that a “safety in numbers” factor may actually encourage participants in a focus group more so than being interviewed on a one-to-one basis.94

2.3.3 Recruitment

Clinical pharmacy service managers from four hospitals (two teaching and one small and one large district general) in the Northwest Clinical Pharmacy Forum, whose pharmacy staff had scored them positively, neutrally and negatively in the safety culture survey were approached by telephone, followed up with an email, to ascertain if they would be prepared for pharmacists in their department to be invited to participate. Chief pharmacists and the hospitals’ Research and Development departments were then contacted to gain full approval for the study. Bryman explains that there are two schools of thought about using natural groups of participants, who know each other, or participants who are unknown to each other in focus groups.74 Either the pre-existing relationships or conflicts of status within the group may contaminate the focus group dynamic or the more natural interactions will improve the dynamic of the group. Hospital pharmacists would be expected to be familiar with discussing matters with departmental colleagues and it was believed that it would be more helpful to increase the cultural diversity of views and to promote greater discussion by inviting pharmacists to attend a focus group at their own hospital site. Rice and Ezzy argue that focus group participants from similar backgrounds are more comfortable talking to one another and more likely to open up during group discussions.95

Once full approval had been granted the clinical pharmacy services managers were then asked to email the invitation letter (Appendix 1) and information sheet (Appendix 2) to all pharmacists in their departments, with the aim of recruiting one pharmacist from each
NHS Agenda for Change bands (6, 7, 8a, 8b-d), and up to a maximum of seven pharmacists.

2.3.4 The interview schedule

After a personal introduction participants in the focus groups were asked to complete their consent forms and to then state their current job title with grading and how long they had been qualified as a pharmacist. A table plan was made so that when listening to the audiotapes the researcher would be able to confirm that particular comments of a participant had been correctly attributed. This was considered to be important in case a key view was misrepresented as being from a junior pharmacist rather than a senior one or vice versa.

To assist with the interview process, and to try to reduce moderator bias, an interview schedule for the focus groups was designed (Appendix 3) from an understanding of attitudes and barriers to reporting incidents elucidated from the literature review (chapter 1).

The schedule was intended to help provide a loose structure for the focus group interview, and in conjunction with open questioning, the plan was to stimulate participant interaction and debate. As the effectiveness of focus groups can be reduced by poor moderation, individual participants were nurtured so that all views were considered and those who spoke the loudest did not take over the group\(^96\) and those who realised that they had a minority view were not disinclined to speak up.\(^97\)

Initially participants were asked for their broad views about medication incident reporting and to describe systems that existed in their hospitals. The aim was to make the participants comfortable, and for the moderator to discover how things currently worked at that hospital, and to find out any problems associated with their reporting system. Specific issues, including understanding of when and what medication errors to report and perceived benefits and barriers to reporting, were then explored. If respondents were not forthcoming in their views, prompts were used to discover if pharmacists had any fears of reporting. In addition they were asked specifically if they could name any positive changes that had occurred following a medication error incident, as according to the literature this appears to be one of the greatest barriers to health professionals reporting incidents per se. Participants were also asked what they thought patients’ views were about pharmacists reporting medication errors, which is something that has not been explored in any of the
previous studies in the literature. Finally the participants were invited to give any examples of how medication error reporting by hospital pharmacists could be improved.

2.3.5 Data Analysis

The audio recordings of the four focus groups were transcribed verbatim but the ability to analyse qualitative data to produce a fair and unbiased view is a real challenge\(^98\), in particular for a first time researcher. Therefore the research supervisor acted as an additional analyst to ensure that any minority views within the focus groups were not underrepresented, particularly if they were at odds with the majority of the group or the moderator.\(^99\)

Numerous methods of thematic or content analysis of interviews are described in the literature and Robson refers to the natural biases and deficiencies of human analysts and describes qualitative analysis as “codified common sense” compared with the reliability of a computerised statistical analysis of quantitative data.\(^100\)

Coffey and Atkinson argue that although the theory of data analysis is important there is no such thing as the perfect model and urge that researchers should never stop thinking creatively and intelligently about their data as it can always positively change their interpretation of the data throughout the whole data analysis process.\(^101\) Similarly Patton reminds researchers that there is no “special recipe” for transferring the raw qualitative data into the ultimate findings, only guidance as to how to perform the analysis.\(^97\)

Crabtree and Miller explain four different possible styles of data analysis for qualitative research.\(^102\) The two extremes are “quasi statistical analysis” which is as scientific, standardised and objective as possible and “immersion/crystallisation analysis” which is as subjective, intuitive and interpretive as possible. The other two types of analysis portrayed as perhaps occupying the middle ground of data analysis and more user friendly, are “template analysis” and “editing analysis”. Template analysis is described as a more subjective version of quasi statistical analysis where likely “coding units” or themes from the data are identified and then deductively revised as the actual data is intensively digested and interpreted. Editing analysis is described as a more objective version of immersion/crystallisation analysis where “coding units”, or themes, are only inductively created after intensive digestion and interpretation, but without a prior template.

As far back as 1967 Glaser and Strauss proposed “Grounded theory” as the “purest” inductive type of analysis, whereby themes are identified from the original transcripts
without any *a priori* beliefs. Melia is critical of the grounded theory type approach to analysing qualitative data suggesting that in the real world researchers use variations of this approach to identify new themes alongside the original themes that would have been anticipated from the literature.

The “framework approach” to thematic / content analysis is another variant of deductive analysis whereby certain assumptions based on the understanding of the literature are utilised at the start to help analyse the data. Ritchie and Spencer explain that it is not a foolproof method and that researchers still need to use their abilities as an analyst to look for meanings and identify new threads within the data, going backward and forward within the stages if necessary to identify new connections.

Framework analysis is presented as a systematic process using five key stages to analyse and sort the data according to key themes: familiarisation, identifying a thematic framework, indexing, charting, mapping and interpretation

1. Familiarisation involves immersing yourself in the transcripts trying to get an overall view of the material, trying to keep an open mind and not being blinded by *a priori* concepts.

2. Thematic framework identification involves achieving a wider and deeper understanding of the material through emerging trends and reliance on *a priori* understanding and beliefs. This requires the researcher to be systematic, but again also open-minded and may take multiple readings to finalise.

3. Indexing involves applying the thematic framework of categories to the whole material and this can help other researchers see how the themes were identified by the original researcher.

4. Charting involves lifting data from the original transcripts and setting the relevant passages underneath the different themes identified.

5. Mapping and interpretation involves bringing together all the stages to elucidate the final emergent themes of the research. This involves the researcher's intuition for the data weighing up the importance of associations, and looking for explanations in line with the original research question.

In the same vein, Miles and Huberman suggest that there are three basic processes that need to be considered in qualitative data analysis. Data reduction, data display and conclusion/verification but they accept that these can be reached successfully by either inductive or deductive methods. One of the key points though is that the attribution and display of the coding units/ themes helps readers to see how researchers have carried out the analysis, which aids the validity of the research.
It was decided that a framework analysis approach would be taken to analyse the focus group transcripts as it met the research objectives for this study. Initially the audio recordings for each of the four focus groups were listened to whilst reading the typed transcripts for immersion in the data. As there is a risk of misrepresenting the views of participants due to the effects of tone and emphasis during transcription. Minor amendments were then made to the typed transcripts and after several readings a draft thematic framework was produced with themes and sub themes based on the data and my a priori understanding of the literature. (Appendix 4) This thematic framework was then used to annotate passages in the scripts of the themes and sub themes emerging from the data. The thematic framework was then refined further to improve clarity and reduce ambiguity to produce the final thematic framework (Appendix 5).

After meticulous indexing of themes the appropriate passages from the scripts were tabulated under the different sub themes (Appendix 6) to allow the final conclusions to be drawn from the rich qualitative data.

2.4 Quantitative Methodology

2.4.1 Introduction

To expand upon the rich qualitative data about the attitudes of hospital pharmacists’ to reporting derived from the focus groups, the second objective of the study was to establish pharmacists’ medication error reporting behaviour. As discussed earlier the use of observational methods to establish actual reporting by hospital pharmacists would have been the ideal option but was wholly impractical for this research study. Therefore a psychology based theoretical model was considered for predicting the reporting behaviour of hospital pharmacists.

2.4.2 Social Cognition Models

Several Social Cognition Models have been used to determine the clinical practice behaviour of health professionals. A recent meta analysis, by Godin et al, of 78 studies using such models found that the overall frequency weighted mean $R^2$ was 0.31 (range 0.001- 0.58) for the prediction of behaviour and 0.59 (0.14 – 0.91) for the prediction of intention (i.e. 59% of the variance of the intention to carry out a clinical behaviour could
be predicted by the theoretical model). The most significant cognitive factors explaining intention (greater than 50% of the time) were beliefs about capabilities or consequences, moral norms, social influences, and social/professional roles and identities. The least frequently significant variables were demographic characteristics, environmental influences and knowledge. The Theory of Interpersonal Behaviour best predicted health professionals intentions ($R^2 = 0.81$) but only three studies used this model. The Theory of Planned Behaviour (TPB) / Theory of Reasoned Action (TRA) was the theory most frequently used in the studies (56/64) with a frequency weighted mean $R^2 = 0.59$. The same author had previously found that the TPB model predicted 41% of the variance in intention of patients to perform health-related behaviours with the constructs “Attitude to Behaviour” and “Perceived Behavioural Control” the most significant variables. Another systematic review of ten studies using TPB, or similar theories of behaviour, in health professionals found that there was a predictable relationship between health professionals’ intentions and subsequent behaviour in clinical practice.

2.4.3 Theory of Planned Behaviour to study Health Professional Behaviours

The TRA / TPB model, however, has already been used to try to understand pharmacists’ intentions to undertake a number of clinical behaviours. Mason used a TRA survey to explore American community pharmacists’ counselling behaviours and found that attitudes and social pressures (Subjective Norms) were significantly strong predictors of behavioural intention to provide verbal instructions and of the length of the patient encounter time.

Farris and Kirking used an adaptation of the TRA to study American community pharmacists’ intentions to prevent and correct drug therapy problems. In this case social pressures and attitudes were significant but relatively poor predictors of intention ($R^2 = 0.18$).
In another study carried out with a larger sample of Canadian community pharmacists (n=230) the assessment of pharmaceutical care was investigated using the Theory of Goal Orientated Behaviour surveys, that included the TPB construct, Perceived Behavioural Control (PBC). Pharmacists were positive about trying to provide, and the benefits of providing, pharmaceutical care with moderate to high intention. PBC had a direct effect on beliefs, evaluation and self efficacy but low PBC scores indicated that community pharmacists did not have workable processes to adopt the provision of pharmaceutical care in the community.\textsuperscript{112}

Herbert et al similarly used a TPB survey to study American community pharmacists’ intentions to provide medication therapy management, and all the TPB constructs were found to be significant predictors of intention. This suggested that pharmacists with a positive attitude, who felt that their peers approved and that they had control over providing services, had a stronger intention to provide medication therapy management.\textsuperscript{113}

Walker et al also used the theory of planned behaviour to predict pharmacists’ intentions about the treatment of vaginal candidiasis with non prescription medicines in the UK and found that attitudes were the best predictor of intention to supply.\textsuperscript{114}

TPB questionnaires have additionally been employed to look at a range of health professional behaviours that might be considered routine violations to work practices, and have parallels with not reporting errors. Routine violations are deliberate departures from rules that describe safe or approved methods of performing a task.\textsuperscript{115} They are typically not intended to cause harm and are tolerated by organisational culture.\textsuperscript{116} Failure to not report medication errors by pharmacists could be considered a routine intentional action that does not cause harm. However reporting is a voluntary activity and so not reporting is not technically a deviation from an approved rule.

Phipps et al used a TPB questionnaire to establish anaesthetists’ attitudes to three behaviours that deviated from accepted best clinical practice.\textsuperscript{117} All of the TPB variables were good at predicting their intention not to carry out equipment checks (overall TPB model $R^2=0.42$), whilst Attitudes and PBC were significant predictors of their strong intentions to reconnect IV fluid bags (overall TPB model $R^2=0.64$). They suggested educational activities for improving attitudes (incident report analysis), addressing the work environment and reducing bottlenecks in the system to improve Perceived Behavioural Control.
Two studies have used TPB to try to understand adherence by hospital staff to hand hygiene recommendations. Jenner et al found that attitudes, and an additional construct “personal responsibility”, but not subjective norms or PBC, were significant predictors of intention to perform appropriate hand hygiene. This suggested that promotional materials to encourage handwashing would be better directed towards health professionals’ sense of personal responsibility for hand hygiene. O’Boyle et al found that all the TPB variables (Attitudes, Subjective Norms, PBC) were significantly good predictors of intention to follow hand hygiene guidance, and to a lesser degree self-reported hand hygiene. However they did not successfully predict actual observed adherence to hand hygiene on the studied critical care units, and the intensity of activity in the clinical unit at the time of observation was negatively associated with observed hand washing (r=-0.32).

TPB surveys have also been used to establish health professionals’ intentions to undertake other less clinical activities like reporting errors, such as documentation on a patient’s chart by nurses. Renfroe et al found that social pressures (Subjective Norms), but not attitudes towards documentation had a significant effect on behavioural intention, suggesting that communicating the high expectations of important others should be tried to improve the quality of documentation.

The assumed link between intention and actual behaviour in the TPB model is however not without criticism and Schwarzer details two deficiencies of TPB/TRA models for predicting behavioural intention and actual behaviour, albeit in changing patients’ health behaviour.

1 Assumption that behavioural change is linear and that you can adopt a one size fits all approach to designing an intervention excludes changing mindsets over a period of time.
2 Models do not account for the “intention-behaviour” gap where people do not actually behave as they intend.

The TPB model, in particular the construct of Perceived Behavioural Control, has also been criticised with Sutton concluding that using PBC as a proxy for actual control, and thus behaviour is an invalid assumption and that there is not a causal link between PBC and actual control over a behaviour.

So although the TPB model is not without its limitations it is the most widely used model, it is the most influential theory for the prediction of social and health behaviours, and
in their review of changing health professionals’ behaviour, Eccles et al suggest that TPB is a good theoretical model to predict clinical practice behaviour.\textsuperscript{124} It was therefore considered to be the quantitative research method of choice for this study.

\textbf{2.5 Theory of Planned Behaviour Methodology}

\textbf{2.5.1 Understanding the Theory of Planned Behaviour}

The Theory of Planned Behaviour (TPB) is a social psychological model for understanding human social behaviour and was developed by Aizen\textsuperscript{125} as an extension of the theory of reasoned action (TRA) established by Fischbein.\textsuperscript{66} At the heart of the theory is an individual’s intention to carry out a particular behaviour. The intention to perform any behaviour is driven by motivational factors that influence behaviour. i.e. how hard is an individual willing to try, or put in effort, to succeed? The theory asserts that there are three independent determinants of intention:

1. \textbf{Attitude towards Behaviour} - an individual's appraisal of the behaviour in question i.e. a person’s judgement that performing a behaviour is good or bad and that in favour of or against performing.\textsuperscript{126}

2. \textbf{Subjective Norm} - the social pressure to perform or not i.e. the more a person thinks that others who are important to them would want them to perform the behaviour, the more they will plan to do so.\textsuperscript{126}

3. \textbf{Perceived Behavioural Control} - the perceived ease or difficulty of performing the behaviour which reflects past experience and expected barriers.

Ajzen states that “as a general rule the more favourable the three determinants the stronger should be an individual's intention to perform but that the relative importance of the three determinants is expected to vary across different behaviours”.\textsuperscript{127}

The theory aims to explain behaviour not just predict it and postulates that behaviour results from individuals’ salient beliefs about that behaviour (see Figure 1).
Figure 1: The Theory of Planned Behaviour (Ajzen 1991)

Behavioural beliefs - assumed to influence “attitudes towards behaviour”
Normative beliefs - the underlying determinants of “subjective norms”
Control beliefs - basis for “perceived behavioural control”

The main reason for undertaking this research was to understand why hospital pharmacists do not routinely perform a behaviour that would be expected of them i.e. reporting medication errors for the benefit of learning and the reduction of similar errors in the future. This can be mapped onto the TPB model as follows:

Behavioural belief: Attitudes towards the behaviour i.e. what happens if I do or do not report medication errors i.e. benefits for patients or adverse consequences for reporter/health professional involved.
Normative belief: who influences me to report i.e. peers, mangers, doctors, nurses?
Control belief: Can I and do I really want to report the error i.e. how hard is it to report, do I have time?

According to Francis et al TPB studies are easier to complete and more informative if six key issues are true. These are presented below with comments about the suitability of a TPB questionnaire for this research question.
1 There is clear clinical evidence about the relevant issue - There is worldwide interest in medication safety and error reporting \(^7,129\)

2 Compliance with the evidence is low or moderate - There is evidence that medication errors are not reported as often as they occur \(^{12,13,14,16}\)

3 Clinical condition is not rare - Estimated that 1.5% of all hospital inpatients are harmed by a medication related adverse event \(^10\)

4 Among the population of interest there is variation in performing the behaviour to be investigated - Limited evidence that pharmacists are reluctant to report medication errors \(^{50,52}\)

5 The behaviour involves a yes/no treatment decision - Pharmacist’s either decide to report or not to report

6 Contact details are easily available to the population of interest - Access to hospital pharmacy research network within the north-west NHS hospitals through researcher and academic supervisor

According to the original “expectancy – value” model of attitudes, individuals’ attitudes develop from the beliefs that they have about the attitude by linking the behaviour outcomes. \(^{130}\) Attributes linked to an individual behaviour are valued as either positive or negative and individuals acquire attitudes towards behaviour dependent on these. In other words, individuals learn to favour behaviours that are considered to have desirable consequences. There is also an argument that a person will naturally have a positive attitude towards behaviour that is easy and vice versa. \(^{109}\)

It is at the level of beliefs that it is possible to learn about the unique factors that induce one person to engage in a said behaviour and to prompt another to follow a different course of action.

One of the differences between the TPB and, its antecedent, the TRA is that the TPB model incorporates the idea of volitional control. i.e. individuals have the intention to carry out that behaviour if they decide they want to perform it or not. Performance of the behaviour also depends on an individual’s actual control over the behaviour and includes non-motivational factors such as availability of opportunities and resources (time, money, skills) and the co-operation of others. So if an individual has resources and intends to perform the behaviour then he or she is likely to succeed in doing so.
Ajzen stresses that actual behavioural control depends on perceived behavioural control, which with behavioural intention helps predict whether the behaviour will be carried out.\textsuperscript{127} He gives two reasons for this: the first is the holding intention constant e.g. two individuals have an equally strong intention to learn to ski and both individuals try to do so but the person who is confident that they can master the skiing is more likely to succeed than the one who doubts their ability; the second is that perceived behavioural control is considered a substitute for actual control but that this may be less realistic if an individual has very little information about the behaviour or it is being carried out in unfamiliar surroundings. He explains the importance of ensuring that the behaviour to be predicted, i.e. reporting medication errors, assesses intentions in addition to the perceived control and that it would be expected that perceived control would become increasingly important as volitional control over the behaviour reduces.

### 2.5.2 Construction of the TPB survey

#### 2.5.2.1 Questionnaire design

The manual for health services researchers on utilising TPB questionnaires\textsuperscript{128} and guidance from Ajzen (2006)\textsuperscript{131} was used to help design the questionnaire.

Indirect rather than direct measures of the three key determinants of intention were used, i.e. belief based variables which measure beliefs upon which the attitudes are based, to allow a better idea of what beliefs to target when designing an intervention to change behaviour.\textsuperscript{128}

Ajzen recommends the need to ideally use indirect measurements from a representative sample of the expected research population\textsuperscript{131} and so the most important beliefs about medication error reporting behaviour by pharmacists identified in the focus groups, in addition to results from the literature review were used to inform what “salient” beliefs should be tested in the questionnaire. (See Table 4)
Table 4: Salient beliefs used for the TPB Questionnaire

<table>
<thead>
<tr>
<th>Behavioural Beliefs</th>
<th>Normative Beliefs</th>
<th>Control Beliefs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increases awareness of a medication safety problem (i.e. positive feedback)</td>
<td>Peers</td>
<td>Seriousness of incident i.e. harm or near miss</td>
</tr>
<tr>
<td>Reduces the future harm</td>
<td>Medical and nursing colleagues</td>
<td>Time pressures</td>
</tr>
<tr>
<td>Affects professional working relationship between pharmacist and doctor</td>
<td>Patients</td>
<td>Excessive workload pressures</td>
</tr>
<tr>
<td>Disciplinary / litigation concerns for trust or individual health professionals</td>
<td>Clinical Risk Managers</td>
<td>Simplicity of reporting</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Format of reporting e.g., anonymity, dedicated person</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Duplication of effort and co-operation of others e.g. documentation in notes or verbal feedback to health professionals involved</td>
</tr>
</tbody>
</table>

All questions used a seven point scale for responses as recommended for TPB surveys.¹²⁸

2.5.2.2 Medication error scenario

TPB questionnaires are known to be challenging to complete¹³²,¹³³, possibly affecting response rates, and hospital pharmacists would not be expected to be familiar with social
psychology research methods. Therefore a pragmatic decision was made to include one medication error scenario, to try to reduce the time taken to complete the questionnaire. A prescribing error scenario was chosen since inpatient prescribing errors are a common occurrence, affecting 7% of medication orders, 2% of patient days and 50% of hospital admissions. In addition, hospital pharmacists are expected to be exposed to multiple prescribing errors daily, particularly when dealing with medicines reconciliation on admission to hospitals.

The scenario used in the survey was derived from a real life cluster of cases at the researcher’s base hospital, where mix ups had occurred between the immunosuppressant, Azathioprine, and the similar sounding antibiotic, Azithromycin. The outcome for the patient in the scenario was intentionally selected to ensure that the pharmacists would consider this to be a real harm incident and not a near miss, as the literature suggests that these are more likely to be considered worthy of reporting. The questionnaire design however allowed for subsequent questions to then ascertain if responses about reporting were any different if no harm had occurred.

“You have just finished your morning visit to your ward and you now need to attend a departmental meeting followed by a teaching session all afternoon. During your ward visit you discovered a medication error which may have caused this hospital admission. A patient had been prescribed Azathioprine 250mg instead of Azithromycin 250mg following an outpatient visit 6 weeks ago and has now presented with severe neutropenic sepsis. You decide to report the medication error via the hospital reporting system but you also make an entry in the clinical notes and contact the original prescriber and pharmacist involved to make sure they understand what has happened”.

2.5.2.3 Measurement of Attitudes to Behaviour

Reviews have shown that Attitudes are the best predictors of intention in the TPB model and that the TPB model assumes that the salient beliefs of an individual are the ones that determine a person's attitude. Therefore the use of the behavioural belief questions determined from the focus group analysis should have enhanced the validity of the questionnaire.

Attitude to Behaviour was assessed using six paired questions. In the example below the first question established a measure of behavioural belief and the second the outcome
evaluation about the belief that the reporting of medication errors reduces the risk of harm in the future.

**Example of Attitude to Behaviour questions**

*Reporting medication errors reduces the risk of harm to another patient due to the same problem in the future*
1 Strongly Disagree, 2 Disagree, 3 Slightly Disagree, 4 Neutral, 5 Slightly Agree, 6 Agree, 7 Strongly Agree

*Reducing the risk of harm to another patient due to the same problem in the future would be*
1 Extremely undesirable, 2 Undesirable, 3 Slightly undesirable, 4 Neutral, 5 Slightly desirable, 6 Desirable, 7 Extremely desirable

The Attitude to Behaviour (AB) scale was then calculated using the formula

$$ AB = \frac{\sum (\text{ behavioural belief} \times \text{outcome evaluation})}{6} $$

, after each score had been converted onto a bipolar scale. (1 = -3 opposing the behaviour, 7 = +3 favouring the behaviour)

**2.5.2.4 Measurement of Norms**

Subjective normative beliefs are the weakest predictors of behavioural intention because in the original TPB model the social pressures to perform behaviour (Norms) only used injunctive norms, which described social approval by others. Subjective Norm was assessed using four paired questions including the social pressures identified in Table 5. In the example below the first question established a measure of the normative belief and the second the motivation to comply with the belief that doing what medical and nursing clinical colleagues think matters.

**Example of Subjective Norm questions**

*My medical and nursing clinical colleagues in my hospital would think I should report the medication error*
1 Strongly Disagree, 2 Disagree, 3 Slightly Disagree, 4 Neutral, 5 Slightly Agree, 6 Agree, 7 Strongly Agree

Doing what medical and nursing clinical colleagues would think I should do matters to me
1 Not at all, 2 Hardly, 3 A little bit, 4 Moderately, 5 Considerably, 6 Very much, 7 Absolutely

The Subjective Norm (SN) scale was then calculated using the formula
SN = ∑ (normative belief X motivation to comply) / 4 *

* After each score had been converted onto a bipolar scale. (1 = -3 opposing the behaviour, 7 = +3 favouring the behaviour)

The inclusion of Descriptive Norms, which describe the perception of what others do, have been found to further improve the prediction of intentions and so two Descriptive Norm questions were included in the questionnaire as an additional predictor of the intention to report.

Example of Descriptive Norms questions

Most pharmacists would....................... report the medication error described in the scenario
1 Never, 2 Very rarely, 3 Rarely, 4 Occasionally, 5 Often, 6 Very often, 7 Always

Most pharmacists would consider reporting the medication error described in the scenario to be..................
1 Extremely undesirable, 2 Undesirable, 3 Slightly undesirable, 4 Neutral, 5 Slightly desirable 6 Desirable, 7 Extremely desirable

The Descriptive Norm (DN) scale was then calculated using the formula
DN = ∑ (descriptive norm) / 2
(1 = least in favour of behaviour, 7 = most in favour of behaviour)
2.5.2.5 Measurement of Perceived Behavioural Control

Perceived Behavioural Control is used as proxy measure for actual (volitional) control and in the original model Ajzen described control factors as either being internal or external, and that if an individual has access to adequate resources and opportunity (i.e. lack of obstacles) to perform a behaviour then there will be a perceived high degree of behavioural control.  

**Internal –** knowledge, skills, willpower, emotions e.g. seriousness of error, interprofessional relationships (telling/identifying prescriber in report)

**External –** time, availability, co-operation/dependence on others e.g. workload pressures, simplicity of reporting form, presence of a medication safety pharmacist

The types of control belief questions used for the PBC construct, with often low internal reliability values, have however been subject to considerable debate in the literature since the original model was designed.  
The debate focuses on whether the PBC construct should be considered as a multidimensional construct consisting of two interrelated components, better described than internal versus external components, and including self efficacy (or perceived difficulty according to Trafimow) and controllability (or perceived control) according to Ajzen (2002).

**Self efficacy -** ease or difficulty of performing behaviour with confidence individual can perform if want to

**Perceived controllability -** belief that they have control over behaviour and performance or non performance is up to the individual

Kraft et al have suggested that PBC is actually just another way of measuring attitude and believe that studies that have only used behavioural beliefs regarding perceived difficulty (or self efficacy) may overestimate the role of PBC in predicting intention of behaviour.  
Leach et al go as far as to say that such studies which only include perceived difficulty measures should be re-evaluated.
Conversely however Trafimow et al have intimated that perceived difficulty control beliefs within a PBC construct are better predictors of behavioural intention and behaviours than perceived control questions.\textsuperscript{139}

In essence the control belief questions used in this study therefore included a mix of difficulty and confidence questions as recommended by the TPB manual for health researchers.\textsuperscript{128} Perceived Behavioural Control was assessed using eleven paired questions based on the salient beliefs in Table 4. In the example below the first question established a measure of the control belief and the second the frequency that pharmacist is under time pressures.

**Example of Perceived Behavioural Control questions**

*Being under time pressure would make reporting medication errors …*

1 *Much less likely*, 2 *Less likely*, 3 *Slightly less likely*, 4 *Neutral*, 5 *Slightly more likely*, 6 *More likely*, 7 *Much more likely*

*How often are you under time pressure?*

1 *Never*, 2 *Very rarely*, 3 *Rarely*, 4 *Occasionally*, 5 *Often*, 6 *Very often*, 7 *Always*

The Perceived Behavioural Control (PBC) scale was then calculated using the formula

\[ PBC = \frac{\sum (\text{control belief} \times \text{frequency})}{11} \]

* After each score had been converted onto a bipolar scale. (1 = -3 opposing the behaviour, 7 = +3 favouring the behaviour)

**2.5.2.6 Measurement of Behavioural Intention**

Behavioural intention to report medication errors was assessed using two questions.

**Example of Behavioural Intention questions**

*How likely is it that you would report the error described in the scenario?*

1 *Very Unlikely*, 2 *Unlikely*, 3 *Fairly Unlikely*, 4 *Neutral*, 5 *Fairly Likely*, 6 *Likely*, 7 *Very likely*

*How strong is your intention to report medication errors in future?*
1 Very Weak, 2 Weak, 3 Slightly Weak, 4 Neutral, 5 Slightly Strong, 6 Strong, 7 Very strong

The Intention (INT) scale was then calculated using the formula

\[ \text{INT} = \frac{\sum \text{(intention)}}{2} \]

(1 = least in favour of behaviour, 7 = most in favour of behaviour)

2.5.2.7 Measurement of Behaviour

Meta-analyses of TPB studies have shown that there is a reliable relationship between behavioural intention and actual behaviour in patients and health professionals. Most TPB studies use self reported measures of behaviour but these overestimate intention-behaviour associations because of consistency, social desirability or memory biases and have limited validity. For example completing a questionnaire, thinking about your intentions to report medication errors, and your actual behaviour when confronted with real life medication error, may well be very different. Therefore there is an argument that for the greatest validity the study should have measured actual behaviour in addition to behavioural intention. Such observational methods of actual behaviour are considered the best criteria for assessing health behaviour change but as discussed already would have been ethically and geographically difficult to design, very time consuming and outside the time available for this research. As a result only behavioural intention was measured in this study.

2.5.2.8 Scoring of Scales

According to Ajzen, both unipolar or bipolar scoring can be applied to the three main TPB constructs, Attitude to Behaviour, Subjective Norm and PBC, without affecting the validity of the model. It is usual practice to use bipolar scoring for normative beliefs and control beliefs and unipolar scoring for the corresponding motivation to comply and the frequency (power) of the control belief under consideration. The scoring of the Attitude to Behaviour construct however is open to debate. Ajzen originally suggested applying bipolar scoring to both behavioural beliefs and the subsequent outcome evaluations to better understand the attitudes to behaviour, but Francis et al argue the opposite (unipolar behavioural belief and bipolar outcome evaluation).
Ajzen’s latest guidance about designing a TPB survey\textsuperscript{131} proposes that there is no way of predicting the best way to score i.e. unipolar or bipolar and suggests seeing how respondents answer the questions and then use the scoring scheme to give the best results.\textsuperscript{a}

\textsuperscript{a}After analysis of the results both behavioural beliefs and the corresponding outcome evaluations were both scored using a bipolar scale to be certain that an extremely undesirable outcome that pharmacists strongly agreed could happen (e.g. trust litigation after reporting a medication error $BB +3 \times OE -3 = -9$) was given the same value as an extremely desirable outcome that they strongly disagreed with (e.g. reporting medication errors does not increase awareness of a medication safety problem $BB -3 \times OE +3 = -9$) and vice versa.

2.5.2.9 Piloting

To make sure that the questionnaire worked as planned the paper and electronic questionnaires were initially piloted.\textsuperscript{144} Six senior hospital pharmacists, from both teaching and specialist hospitals, undertook the survey to test for face validity, wording layout, length of time for completion etc. All the pharmacists noted that the questionnaire was unlike anything they had ever completed before and found the format challenging. One of the Subjective Norm questions (*The people who taught me pharmacy would think I should report the medication error*) was removed completely as the pharmacists said that they had never been taught about medication errors and reporting at university, so it was not relevant. Minor changes to the wording of a number of questions were made following suggestions from the pilot.

2.5.2.10 Final Questionnaire

See Appendix 7 for the final questionnaire

2.5.3 Study setting

The same study sites were chosen as discussed in section 2.3.1

2.5.4 Sampling

The analysis of the questionnaire data needed to involve exploratory analysis using multivariate statistics and so the required sample size was estimated according to the
guidance typically provided for multivariate analyses, which suggests a minimum of forty participants per predictor variable for a stepwise multiple regression.\textsuperscript{145} Three predictor variables from the Theory of Planned Behaviour were to be used: behavioural beliefs; subjective norm; and control beliefs with an additional predictor of the number of years experience in hospital pharmacy. Therefore, the sample size required was estimated to be approximately 160 participants.

Good response rates to questionnaires are crucial for the validity of survey based research as poor response rates are a potential source of bias, with characteristics of non-respondents likely to differ from respondents.\textsuperscript{146} It is suggested generally that postal survey response rates of 50–59\% are barely acceptable.\textsuperscript{147} However response rates for TPB surveys are expected to be around 50\%\textsuperscript{128} and prediction of intention in TPB surveys has been shown to be significantly better when sample sizes are greater than 150 participants.\textsuperscript{106}

A convenience sample of all 600 hospital pharmacists, working in the twenty one hospitals that are part of the Northwest Clinical Pharmacy Forum, which had previously participated in a safety culture survey\textsuperscript{91}, was therefore invited to complete the questionnaire to try to maximise the number of responses for analysis.(Table 5)

**Table 5: NHS Hospitals that participated in the survey**

<table>
<thead>
<tr>
<th>Teaching hospitals:</th>
<th>Aintree University Hospitals Foundation Trust</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alder Hey Hospital Trust</td>
</tr>
<tr>
<td></td>
<td>Central Manchester and Manchester Children’s University Hospitals Trust</td>
</tr>
<tr>
<td></td>
<td>Lancashire Teaching Hospitals Trust</td>
</tr>
<tr>
<td></td>
<td>Liverpool Women's Hospital Trust</td>
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<tr>
<td></td>
<td>Royal Liverpool University Hospital</td>
</tr>
<tr>
<td></td>
<td>Salford Royal Foundation Trust</td>
</tr>
<tr>
<td></td>
<td>University Hospital of South Manchester Foundation Trust</td>
</tr>
<tr>
<td></td>
<td>Wirral Hospital Trust</td>
</tr>
</tbody>
</table>
District general hospitals: Blackpool, Fylde and Wyre Hospitals Trust
Bolton Hospitals Trust
East Lancashire Hospitals Trust
Macclesfield District General Hospital
North Cheshire Hospitals Trust
North Cumbria Acute Hospitals
North Manchester General Hospital
Royal Oldham Hospital
Southport and Ormskirk Hospital Trust
St Helens and Knowsley Hospitals Trust
Wigan, Wrightington and Leigh NHS Trust
Trafford NHS Trust

2.5.5 Recruitment

Best practice for surveys of health service staff and patients suggests that theoretically respondents will return a survey if the anticipated benefits of filling it in are at least equal to or better than the effort of responding and they offer three broad methods to maximise response rates:146

Minimising cost of responding: making questionnaire clear/concise and simple to complete; reducing mental effort and feelings of anxiety/inadequacy; avoidance of subordination of respondent to researcher; reduction of monetary costs e.g. providing prepaid return envelopes.

Maximising rewards of responding: making questionnaire topic interesting; expression of positive regard for respondents individual contribution; expression of appreciation in all communication; support of respondent’s values: incentives monetary or provision of results.

Establishing trust: establishing benefits of participation; establishment of credentials of research team; building on relationships of reputable others e.g. University.
The "saliency" of the topic is considered to be very important and this was definitely the case for pharmacists and medication error reporting after the recent jail sentence for a community pharmacist who had made a dispensing error.\textsuperscript{148}

Higher response rates have also been shown to be associated with written reminders\textsuperscript{149}, higher after two rather than one reminder.\textsuperscript{146}

Clinical pharmacy services managers in the twenty one hospitals were asked to circulate the email invitation and information sheet appealing to all pharmacists in their department to take part in the questionnaire (Appendices 8 and 9). Pharmacists were then given the choice to complete paper copies, and return them via freepost return delivery, or an online version of the questionnaire via the university’s secure website. Reminder emails were sent after 2 and 4 weeks.

\textbf{2.5.6 Data analysis}

The questionnaire was subjected to multivariate statistical analysis using Statistical Package for the Social Sciences (SPSS Version 15)\textsuperscript{150}, in accordance with the standard evaluation of Theory of Planned Behaviour surveys.\textsuperscript{127,128} This involved multiple regression to determine the relative influence of a number of variables on the pharmacists' behavioural intention to report medication errors. These variables comprised the three major constructs from the Theory of Planned Behaviour (i.e. the pharmacist’s own attitude to the behaviour; the pharmacist’s perception of other people's attitudes towards the behaviour; the pharmacist’s perception that he or she has control over the behaviour) plus demographic variables (number of years experience at the current grade and at the current site).

\textbf{2.5.7 Free Text Comments}

The questionnaire included a free form box to allow all respondents to record their views about the subject of medication error reporting or anything else, including the survey itself. Responses were analysed thematically to check resonance with the themes elucidated from the focus groups.
2.6 Validity and Reliability

These two concepts are central to the integrity of any research findings, be they qualitative or quantitative, and Pope and Mays offer two goals for qualitative researchers to ensure rigour in their research. 98

1. Give an account of the methodology and data that will stand independently so that another researcher can analyse and produce similar conclusions

2. Produce a plausible and coherent explanation of the phenomenon under scrutiny

It has been argued that the strength of qualitative research is its validity, whereas the strength of quantitative research lies in its reliability. 151

Ensuring validity in qualitative research involves the need for reflexivity i.e. an understanding of one’s own influence on the research and the personal and intellectual biases of the researcher should be a clear at the outset to enhance the credibility of the work. 152,153 As a recognised regional expert in medication safety this meant the need to be aware; that participants may have been “put off” taking part in the focus groups, of the possibility that participants said something that they thought was desired, not to have led participants due to self beliefs on the subject. Therefore it was agreed that the research supervisor performed an additional thematic analysis of the focus group transcripts to limit any possible bias.

The use of multiple focus groups should further increase the external validity of the study as the results will include a range of views and experiences of hospital pharmacists and any disagreement or differences in attitudes between (or within) focus groups could be expected to be similar to everyday discussions about any subject. 154
Chapter 3: Ethics

The Department of Health research governance framework clearly states that “the dignity, rights, safety and wellbeing of participants must be the primary consideration in any research study” but also makes clear that research which duplicates original work or is not of sufficient quality to add to the existing knowledge base on the subject, is also unethical.\textsuperscript{155}

3.1 Ethical considerations

The four main ethical principles that needed to be addressed in the research study were:\textsuperscript{156}
- Preventing harm
- Informed consent
- Privacy
- Deception

3.1.1 Preventing harm to participants

Participants would not come to any physical harm from this study but mental harm, including distress, anxiety or effects to self-esteem, needed to be considered. It was possible that some issues raised by participants in the focus groups might be sensitive i.e. admitting not reporting serious errors via the hospital reporting system, in particular for junior grades who may have felt reluctant to give honest feedback in front of more senior pharmacists. Although the risk of any mental distress was considered to be minimal, all participants were dealt with in a sensitive and encouraging manner and reminded at the start of the need to keep all information confidential. Pharmacists are very familiar with the need to maintain confidentiality as part of their professional code of ethics\textsuperscript{157} and this did not present a problem.

The subject matter of the questionnaire could have been considered sensitive, as some of the questions referred to the participant's own adherence to expected practices about reporting medication errors but the questionnaire participation was completely voluntary and anonymous so again this presented minimal ethical dilemma.
The only other indirect risk to participants was simply that the focus groups and/or the completion of the questionnaire might have been an intrusion into their time, but any involvement was voluntary so pharmacists had a choice to not take part if they so wished.

3.1.2 Informed consent

The process of informed consent was a voluntary one and pharmacists who were interested in taking part in the focus groups were given a participation information sheet (Appendix 2) which made clear that they were under no obligations, and that they could decide to withdraw at any time before the focus group, which would not affect their working conditions or rights in any way. They were encouraged to seek clarification and ask questions of the research team before they signed the consent forms (Appendix 10), which were then collected at the beginning of the focus group.

Pharmacists invited to take part in the questionnaire were also provided with an information sheet explaining the purpose of the study and the nature of their participation (Appendix 9). Those participants who completed and returned the questionnaire were deemed to have given informed consent to take part in the study, and a statement to this effect was provided on the information sheet.

3.1.3 Privacy

Privacy for study participants is linked to confidentiality and anonymity and must be total to give participants confidence to speak or act freely without fear of any personal repercussions. All qualitative and quantitative data (audio files, transcripts, consent forms, questionnaires and contact details) were treated as strictly confidential, stored on password protected computers or in locked drawers in secure locations in the Pharmacy Practice Unit at the University of Manchester. To comply with the Data Protection Act 1988 all data will be kept for a maximum period of 5 years after the study has been completed, after which time all tapes and computer files will be destroyed.

Only the research supervisor (Chief Investigator of the study) and the researcher have access to this data and details of the individual pharmacists and hospitals who participated will also be kept strictly confidential, ensuring that in the analysis and any relevant publications such information, or attributed quotations, will be anonymous. Although no access to patient records was needed participants in the focus groups were asked not to mention any patients, involved in any errors, by name. However, if any details
of patients had been inadvertently given by participants, they would not be included in the transcripts.
The questionnaire did not ask for any information that would lead to the identification of specific individuals so did not affect participant privacy.

3.1.4 Deception

This may occur if a researcher is not fully transparent about the reasons for performing the research but this was not considered to be a relevant ethical concern for this study.

3.2 Local ethical committee approval

Initially advice was sought from the local research ethics committee (LREC) to see if ethics approval was needed for the study. As the study involved interviewing NHS staff on NHS premises full ethics approval was warranted. A research protocol was designed and a NHS research ethics committee (NHS REC) application form was completed on-line via the Integrated Research Application System. These were then submitted to the South Manchester LREC, who then requested attendance at a meeting on the 11th December 2008. An outline of the study was presented to the panel members and questions about the ethics of the study were answered. The committee gave a favourable opinion to the study (Appendix 11) but did raise specific concerns about: one, the risk of junior pharmacists in a focus group being reluctant to give their opinion about reporting due to the presence of more senior staff who might be their line manager; and two, that any disclosure about a serious medication error that had occurred, but that had not been reported, might cause conflict and break confidentiality. The committee was reassured that as a senior pharmacist the researcher would be able to manage any such disclosures and ensure that, after the interview, any errors that caused serious harm to a patient were reported through the appropriate trust reporting system. The concern about the risk of hierarchical pressure causing non response from junior pharmacists was accepted as a limitation of the study but it was argued that recruitment to a focus groups just for junior grades, held at one central location, might be expected to be more difficult as it would involve travelling and time away from the work place.

The committee also asked for the focus group consent form to be amended to ensure that it was explicit that the interviews would be audio-taped, and that any transcribed material would be anonymous in the analysis and in any future publications (see Appendix 7). Although not truly an ethical issue the committee also wished to see a copy of the final
theory of planned behaviour questionnaire, if any changes were made following analysis of
the focus group discussions. (A copy of the letter received by the Ethics Committee to
confirm approval of the study is shown in Appendix 11)

3.3 University research ethics approval

Authorisation was also required for the study from the University of Manchester and after
submission of the NHS REC, the research protocol and an insurance application form, approval was granted on 3rd April 2009.

3.4 Local NHS hospital research and development approval

The research governance leads for each of the 20 hospitals in the North West NHS region
were contacted for permission to perform the study. The hospitals that have been selected
to take part in the focus groups additionally requested the researcher to have an honorary
work contract, to allow the focus groups to be performed on their particular hospital site.
Chapter 4 – Results

4.1 Focus Groups

4.1.1 Introduction

Four hospitals agreed to take part in the focus groups, two of them were large university teaching hospitals whilst the other two were moderately sized district general hospitals. (see Table 6) The size of the focus groups varied between two and six pharmacists and the overall gender mix was twelve female to five male, which is in line with hospital pharmacy workforce data.\textsuperscript{158}

The experience of the participants varied between one and twenty three years qualified with a reasonable mix of junior and senior graded pharmacists. Three out of the four hospitals had paper incident reporting forms and one had a fully electronic system. The three hospitals with paper forms had two different types of error reporting forms, one which was trust wide for reporting any type of incident, including medication errors, and another a simpler internal form that was exclusively for pharmacy staff to report either dispensing errors or other medication errors only.

Each of the focus groups lasted between 40 and 60 minutes. In general terms two of the pharmacy departments appeared very comfortable reporting medication errors and were very positive about the benefits of reporting, due to a perception of strong pharmacy leadership and a history of constructive changes following medication error reporting. In fact one of those hospitals had a medication safety pharmacist whose role it was to escalate the internal pharmacy reporting forms, via the trust wide system, on behalf of the reporting pharmacist when the incident appeared to be a serious or a repetitive system type error.

The other two pharmacy departments appeared to have an overriding anxiety about the effect of reporting on their professional relationships with other health professionals and one appeared adversely affected by the recent internal investigation of a medication error.

As might be expected each of the focus groups, despite an interview schedule, was different in that some required very little intervention by the moderator, as there was good interaction between all participants, and others required more probing questions due to
limited or similar responses by participants. For example one focus group was so positive about error reporting that originally they perceived no apprehension about reporting others, which in all the other focus groups had been volunteered early on.

Table 6: Characteristics of the Focus Groups

<table>
<thead>
<tr>
<th></th>
<th>Focus Group 1</th>
<th>Focus Group 2</th>
<th>Focus Group 3</th>
<th>Focus Group 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of hospital</td>
<td>District General</td>
<td>University Teaching</td>
<td>District General</td>
<td>University Teaching</td>
</tr>
<tr>
<td>Number of acute beds</td>
<td>350</td>
<td>900</td>
<td>750</td>
<td>1100</td>
</tr>
<tr>
<td>Number of Focus Group participants</td>
<td>5 female</td>
<td>4 female 2 male</td>
<td>1 female 3 male</td>
<td>2 female</td>
</tr>
<tr>
<td>Hospital pharmacy experience of participants</td>
<td>F1 23 years F2 18 years F3 3 years F4 1 year F5 13 years</td>
<td>F1 4 years F2 5 years F3 3 years F4 6 years M1 4 years M2 20 years</td>
<td>F1 6 years M1 4 years M2 11 years M3 22 years</td>
<td>F1 1 year F2 2 years</td>
</tr>
<tr>
<td>Type of medication error reporting system</td>
<td>Paper trust wide incident form plus pharmacy specific dispensing error form if error detected before leaving department</td>
<td>Paper trust wide incident form plus pharmacy specific form for recording medication errors identified in paediatrics only</td>
<td>Paper incident form specifically for medication errors (Escalated to trust wide incident form by dedicated pharmacist as necessary)</td>
<td>Electronic trust wide incident form</td>
</tr>
</tbody>
</table>
For these reasons the analysis of the focus groups was performed using the responses from all 17 participants across the four hospitals and not by individual hospital. Seven main themes were identified from the framework analysis and are covered in detail below.

4.1.2 Theme 1: Environment

All pharmacists who participated in the focus groups worked within NHS hospitals and it is important for context to firstly address the overarching culture that emerged around reporting and safety within such organisations. This first theme is divided into six sub themes.

Job role

Participants stated that identifying medication errors was an essential part of the role of a hospital pharmacist which the doctors, nurses and the organisation itself expected them to carry out.

That’s why I’m here, supposed to be picking up these things.
(Focus group one- Female with 18 years pharmacy experience)

You see it as part of your job to be dealing with this and be a safety mechanism for the prescribers.
(Focus group one- Female with 23 years pharmacy experience)

However it varied whether this meant that the reporting of the medication errors was also seen as part of their job, depending on their team relationships.

I work as part of a clinical team and I would be assumed to fill in the forms, not so much that we are policing the area, but that is recognised as one of the roles that I carry out
(Focus group three - Male with 11 years pharmacy experience)

Obviously they’re orthopaedic surgeons .... they just don’t take very good medication histories…I would under-report quite a lot because it happens all the time, and that’s, to me that’s part of what my job is.
Workload pressures

The pressures of working as a pharmacist in a busy hospital featured strongly in the early part of the focus groups. Comments included the fact that, due to the prevalence of medication errors, if they were all reported it would significantly impact on their day-to-day job as a pharmacist.

*Its so endemic, there are just so many of them*..

(Focus group two - Male with 20 years pharmacy experience)

*Cos if we reported every time something was missed off a patient’s drug history we’d probably make a report about every patient…well, you’d have no time to do anything else.*

(Focus group four- Female with 1 year’s pharmacy experience)

*I don’t know whether that actually gets done as much as it should do, because like who has time when you’re in the dispensary*…

(Focus group one- Female with 18 year’s pharmacy experience)

The act of reporting an error did not appear to be considered to be as important as caring for the patient due to the time involved.

*Time constraints. I mean it’s more important to get your prescription out to the patient than to sit down and write a report*

(Focus group one- Female with 23 years pharmacy experience)

It was conceded that being busy was, not really, a good enough excuse not to report errors but that there was maybe a general apathy to reporting amongst pharmacists due to the scale of the problem.
I think we accept quite a sort of background level of minor errors that maybe we shouldn’t do
(Focus group four- Female with 2 years pharmacy experience)

Blame culture

Participants, even in the most positive pharmacy departments, were acutely aware that reporting systems were still associated with a blame culture within hospitals.

Well, it’s supposed to be a no-blame but ... you still think that someone’s gonna get in trouble for it cos you have to put down people’s names and things
(Focus group one- Female with 3 years pharmacy experience)

People still think, it’s a form, my God, someone’s gonna come down from up on high and shoot me.
(Focus group two - Male with 4 years pharmacy experience)

Inter professional differences

Interestingly groups articulated the inter-professional differences in attitudes to reporting medication errors between nurses, doctors and pharmacists which the literature review has shown and may be about perceived job roles within the hospital teams and professional priorities.

Clinicians won’t fill out like a clinical incident forms about prescribing errors or things like that, they will fill out clinical incident forms because x-rays weren’t available
(Focus group two - Male with 20 years pharmacy experience)

The nursing staff generally think that they’re not for drugs really, because it’s a non-specific form about any incident, clinical or not...some of that, I think, is patient fell out of bed then there can’t be any apportioning of blame to anybody other than the patient for wriggling around in the bed. I think that’s where they’re quite happy to fill them out,
(Focus group two – Female with 5 years pharmacy experience)

Views were also expressed by the pharmacists that different health professionals were treated differently following investigations of incidents giving a feeling that this was unfair to pharmacists.

*Though I wasn’t the only person that made a mistake… but the nurses on the ward didn’t get anything like that….*

(Focus group one – Female with 18 years pharmacy experience)

*Think there is certainly a perception and probably not an unwarranted one, that the way medical staff are dealt with, treated, approached, when it comes to when an error has happened is a lot different.*

(Focus group three - Male with 4 years pharmacy experience)

Participants gave further examples of inter professional differences regarding the use of incident forms as a threat. Doctors do perceive the reporting of incidents as a punitive process\(^\text{42,43,46}\) and there does appear to be a culture of both nurses and doctors threatening to complete incident forms if pharmacy had done something wrong regarding medication. This appeared to be in response to pharmacists in a particular area who report medication errors where they believe the system needs correcting.

**Management**

As in all organisations, the pharmacists had an opinion on the effect, positive or negative, of managers within departments and those most senior in the organisation itself. In one hospital the junior pharmacists expressed a belief that senior hospital managers did not realise the extent of prescribing errors detected by pharmacists, but at the same time were slightly unhappy that one of their managers was keen for them to report errors for that very reason.

*I suppose the people high up in the organisation don’t know of all these errors, do they. They don’t know, do they. They should come round with a pharmacist for the day and see what, how many errors we pick up but don’t report*

(Focus group four – Female with 1 year’s pharmacy experience)
We should and I know that x, you know, is always on our cases to report them, because essentially that proves our service warranted and needed.

(Focus group four – Female with 2 years pharmacy experience)

There was awareness that hospital pharmacists’ attitudes to reporting medication errors could be influenced by a manager’s style of dealing with those errors. This concept of feeling comfortable to report medication errors in a “safe environment” was exemplified at one of the trusts in the focus group who had real belief in their department’s and their trust’s positive attitude to reporting.

I would always feel confident that as an individual professional I would be supported, certainly by the pharmacy system, I would hope by the Trust system as well, to follow that through, rather than being a lone ranger.

I think as a locum, when I used to locum as a junior pharmacist, you’d pick errors up that GPs made regularly and the dispenser would say, ‘Oh, he always does that.’ Do you know what I mean? That kind of thing, and I think, in a way, they’ve probably not tackled incident reporting as well as we have in hospital, have they.

(Focus group three - Male with 4 years pharmacy experience)

I suppose in the hospital environment it’s where I’m comfortable, it’s where I work, I know how I can help change, bring change about. I know fill an incident report form, that that, yeah, it can be negative but nine times out of ten I’m hoping it’s going to be a positive outcome. In the community, with a GP, I suppose, I don’t know, it’s outside my comfort zone.

(Focus group three - Female with 6 years pharmacy experience)

**Direct communication**

Whilst generally comfortable writing in medical notes about patients’ care, participants had anxieties about recording medication errors in medical notes in addition to, or as opposed to, reporting via the accepted system.

Pharmacists felt that speaking directly to the professionals involved could be more successful and less long winded than any investigation of a reported medication error.
There are better ways of dealing with things, that still achieve the same end. Like yesterday…. they could’ve filled a incident form in about that, but instead of which we’ve dealt with it, we’ve sorted it, the consultant is informed, the policy’s going to be reviewed, the patients, you know, had the treatment that they need, even though it’s not in the guidelines, and .. there’s none of the witch-hunt, kind of nobody’s cross or upset about it and everybody’s like ‘Oh, thanks a lot, we’re gonna sort this out now.’ And that means that the problem is resolved but we didn’t fill an incident form in even though we could’ve. (Focus group one - Female with 18 years pharmacy experience)

**Summary**

When considering the attitude of hospital pharmacists to reporting medication errors the first theme that emerged was the NHS hospital environment in which they operate. Pharmacists understood the “endemic” extent of the problem and accepted that it is part of their job in a hospital to identify and report medication errors. However because workload pressures are so intense the medication errors just do not get reported as often as they should, even if they wanted to report them all. The concept of a blame culture regarding reporting errors in hospitals appears to still exist in 2009. Even if pharmacists were happy reporting themselves there were still concerns about inter professional differences in views about reporting between doctors and nurses and the use of reporting as a threat against another department.

Pharmacists appeared to feel more comfortable reporting where there was a history of departmental and/or hospital belief in the benefits of reporting but may not warm to managerial requests to just report more to justify hospital pharmacists’ worth.

There was also a belief that speaking directly to the health professionals involved in any errors could be more successful and less stressful than formally reporting the incident.

**4.1.3 Theme 2: Anxieties**

The literature showed that barriers to reporting incidents by nurses and doctors are in part influenced by fears of litigation and disciplinary action. During the focus group interviews several participants questioned the use of the word “fear” as being too strong in the context of barriers to reporting medication errors. Therefore the theme was designated as anxiety to reflect this. The overall theme is split into three sub themes but the overwhelming theme
was one of concern about professional relationships, following the reporting of medication errors.

**Professional relationships**

Concerns about adversely affecting professional working relationships was the most common thread running through all the transcripts regarding attitudes of hospital pharmacists to reporting medication errors. At the most basic level pharmacists were concerned about reporting the, mostly unintentional, actions of others.

*It’s just that when you go and say, ‘I’m gonna be filling in an incident form about such and such.’ There’s kind of a look as if to say, ‘You’re a traitor.’…. ‘You’re meant to be on our side, you work on our ward.’*

(Focus group two - Male with 4 years pharmacy experience)

Several pharmacists, junior and senior, described personal experiences of conflict with another health professional following the reporting of a medication error, and then described how it made them think twice about reporting again.

*I had a bad reaction to that, so it kind of has put me off reporting it cos it does turn it into a huge great big mess…so I kind of wanna view it as my last resort*

(Focus group four – Female with 2 years pharmacy experience)

*I’m not a particular fan of conflict and so I don’t like having to cause huge like situations on the ward, when I’m saying, ‘Why wasn’t this dose given?’ I’m being sort of the policeman for a situation…think would put me off from reporting.*

(Focus group four – Female with 1 year’s pharmacy experience)

There were contrasting views about whether working as part of a small multidisciplinary team made these anxieties greater or not.

*If you’re working in a fairly discrete clinical team, pharmacists have, I think, historically, had difficulty finding a role within a team, finding acceptance of people accepting pharmacists’ roles, and I think sometimes you may be a little cautious about wanting to jeopardise that, particularly if it’s a team that you work closely with.*
(Focus group three - Male with 4 years pharmacy experience)

I would feel more comfortable if it was a team I worked in, but I don’t think the fact that it would be someone else, you know, say for example I was working a weekend or I was on-call, I wouldn’t feel hindered in reporting that, on the basis I would feel I would be jeopardising what I was doing for the patient, on the basis that someone could quite easily make that mistake …you know, we need to get it right for the patient.

(Focus group three - Male with 4 years pharmacy experience)

Pharmacists accepted that the reporting of errors can make health professionals defensive and examples were given where the pharmacist had reacted, when they themselves had been involved in an error.

It’s understandable ..I mean they’ve reported me before…but I took that as a personal dig, and I didn’t mean to and I know that they didn’t mean it in that way, but it’s just an instant, it’s a reaction, isn’t it, you get your back up and …

(Focus group four – Female with 1 year’s pharmacy experience)

Strategies for overcoming these tensions appear to be twofold. Pharmacists described explaining to the health professional why they were filling out the incident form in an effort to reduce bad feeling, as well as educating individuals for the future.

If it’s me and I’m filling one in about a doctor, I tend to … tell them that I’m doing it, but not as a kind of, ‘I’m filling an incident form.’ But actually saying, ‘Obviously it’s really important that this doesn’t happen again and if you didn’t know then that means lots of other people didn’t know about this and so I have to fill this form in to make sure that this gets identified by the Trust, so that it doesn’t happen and other people get warned about this. And it’s not against you

(Focus group one – Female with 18 years pharmacy experience)

Alternatively pharmacists chose not to report at all, particularly when it involved a newly qualified doctor, or only reported once sure that all the necessary data, including the professionals involved, had been collected.
If you’re, you’ve got a new house officer and they make a mistake and it’s because of their inexperience, you’re probably more likely to sit down and say, ‘You’ve put this medication on the wrong person, what can we do about it?’ And then if they do it again you fill out an incident report, but possibly on the first one you’re less likely to because you’re building a professional relationship and also you have an inexperienced colleague who you can educate.

(Focus group two – Female with 6 years pharmacy experience)

Not knowing the full detail of exactly the entire incident … but if you don’t know, you don’t wanna lay the blame at somebody, so to speak, if they’ve really not been involved and if you don’t know the full

(Focus group two – Female with 3 years pharmacy experience)

**Personal**

A small number of pharmacists, from one of the focus groups, recounted their own personal experiences after being investigated for involvement in a medication error and they were adamant that it had turned into a “witch hunt “and that such investigations, though valid, needed to be performed more sensitively.

But somehow that’s not the attitude that’s taken. There’s a sort of witch-hunt surrounding it; Who did this? Who did that? And it can really affect you and your confidence and how you just feel about everything, if you know that you’ve made a serious error, you know, and it’s being investigated, it’s horrible

(Focus group one – Female with 13 years pharmacy experience)

It was clear that such an experience could cloud decisions to report medication errors in the future.

**Seniority**

There was an agreement amongst participants, including the more senior ones that junior pharmacists would have greater concerns about reporting more senior health professionals involved in medication errors.
As a band 6 or band 7 it’s very intimidating when you’re working with senior doctors, to be filling out forms, when you’re just looking like you’re picking up errors
(Focus group three – Female with 6 years pharmacy experience)

I just say, ‘I’m gonna complete one anyway.’ And I don’t ask them for permission any more, I just do it. I can see why a more junior graded pharmacist would have hesitation
(Focus group three – Male with 22 years pharmacy experience)

Examples were cited where senior doctors and nurses made it quite clear that they did not think the pharmacist should be reporting the medication error, which further exemplified the strain that reporting errors applies to professional relationships.

I made .. an unfortunate error of suggesting to a senior doctor that he fill out an incident report on something that had happened on a ward and had my head bitten off
(Focus group two – Female with 6 years pharmacy experience)

I also think it is about maintaining a professional….some of the pharmacists have had an extreme difficulty with consultants and nurse managers saying you shouldn’t fill out, like cos it’s almost some people would see that as a black mark against their department
(Focus group two – Male with 20 years pharmacy experience)

Summary

Hospital pharmacists work very hard to be accepted as equal partners in multidisciplinary clinical teams$^{159,160}$ and to not be seen as “policemen”.$^{161}$ It was extremely clear that pharmacists worried about the effects of reporting medication errors on these relationships. Unless the pharmacist was comfortable that the team they worked within was prepared for and wanted them to report the medication errors that occur there was a real hesitancy about reporting. Pharmacists understood the tensions created by medication error reports and they have adopted strategies to try to reduce this conflict such as educating prescribers about their actions. However pharmacists of all grades appeared to sometimes choose not to report medication errors because of these anxieties.
Tensions appeared to be greatest where senior medical and nursing staff have openly tried to discourage pharmacists from reporting.
Personal fears about reporting medication errors were only raised by pharmacists in one focus group where a stressful departmental investigation had recently occurred. This is in contrast to the literature regarding medical and nursing staff where personal fears are one of the most important barriers to reporting errors.

4.1.4 Theme 3: Incident

Perhaps unsurprisingly the nature of the medication errors themselves was the most frequently identified issue that influenced pharmacists’ decisions to report a medication incident or not. This theme is subdivided into 8 sub themes.

Severity (actual versus potential harm)

The vast majority of participants were in no doubt that the actual severity of a medication error overrides everything else when considering reporting.
Due to the prevalence of errors and associated workload pressures already discussed hospital pharmacists first think whether the patient came to, or could have come to, any harm before considering whether to report.

*I think if it’d actually been an actual harm to the patient or a significant, what I thought was a significant near miss*
(Focus group three – Male with 4 years pharmacy experience)

*I go on severity. Like today I had a penicillin allergic patient given Augmentin and it turns out she wasn’t penicillin allergic but to me that could’ve been really serious and could’ve resulted in definite patient harm if not death Report kind of incidents that either were, like happened and were severe or quite serious near misses.*
(Focus group two – Female with 3 years pharmacy experience)

An interesting analogy regarding severity was drawn with which adverse drug reactions should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA).
I mean I always think of things in terms of could it prolong their stay in hospital or could it ...similar to, I suppose, the adverse drug reactions really, where, you know, if it resulted in or prolonged hospital admission or caused them some damage of some description.

(Focus group one – Female with 18 years pharmacy experience)

The importance of always reporting “near miss” errors was however questioned given the amount of effort involved in reporting medication errors.

Like unless something’s happened and it’s caused harm you don’t see it as an incident and it’s not like worth creating a lot of hassle for something that hasn’t actually caused any harm or done anything

(Focus group one – Female with 1 year’s pharmacy experience)

This issue about not reporting errors with only a potential for patient harm was also identified as being probably being unfair to both patients and health professionals.

I think every time it comes to severity, you’re doing it for the patient, aren’t you...so those ones, the severity, all driven by this is a particularly serious event that you can’t not report it. you shouldn’t make any difference, all patients should be cared for absolutely, but if you think about it being your relative, even the most minor medication error becomes hugely significant

(Focus group four – Female with 2 years pharmacy experience)

Not fair to the person who’s been unfortunate enough to make the serious error. Cos you are pillorying them and you’re ignoring someone else who might have made three times as many errors that were minor

(Focus group one – Female with 13 years pharmacy experience)

These were both extremely valid points, which other focus group participants understood, but essentially dismissed due to the sheer scale of the problem and the practical need to target which errors are reported.

A number of other sub themes emerged that indirectly linked the severity of the incident with the consideration to report, namely the drug itself, repetition of the error and system or omission type errors.
Drug

It was clear that the drug or the dose of the drug involved in a medication error is part of the decision making process regarding harm or potential harm from a medication error.

*If I dispense the wrong strength of ketovite ..really even if you’ve given it to a tiny baby it wouldn’t have mattered, but because it was vancomycin it could’ve ..given somebody like permanent renal failur*e

(Focus group one – Female with 18 years pharmacy experience)

The counter argument was again highlighted, by the same focus group who hypothesised that all errors should be reported, regardless of severity due to the belief that otherwise it was unfair to the health professionals involved.

*But methotrexate 2.5 and methotrexate 10 is exactly the same relationship as atenolol 25 and atenolol 100 but the results of muddling them up aren’t the same, but it’s the same error, so really you should be reporting them as an error type. That’s what I always feel .. I wouldn’t report the atenolol but really you should because it's exactly the same thing, isn’t it.*

(Focus group one – Female with 13 years pharmacy experience)

Repetition

The issue of repeated errors by the same individual or by multiple individuals was also raised as affecting pharmacists’ thought processes regarding severity.

*I don’t know how I would define significant, but something that I’d maybe seen a trend of, that might make me start thinking, ‘This is a trend I’m seeing, unless I start reporting this nobody else is going to see this*

(Focus group three – Male with 4 years pharmacy experience)

*cos if you know a doctor who, on a regular occasion, makes the same error and if you don’t fill out an incident form they’re never gonna get pulled up, whereas if you do fill an incident form then they might.*
System errors

Some participants appeared to have more confidence in the reporting of errors where they perceived the system involved could and should be changed for the better.

*I do believe that you can actually change things by reporting...I think I probably am tending more towards system error than an individual person has got mixed up and missed off a drug or made a sort of error in prescribing something that's not minor*

(Focus group one – Female with 18 years pharmacy experience)

*The poor patient had brought all their meds into the hospital and we’d lost them. So like they had, they needed to dispense sixteen medicines because of a breakdown in their system, and to me that’s a classic one that you would report because your department would benefit from it, the patient would benefit from it*

(Focus group two – Male with 20 years pharmacy experience)

Omission errors

The increasing importance of medicines reconciliation, the process of pharmacists establishing and documenting exactly what medicines a patient takes on admission to hospital was additionally identified by participants as a reason why the nature of the error was so key when considering reporting.

*Cos if we reported every time something was missed off a patient’s drug history we’d probably make a report about every patient...*

(Focus group four – Female with 2 years pharmacy experience)

Other sub themes regarding the incident itself included the need for justification, whether it occurred internal or external to the pharmacy department and personal judgements about whether to report.
Justification

The practice of reporting incidents to justify one's actions or to cover oneself was highlighted but appeared to be in response to a culture within the hospital, and the need to conform with this practice.

I think if you think something's gonna come back at you as well and you kind of want, I know it's not the attitude to have but if you know something's going to come back at you, well, I want an incident report form done, one, to put my side of the case forward and it's documented and it's down and it's there
(Focus group two – Female with 3 years pharmacy experience)

I would often go by what the patient was like as well, if I know they're an obstructive....it's defensive because you know they're gonna cause a problem, they're gonna probably bring in PALS or liaison people, so you do, again, you cover your back
(Focus group two – Female with 4 years pharmacy experience)

Internal versus external to pharmacy

Two of the focus groups mentioned that reporting behaviours were different depending whether the incident occurred within the pharmacy department or not. This appeared to reflect the difference in safety culture inside and outside the pharmacy department.

If we got a dispensing that said 'Metformin MR' and the box was plain with an MR label on a ward we would fill in a Trust form cos we’d found that. But when the doctors prescribed plain and we later find out that they’re on MR we don’t fill out an incident form for that, which is, that’s exactly the same error
(Focus group one – Female with 13 years pharmacy experience)

Negligence

There was some discussion that evidence of negligence by a doctor might make a pharmacist more likely to report a prescribing error, and that if a recurring problem this might be helpful in an assessment of “fitness to practice”.

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If there’s any sort of suspicion that it might be negligence….but you go through the process in your mind, thinking, is this just an honest omission or is this dangerous?

(Focus group three– Male with 11 years pharmacy experience)

**Personal judgement**

It was quite clear from all focus group participants that each pharmacist held different thresholds for reporting medication errors dependent on a particular set of circumstances affected by the sub themes identified above.

*The classic is everybody’s got different thresholds for reporting different things…It probably varies on the day of the week and it varies on your mood ..and it may be less on a Sunday than on a Monday*

(Focus group two – Male with 20 years pharmacy experience)

...comes down to that subjective assessment of what’s the consequence or could’ve been the consequence

(Focus group one– Female with 18 years pharmacy experience)

There was also an understanding that a pharmacist’s beliefs and/or experiences may tarnish their reporting threshold and that may be they should think less, report more and let somebody else decide if or what action needs to be taken.

*Because it’s your bug-bear you’ve kind of blown it out of all proportion and sort of you think it’s much worse than it is or better*

(Focus group one– Female with 18 years pharmacy experience)

*So maybe I’m kind of thinking, oh, they can’t do much about that. Whereas I should be letting someone else think that or decide what can be done and what actions can be taken, rather than me deciding on my own.*

(Focus group one– Female with 1 year’s pharmacy experience)
Summary

The severity of the incident itself (i.e. actual harm or potentially serious harm) appeared to be the primary issue for hospital pharmacists when considering reporting a medication error. They appeared most likely to be motivated to report with a drug with: a) potential for serious harm b) a pattern of repetition or negligence by an individual or multiple health professionals c) a perceived systems type error.

Incidents with only a potential for patient harm (including prescribing omission errors on admission to hospital detected through medicines reconciliation) were generally accepted as being as important in theory, but just occurring too frequently to be reported with any regularity. The injustice to both patients and health professionals and the failure to possibly identify patterns of error by not reporting were however accepted as negatives to this approach.

Participants highlighted a practice of sometimes reporting an incident to justify themselves and being more likely to report the same type of error made by pharmacists in the dispensary, rather than by doctors on ward. These both appear to refer back to the sub themes of a blame culture in some hospital working environments and anxieties about reporting other health professionals.

Overall there was an acceptance that:

- all hospital pharmacists have different thresholds for reporting the same medication errors, which includes a complex and subjective assessment
- ideally hospital pharmacists should report more and leave the thinking about the need for possible action to somebody who has access to all reports

4.1.5 Theme 4: System

Although three of the hospitals had more than one paper reporting form for reporting medication errors and one just had a single electronic form 5 sub themes about reporting systems per se were identified.

Dataset

There was a belief that the reporting system, paper or electronic, was not user-friendly and too complex, unless it was designed specifically for reporting medication errors. Requests for information such as witness of the incident, e-mail address of the person involved were
perceived as unnecessary and contributed to pharmacists not filling in as many reports as they might do.

*Because of the time and the effort and the complicatedness of the form that we don’t tend to fill in as many*

(Focus group two– Male with 4 years pharmacy experience)

Pharmacists are trained to be very “detail conscious” and participants agreed that if pharmacists were going to complete an incident they would spend additional time making sure they had all the necessary details, rather than submitting an incomplete form.

*Balance between what data-set is workable, because pharmacists being pharmacists, give us a form, there’s sixty boxes on it, we’ll attempt to fill sixty boxes because that’s what we do*

(Focus group two– Male with 20 years pharmacy experience)

*If you’ve forgotten a little bit of the detail and you can’t complete the form, then you sort of… oh well…*

(Focus group four – Female with 1 year’s pharmacy experience)

**Time**

The frustration about all the information required to report an incident seemed to directly affect pharmacist views about the excessive amount of time needed to complete an incident form.

*Cumbersome…there’s a lot of bits and pieces to fill in, which I can appreciate that you need to be able to analyse the situation, but I find it quite time consuming*

(Focus group four– Female with 1 year’s pharmacy experience)

*Not knowing the full detail of exactly the entire incident … Because you think, I’m gonna have to go back and look through all the notes, blah-blah-blah, and again it’s probably a time thing but if you don’t know, you don’t wanna lay the blame at somebody, so to speak, if they’ve really not been involved and if you don’t know the full*

(Focus group two– Female with 3 years pharmacy experience)
Interestingly the theme of anxiety about reporting and its effect on professional relationships seems to be linked and pharmacists admitted that they would rather spend additional time getting the details correct before risking blaming anyone for an error.

**Paper versus electronic**

In the one trust where an online reporting system was used the participants disagreed about whether electronic reporting was quicker or easier. One pharmacist thought the paper system would be easier. Another pharmacist, who had worked in hospitals with both paper and electronic reporting systems, understood the value of the electronic system in producing consistent information.

*I think the online, online’s the way to go. Like other places I’ve worked I’ve had like, honestly, the A3 size things.. It’s essentially the same sort of questions it asks, and there’s a red, amber, green, and if it’s red this needs to be reported directly to your head of department and things. But that, I find that ridiculous, that’s just like long-winded and total waste of paper.*

(Focus group four– Female with 2 years pharmacy experience)

**Form confusion**

In the three hospitals which had more than one type of incident reporting form it was apparent that pharmacists had different views about which form should be used when,

*If it’s like a serious one I’ll do both but I tend to find I do the pink one.*

(Focus group two– Female with 3 years pharmacy experience)

*Well, if it’s a serious one surely you should just be filling in a clinical incident*  
(Focus group two– Male with 4 years pharmacy experience)

and that “pharmacists shy away from the process because they don’t understand that”.
Anonymity

One of the trusts had a hospital wide anonymous reporting system which they believed was fundamental to good reporting culture (see improvements theme). In one of the other trusts the junior pharmacists felt that it did not matter if you could report anonymously, as it was inevitable that the person involved would know that the ward pharmacist had reported them.

You don't put names, but they'll know. They'll know who reported you….

(Focus group four - Female with 2 years pharmacy experience)

They also thought that if you did not report the name of patient involved it would be unhelpful for investigating the problem, and may prevent the identification of a repetitive problem with a particular health professional.

Summary

Incident reporting forms not exclusively designed to medication error reporting were felt to be cumbersome and had too many unnecessary fields that had to be completed. As pharmacists are trained to be extremely detail conscious this appears to mean that they either; don't complete the forms due to the amount of time needed; or because of anxieties about professional relationships they go to great lengths to complete the form to make sure they do not incriminate a health professional incorrectly. The presence of more than one incident form appeared to cause misunderstanding and confusion about which types of errors should be reported, and on what forms. There was disagreement about the importance of anonymous reporting, with junior pharmacists confident that health professionals would know anyway if their ward pharmacist had reported them. Participants who had been exposed to an electronic reporting system disagreed whether it would be easier than a paper system.

4.1.6 Theme 5 : Learning

The patient safety guru Lucian Leape asserts that one of the greatest barriers to health professionals reporting errors is a lack of positive outcomes or perceived learning from the incidents they report.\textsuperscript{162} This theme of learning, or lack of, is subdivided into 5 sub themes.
Improve patient safety/care

The focus groups were asked about the benefits of reporting medication errors and they all stated that, despite all the concerns about reporting, it was all about trying to improve patient safety and thus patient care.

*A tool to improve the management of patient care, to improve the quality of what we do and improve the experience of the patients going through the system*

(Focus group three– Male with 22 years pharmacy experience)

*I think they do protect patients in the long run*

(Focus group two– Female with 4 years pharmacy experience)

Aligned with previous sub themes about pharmacists being more likely to report systems and repetitive errors participants were clear that reporting was necessary to identify a safety problem, to allow efforts to then be made to prevent re-occurrence.

*The useful thing that I find from the incident reporting is that we can identify trends, you know, in a general area, rather than just saying we do something badly, we can pinpoint why, where and when we do things badly, and start trying to focus on maybe smaller parts of the process rather than just being overwhelmed.*

(Focus group three– Male with 4 years pharmacy experience)

*Essentially it’s there, isn’t it, for changes, and to flag up trends or any preventable sort of errors in medication, be it like prescribing or administration*

(Focus group four – Female with 2 years pharmacy experience)

It was recognised that preventing repetition was important at both ward/department level and at a hospital wide level, depending on the type of error.

*I think it does influence change, in a sense. Because if you did report a missed dose and it was something really important, some antiepileptics or antibiotics or something, and a patient could’ve come to real harm from it, then it is fed back to the ward sister and it is fed back….they’re then gonna go and find the people, aren’t they, and do something about*
it, cos they don’t want to have more reports coming in about their staff members under their leadership
(Focus group four – Female with 1 year’s pharmacy experience)

Obviously it’s really important that this doesn’t happen again and if you didn’t know then that means lots of other people didn’t know about this and so I have to fill this form in to make sure that this gets identified by the Trust, so that it doesn’t happen and other people get warned about this
(Focus group one – Female with 18 years pharmacy experience)

Positive feedback

Interestingly only two of the focus groups admitted that they had ever received feedback about medication errors that had been reported, either at a personal or departmental level.

Ones are coming back to me and we are, I’ve got to feed them back to the weekly staff meetings
(Focus group two– Female with 5 years pharmacy experience)

X often has a chat with people to see what could we do differently, how could we improve it?
(Focus group three – Male with 11 years pharmacy experience)

Reporter confidence

The focus group at the hospital most positive about reporting medication errors was convinced that keeping pharmacy staff well informed about the positive reasons for reporting, and actively supporting them in making decisions about reporting, had been crucial in improving reporting rates.

I think we’ve done a good job in explaining the benefits of why we’re doing it, it’s not just to come and hit you with a big stick, you know, and tell you what you’re doing wrong
(Focus group three – Male with 11 years pharmacy experience)
I can see why a more junior graded pharmacist would have hesitation but I think we would offer them enough support within the department, either directly through line manager or through medicines safety department, to try and encourage them to complete forms wherever they feel it’s appropriate, and if they had any hesitation or doubt they would come to us, discuss it, and then we would go and support them to complete the necessary forms. So I think we give support at an early stage for people.

(Focus group three – Male with 22 years pharmacy experience)

A more junior pharmacist at that hospital, who had previously worked at a different hospital, was very positive about the benefits of reflective learning used within that pharmacy department and felt that it had made a great difference to their confidence in reporting.

Reflective learning...encourages you to find the reasons why. It doesn’t have, ‘because you’re an idiot.’ on the list of reasons why the mistake was made, it’s ‘Was it busy?’ ‘What else was going on?’ ‘What pressures were on you?’ And you start looking at the way you work

(Focus group three – Male with 4 years pharmacy experience)

Changes in practice

When challenged to think about changes to practice made as a result of medication error reporting the two focus groups that were less positive were however able to give examples of change or some positive feedback that induced change.

We have now got a much better relationship with the medical staff as trainers and tutors, after a fairly large prescribing error. They then saw us as a source of information that they weren’t using and we’ve become much more involved in induction and actually doing a bit of teaching of prescribing.

(Focus group one – Female with 18 years pharmacy experience)

It’s to show that we’re needed and then we get more funding for more pharmacists Which is actually a reason that we’ve been told. That’s true. . That’s what we’ve been told, report as much as you can because it shows the job that we’re doing.

(Focus group four – Female with 2 years pharmacy experience)
The other more positive focus groups were proud of the fact that processes had been changed, both in the pharmacy department and at ward level, due to reporting, even to the extent that a new pharmacist post had been created.

*We’ve got a massive, or we’ve got a major pedigree of like changing things in terms of prescribing, as a result of people flagging issues up and like the issues could be flagged up in a multitude of ways but a clinical incident form might be one of the ways that are used to kind of like flag that up*

(Focus group two – Male with 20 years pharmacy experience)

*Post was created on the back of incident reporting around anticoagulation errors*

(Focus group three – Male with 22 years pharmacy experience)

**Inaction**

It was evident that in the two pharmacy departments with the lack of feedback and visible changes in practices there was frustration about the perceived inaction.

*If I came across that doctor the only way I would’ve known this was a problem would be if they’d happened to mention it to me on more of a social chit-chat thing, rather than any kind of formal feedback, and I do think that's a problem.*

(Focus group one – Female with 18 years pharmacy experience)

*I don’t know how it works afterwards, I don’t know how much, does a team come and look at the notes and look at the patient cardex for them? I don’t know how it’s followed up really. I know they’re emailed out to loads of people, I’m not sure what the follow up procedure is….you never get feedback on ones you’ve reported yourself*

(Focus group four – Female with 1 year’s pharmacy experience)

Even one of the relatively positive groups however intimated that their department was not as good as it used to be at taking action, and were concerned about the negative message that it sent to new pharmacists about reporting medication errors.
I think that's a major, like a major deterrent to doing it, if you don’t think anything’s gonna happen why waste your time filling one out? If you don’t think anyone’s gonna read it.
(Focus group two – Female with 6 years pharmacy experience)

If you know that nothing’s gonna be done about it really there’s gonna be no benefit from reporting and .. you don’t
(Focus group two – Female with 5 years pharmacy experience)

Summary

There was universal agreement between participants about the theoretical benefits of reporting to improve medication safety by identifying persistent problems, to which solutions could then be found.

There was however a clear split between the focus groups and their experiences about positive feedback and change following reported errors. Two of the focus groups described their frustration at not receiving formal feedback about errors reported and even struggled to detail any positive changes that had occurred as a result of the error reporting. By contrast two focus groups were proud of the positive changes that had been made as a result of error reporting, even resulting in the funding of an additional pharmacist post.

Confidence in reporting medication errors was unmistakable in those pharmacists who worked, or had worked, in a hospital pharmacy department demonstrating the positive benefits of reporting and supporting their pharmacists to feel comfortable to do so.

4.1.7 Theme 6 : Patients’ Views

Participants were asked specifically what their views were regarding patient attitudes to hospital pharmacists reporting errors. This was an area that had not been considered in the literature and was deemed an important question given the modern NHS mantra of “patient empowerment”163. Most participants admitted that this was something that they had not really thought about and opinions were divided, but 3 sub themes were identified.
Patient beliefs

The positive view was that patients are sympathetic to human errors and would think it was a pharmacist’s responsibility to report medication errors. A more negative view was that patients think there is too much paperwork and bureaucracy in hospitals and either do not have a strong view about reporting errors, as long as lessons are learnt, or have a perception that health professionals “cover things up” when errors are made.

Relationships with Health Professionals

The topic of professional relationships was again identified and there was a belief that a patient’s relationship with their doctor or nurse probably played a part in their attitude to pharmacists reporting medication errors.

*I think that it’s different with my patients because we know them quite well, we have quite a small group of patients and they come in a lot’ They’d say, ‘Oh yes.’ If I went and said that such and such a nurse has made a mistake with your medication so I’m going to fill in a form about it, she’d say, ‘Oh no, don’t.’ I think it would be because they feel like they have a relationship with that professional and they don’t want to get them into trouble*

(Focus group two – Female with 4 years pharmacy experience)

Empowerment

In one hospital, where the pharmacists were very positive about the benefits of reporting medication errors, there was strong support for the concept of patients getting involved and identifying when medication errors have occurred.

*Actually challenging, empowering the patients to speak up or their relatives to speak up on behalf of the patients…I think we need to do more to encourage them to report to us to then take further onwards, because that will then lead to further improvements in practice*

(Focus group three – Male with 22 years pharmacy experience)

An analogy was drawn with NHS campaigns to empower patients to ask health professionals about important aspects of their care, with the aim of improving compliance
with an intervention to reduce risk of harm and further improve overall levels of care. 164,165

Medicines errors are becoming more recognised now, we’re having this, about empowering the patients with (thrombo-prophylaxis) you know, you get these posters now in your GP’s surgery ‘Are you washing your hands?’ business. Okay. Not every patient will do it, but some will and it only takes a few to kind of kick start the system (Focus group three – Male with 4 years pharmacy experience)

Positive ideas about empowering patients were tempered with an account where the strong views of a patient appeared to result in the unnecessary suspension of a nurse involved in a medication error.

Summary

There was overall ambivalence about what patients thought about hospital pharmacists reporting medication errors, because it that had not really previously been considered by the participants before. However concerns were raised about how professional relationships, this time between the patient and practitioner, might play a part in patients’ attitudes to pharmacists reporting medication errors. One focus group felt that empowering patients to identify medication errors and encouraging health professionals to report them could improve medication practices further.

4.1.8 Theme 7: Improvements

The final theme is a collection of 6 sub themes about how to possibly improve the reporting of medication errors by hospital pharmacists.

Feedback

Building confidence about reporting, through feedback to staff, was the most frequently identified suggestion for improving the reporting of medication errors. Communicating that reporting makes a difference to patient care by learning from mistakes, and is not about castigating the individual health professionals involved, was acknowledged as being vital.
Knowing that what you’re doing is actually being seen, read, heard by someone, and something is actually being done about it. And trying to get rid, trying to promote the open and learning, you know, so that people don’t have this antiquated idea that we’re actually out to get them, that we’re actually trying to do it for the benefit of not only the patient but their ward at the same, or their area at the same time.

(Focus group two – Male with 4 years pharmacy experience)

Sensitive feedback by managers and giving clinical teams the opportunity to find their own solutions was recognised as an important aspect.

Ensure that these things are dealt with sensitively. That managers, or whoever has to handle it are told this, that’s the way they have to deal with it.

(Focus group one – Female with 23 years pharmacy experience)

System failures, professional solutions... if you look at most of the errors that happen are breakdown in system and if you actually get your healthcare professionals to work together and analyse and promote it it’s like sometimes the best solutions come from the least expected source

(Focus group two – Male with 20 years pharmacy experience)

Some pharmacists thought that the issuing of letters to reporters after an incident might help to improve reporting if they were more positive than “Thank you very much we have received your form”.

Targeted reporting

Due to the sheer scale of medication errors in hospitals all participants were in favour of targeted reporting, rather than setting the goal of reporting all medication errors every day.

Probably should do it one week every two or three months, just so that you do have a picture, or a baseline.

(Focus group one – Female with 13 years pharmacy experience)
I personally know I’m more inclined to do it if I know it’s something that’s flagged up for a day, you know, like I’ve mentioned. I think I work better like that. It’s marketed, sort of thing.

(Focus group four – Female with 1 year’s pharmacy experience)

Even the participants at the most positive hospital articulated the need for a clear strategy so that pharmacists knew what they are expected to report, and not report.

People can become a bit snow-blind to kind of multiple reports of lots of things going on without any clear focus about what you’re trying to do to improve it. So targeting certain sub-sections of a Trust for monitoring a specific target is one area, but then deciding what you are gonna report and not gonna report is key.

(Focus group three – Male with 22 years pharmacy experience)

Form simplicity

There was support for the reporting form to be as easy and as quick as possible to complete with a number of ideas suggested to achieve this.

One idea was just completing the simplest of datasets at ward level, using a proforma which could then allow the completion of the full form at a later time, possibly by someone else.

..whether you could have a paper, one side of A4, that you could stick in your own ward folder, so you could carry it round with you, just photocopies of it, which contains all the basic bare information that you need, so that you could quickly, when you’re on a ward, scribble in the necessary information and then when you’d got ten minutes you go and sit at a computer and type it up from the bit of paper on to the system.

(Focus group four – Female with 2 years pharmacy experience)

Another idea using an answer machine again relied on the frontline pharmacist reporting the basic details for somebody else to then investigate. However this was accepted as not being appropriate for serious errors e.g. incorrect chemotherapy.

I think other hospitals, certainly in the past, have just got it on an answer machine, so you pick up the phone and say, ‘This has happened.’ Put the phone down and, well, there’s
your data-set, you’ve got as much as somebody will give and you can then, you can get a lot more reporting because it’s so, so easy and it’s anonymised,

(Focus group two – Male with 20 years pharmacy experience)

**Drug specific forms**

Drug specific error reporting forms, used in one hospital already, were seen as a way to simplify the data capture.

*internal pharmacy form….is something that you could use pretty quickly. You know, I can usually fill one of those in in ten minutes, whereas obviously an IR1, because it is a more formal form takes longer to fill in because you have physically got to find out quite a bit of information to fill it in correctly.*

(Focus group three – Male with 4 years pharmacy experience)

**Technology**

All the participants who currently used paper reporting systems thought that changing to an electronic format would be easier and better at capturing data whilst the pharmacist who had only ever used an electronic reporting system thought that a paper form would be easier! The single pharmacist, who had used both paper and electronic reporting systems, favoured an electronic system as the way forward to improve error reporting.

One other interesting idea was to link the electronic reporting system to the patient’s electronic patient clinical record, to prevent duplication of effort and allow the information to be tagged to that individual patient.

**Anonymity**

Pharmacists from one of the trusts who already had a hospital wide anonymous reporting system believed it had been fundamental in fostering a healthy culture of reporting. However opinions were divided amongst other participants as to whether anonymous reporting would improve medication error reporting.

*I think as well if you had the option not to fill in people’s names, if it was obviously a process error and they were just unlucky in that they were the one that made the error*
(Focus group two – Female with 4 years pharmacy experience)

*I think you’d get more people actually reporting if you made it less official, cos it just seems really, really big when you do it*

(Focus group one – Female with 3 years pharmacy experience)

*But you can’t follow it up unless you know who’s involved, and the whole thing does involve following it up, doesn’t it? If you didn’t have to put your name to it as a reporter, that’s open to abuse as well, isn’t it? I don’t think it would improve the quality though because you just wouldn’t know, wouldn’t be able to follow anything up*

(Focus group one – Female with 13 years pharmacy experience)

**Summary**

The need for pharmacists to not feel chastised by reporting and to receive positive feedback about errors, and any changes subsequently implemented, were regarded as the primary drivers to improve medication error reporting. Given the prevalence of medication errors in hospitals proposals for improving reporting were centred around a simpler reporting system and reliance on targeted reporting by pharmacists. Drug specific error reporting forms with the simplest of datasets were considered the best practical way to improve reporting, with ideas including the use of other staff to fully report errors once the front line pharmacist had collected the basic information. There was general support that electronic forms/systems would be easier than paper ones but divided opinion as to the added benefit of anonymous reporting.

**4.1.9 Focus Groups Summary**

This study found that UK hospital pharmacists understand that is part of their role to report medication errors and ultimately improve patient safety. However due to the “endemic” nature of medication errors and their hospital working environment they just do not report medication errors as often as they would wish. The culture of blame highlighted by others in the past 10 years[^47][^51][^55][^59] is still very much recognised by pharmacists in the NHS in 2009 and there are anxieties about reporting other health professionals due to close working relationships with medical and nursing staff. Hospital pharmacists do seem to have adopted strategies to reduce such tensions, by educating doctors at the time of an
error or just not reporting at all. Personal fears about disciplinary action/ litigation for making an error were limited and are in contrast to work with hospital nursing and medical staff where personal fears were one of the most important barriers to reporting errors.\textsuperscript{32,43}

Once happy to report it is clear that hospital pharmacists all have different personal thresholds for reporting medication errors. Decisions about whether to report include a complex and subjective assessment of the error but serious patient harm is undoubtedly the primary driver. Yet there is an acceptance that such subjective reporting strategies limit the ability to identify hospital wide system and repetition errors.

Reporting forms, unless designed specifically for medication errors are considered too cumbersome and time consuming to complete. The detail conscious nature of pharmacists adds to their anxieties about inter-professional relationships as they feel they have to find out and record every possible detail to ensure they do not incriminate a health professional unnecessarily.

The differences between the focus groups showed clear evidence that positive feedback about errors and witnessing positive changes to systems following errors, rather than poor feedback and inaction encourages pharmacists to feel more confident about reporting.

The key to improving the reporting of medication errors by hospital pharmacists appears to be threefold, and in the following order of importance:

\begin{itemize}
  \item \textbf{1 Confidence:} Personal confidence to report health professional colleagues and overall confidence that they will see positive outcomes from the reports
  \item \textbf{2 Clarity :} Given the endemic nature of medication errors greater clarity about which medication errors should and should not be reported with the use of targeted reporting (cf MHRA ADR reporting)
  \item \textbf{3 Simplicity:} Simpler drug specific reporting forms which might include completion of form by others
\end{itemize}

Given that from 1\textsuperscript{st} April 2010 error reporting is now supposed to be mandatory in the NHS there was some support for empowering patients to both identify medication errors and encourage health professionals to report them in a similar way to DH infection prevention strategies regarding hand washing.
4.2 Theory of Planned Behaviour

4.2.1 Results

In total 284 questionnaires were returned by hospital pharmacists, after two email reminders were sent via the hospitals’ clinical pharmacy managers (180 paper, 104 electronic). Fourteen questionnaires were discarded as they were incomplete.

So in total 270 questionnaires were available for analysis, 179 paper (66.3%) and 91 electronic (33.7%). The overall response rate was 45% (270/596). The demographic characteristics of the participants are shown in Table 7. The majority of respondents were female (79.3%), working primarily in clinical pharmacy roles (83.4%), in either district general (49.2%) or teaching hospitals (43.9%). 161 (61.5%) participants were senior pharmacists, with NHS jobs graded at AfC Band 8 and above. The mean age of the participants was 35.97 (SD 9.59) with a corresponding mean number of years working as a hospital pharmacist of 11.67 (SD 8.79).

The data from the questionnaires was entered into SPSS version 15 and checked for data entry errors and missing data. When the paper surveys were entered into an electronic spreadsheet every tenth questionnaire was checked for transcription errors and none were found. Two items were identified as out of range and the entries changed after checking the original paper copy of the survey. Missing data was investigated using SPSS Missing Value Analysis and in total 631 data items (4.33%), were found to be missing, across all 54 questions. As this constituted less than 5% of the entire data set the impact was considered to be low and so pair wise deletion of missing data was adopted.

The distribution of the independent variables (TPB predictors) was examined using the non-parametric Kolmogorov-Smirnov (KS) test and all the KS values were non-significant indicating satisfactory normality. Visual inspection of the plots also revealed an acceptable normal distribution. Further analysis for outliers identified six cases where the mean AB, SN and PBC scores were all at the extreme of the normal ranges. No visual pattern was obvious but two of the six respondents made comments at the end of the questionnaire which correlated with extreme views e.g. difficulty of reporting PBC score -8 (mean -0.95 SD 2.77) The outlying data was therefore accepted as genuine and not removed or transformed.
Table 7 Demographic characteristics of the hospital pharmacists

<table>
<thead>
<tr>
<th>Demographic</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
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<td>261</td>
<td>35.97</td>
<td>9.59</td>
<td>23-64</td>
</tr>
<tr>
<td>Years of experience</td>
<td>262</td>
<td>11.67</td>
<td>8.79</td>
<td>0-41</td>
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<table>
<thead>
<tr>
<th>Demographic</th>
<th>Classification</th>
<th>Frequency</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
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<td>55</td>
<td>20.7</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>211</td>
<td>79.3</td>
</tr>
<tr>
<td>AFC Job grade</td>
<td>Band 6</td>
<td>41</td>
<td>15.6</td>
</tr>
<tr>
<td></td>
<td>Band 7</td>
<td>54</td>
<td>20.6</td>
</tr>
<tr>
<td></td>
<td>Band 8a</td>
<td>97</td>
<td>37</td>
</tr>
<tr>
<td></td>
<td>Band 8b</td>
<td>39</td>
<td>14.9</td>
</tr>
<tr>
<td></td>
<td>Band 8c</td>
<td>18</td>
<td>6.9</td>
</tr>
<tr>
<td></td>
<td>Band 8d</td>
<td>5</td>
<td>1.9</td>
</tr>
<tr>
<td></td>
<td>Band 9</td>
<td>2</td>
<td>0.8</td>
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<tr>
<td></td>
<td>Locum</td>
<td>6</td>
<td>2.3</td>
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<tr>
<td>Primary role</td>
<td>Clinical</td>
<td>206</td>
<td>83.4</td>
</tr>
<tr>
<td></td>
<td>Dispensary</td>
<td>9</td>
<td>3.6</td>
</tr>
<tr>
<td></td>
<td>Technical</td>
<td>11</td>
<td>4.5</td>
</tr>
<tr>
<td></td>
<td>Medicines Information</td>
<td>12</td>
<td>4.4</td>
</tr>
<tr>
<td></td>
<td>Chief Pharmacist</td>
<td>2</td>
<td>0.8</td>
</tr>
<tr>
<td></td>
<td>Manager</td>
<td>3</td>
<td>1.2</td>
</tr>
<tr>
<td></td>
<td>Medicines Management</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td></td>
<td>Clinical Trials</td>
<td>1</td>
<td>0.4</td>
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<tr>
<td></td>
<td>Education</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td></td>
<td>Governance</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>Type of Hospital</td>
<td>Teaching</td>
<td>116</td>
<td>43.9</td>
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<td></td>
<td>DGH</td>
<td>130</td>
<td>49.2</td>
</tr>
<tr>
<td></td>
<td>Specialist</td>
<td>18</td>
<td>6.8</td>
</tr>
</tbody>
</table>

Table 8 shows the descriptive statistics and the Cronbach \( \alpha \) reliability values for each of the TPB predictors (AB: Attitude to Behaviour, SN: Subjective Norm, PBC: Perceived
Behavioural Control, DN: Descriptive Norm) in addition to the dependent variable, Intention (INT). Respondents showed a strong intention to report medication errors and had strong normative beliefs that others (including other health professionals, patients and risk managers) would want them to report (Subjective Norms), and that their pharmacist colleagues would report such medication errors (Descriptive Norms). Pharmacists also favoured reporting medication errors as a good thing to do (positive AB), but were ambivalent about how difficult it was to report them (PBC). The reliability values for all the variables were low, except for the Subjective Norms. Cronbach alpha values below 0.7 are considered to suggest a less reliable scale, but when dealing with psychological constructs lower values can be expected, because of the diversity of items being measured. \(^{167}\)

Table 8 Descriptive statistics and reliability values for TPB measures

<table>
<thead>
<tr>
<th>Variable</th>
<th>Scale</th>
<th>Mean</th>
<th>Standard deviation</th>
<th>Cronbach Alpha</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attitude to Behaviour</td>
<td>-9 to +9</td>
<td>2.15</td>
<td>1.88</td>
<td>0.37*</td>
</tr>
<tr>
<td>Subjective Norm</td>
<td>-21 to +21</td>
<td>9.39</td>
<td>4.2</td>
<td>0.75</td>
</tr>
<tr>
<td>Perceived Behavioural Control</td>
<td>-21 to +21</td>
<td>-0.95</td>
<td>2.77</td>
<td>0.58</td>
</tr>
<tr>
<td>Descriptive Norm</td>
<td>+1 to +7</td>
<td>6.07</td>
<td>0.97</td>
<td>0.44</td>
</tr>
<tr>
<td>Intention</td>
<td>+1 to +7</td>
<td>6.20</td>
<td>0.79</td>
<td>0.55</td>
</tr>
</tbody>
</table>

* Attitudes 1 and 2 reverse scored

For the reliability analysis of attitude to behaviour, the first two pairs of questions (that reporting increases the awareness of a particular problem, that reporting reduces the risk of harm to another patient in the future) were both reverse scored, as the opposite responses were expected compared with the other items. Cronbach\(^{168}\) suggested that if different factors exist within the same scale then the reliability formula should be performed separately for the groups of items relating to the different factors. Given that the attitudes to behaviour questions included both the benefits of reporting (behaviours 1 and 2) and the fears of reporting (behaviours 3, 4, 5, 6) separate analyses were undertaken, giving an
improved alpha value of 0.54 for the fear of reporting behaviours but the same, 0.37, for the behaviours associated with benefits.

The correlations between each of the TPB predictors and the dependent variable, intention, are shown in Table 9 and there was a moderate relationship between the Attitude to Behaviour (AB), Descriptive Norm (DN) and Perceived Behavioural Control (PBC) with the intention to report medication errors.

Table 9 Pearson’s correlation between TPB variables * P<0.05 **P<0.01

<table>
<thead>
<tr>
<th></th>
<th>Attitude to Behaviour</th>
<th>Subjective Norm</th>
<th>Perceived Behavioural Control</th>
<th>Descriptive Norm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjective Norm</td>
<td>0.25**</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Perceived Behavioural Control</td>
<td>0.17**</td>
<td>0.06</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Descriptive Norm</td>
<td>0.17**</td>
<td>0.17**</td>
<td>0.15*</td>
<td></td>
</tr>
<tr>
<td>Intention</td>
<td>0.32**</td>
<td>0.17*</td>
<td>0.36**</td>
<td>0.38**</td>
</tr>
</tbody>
</table>

For the regression analysis, the variables age and experience were found to be very highly correlated (R=0.86) suggesting multicollinearity and so only experience was used in the final regression model, as this was found to correlate better with intention to report than age. The final regression model is shown in Table 10, R= 0.568, R²=0.323, adjusted R²=0.293 and Durbin Watson =2.042. The coefficients indicated that in descending order Perceived Behavioural Control, Descriptive Norms and Attitudes to Behaviour had statistically significant influence over the intention to report (32% of the variance accounted for overall by the predictors).

Demographic variables (age, gender) usually influence behavioural intention through their influence on the core TPB predictors. However the coefficients showed that respondents’ gender and grade of job had a statistically significant influence over the intention to report medication errors, with more senior pharmacists and female pharmacists...
being more likely to report (+ Beta with significant t value). This may however be due to
the fact that the sample was predominantly made up of female pharmacists. AFC grade
was found to be an independent predictor of intention to report (R= 0.187 p< 0.003)
whereas gender was found to be an independent predictor of both intention to report
(R=0.19 p< 0.003) and Descriptive Norms (R=0.19 p< 0.02). Therefore the Baron Kenney
procedure was used to test for a mediator effect between gender and Descriptive Norms.170
When Descriptive Norms were entered into the Gender-Intention model the beta value was
reduced to a non-statistically significant value. Thus the relationship between gender and
intention to report medication errors is accounted for by the effect of gender on Descriptive
Norms i.e. that female respondents have a stronger intention to report medication errors
because their beliefs about other pharmacists reporting differ from those of male
respondents.

Table 10 Regression coefficients for reporting medication errors * P<0.05 **P<0.01

<table>
<thead>
<tr>
<th>Step</th>
<th>R² change</th>
<th>Predictor</th>
<th>Beta</th>
<th>t</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.1**</td>
<td>Gender</td>
<td>0.28</td>
<td>4.00**</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AFC grade of job</td>
<td>0.23</td>
<td>3.03**</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Primary role</td>
<td>-0.10</td>
<td>-0.152</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hospital type</td>
<td>-0.53</td>
<td>-0.80 ns</td>
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<tr>
<td></td>
<td></td>
<td>Years of hospital experience</td>
<td>0.04</td>
<td>0.51 ns</td>
</tr>
<tr>
<td>2</td>
<td>0.22**</td>
<td>Gender</td>
<td>0.19</td>
<td>3.06**</td>
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<tr>
<td></td>
<td></td>
<td>AFC grade of job</td>
<td>0.19</td>
<td>2.74 **</td>
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<tr>
<td></td>
<td></td>
<td>Primary role</td>
<td>-0.02</td>
<td>-0.35 ns</td>
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<td></td>
<td></td>
<td>Hospital type</td>
<td>-0.03</td>
<td>-0.58 ns</td>
</tr>
<tr>
<td></td>
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<td>Years of hospital experience</td>
<td>0.05</td>
<td>0.79 ns</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Attitude to Behaviour</td>
<td>0.18</td>
<td>2.95*</td>
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<tr>
<td></td>
<td></td>
<td>Subjective Norm</td>
<td>0.06</td>
<td>0.95 ns</td>
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<tr>
<td></td>
<td></td>
<td>Perceived Behavioural Control</td>
<td>0.28</td>
<td>4.65**</td>
</tr>
<tr>
<td></td>
<td></td>
<td>: Descriptive Norm</td>
<td>0.22</td>
<td>3.63**</td>
</tr>
</tbody>
</table>

As Attitudes to Behaviour and Perceived Behavioural Control were both found to predict
the intention to report the medication error in the scenario, the individual beliefs and their
respective regression coefficients were then analysed to determine their individual
Table 11 shows the mean scores for the behavioural beliefs which found that pharmacists were rather equivocal about the possible negative aspects of reporting but strongly endorsed the idea that reporting reduces the chance of similar harm happening to another patient in the future.

Table 11 Mean scores for behavioural beliefs on a scale from -3 (extremely unlikely outcome of reporting medication errors) to +3 (extremely likely outcome of reporting medication errors)

<table>
<thead>
<tr>
<th>Belief</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>BB1 Increases awareness of a problem</td>
<td>0.58</td>
<td>2.48</td>
</tr>
<tr>
<td>BB2 Reduces risk of a similar error</td>
<td>2.13</td>
<td>0.98</td>
</tr>
<tr>
<td>BB3 Risk of litigation for hospital</td>
<td>-0.58</td>
<td>1.52</td>
</tr>
<tr>
<td>BB4 Risk of disciplinary action for prescriber</td>
<td>-0.67</td>
<td>1.46</td>
</tr>
<tr>
<td>BB5 Harms professional relationship</td>
<td>-0.59</td>
<td>1.57</td>
</tr>
<tr>
<td>BB6 Risk of disciplinary action for pharmacist</td>
<td>-0.36</td>
<td>1.58</td>
</tr>
</tbody>
</table>

Table 12 shows that increasing the awareness of medication error problems and reducing the risk of similar harm in the future through reporting errors were both statistically significant predictors of the pharmacist’s intention to report.

Table 12 Regression coefficients of behavioural belief items in the prediction of intention to report medication errors * P<0.05 ** P<0.01

<table>
<thead>
<tr>
<th>R</th>
<th>Adj R²</th>
<th>Predictor</th>
<th>Beta</th>
<th>t</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.33**</td>
<td>0.08</td>
<td>Increases awareness of a problem</td>
<td>0.17</td>
<td>2.76**</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reduces risk of a similar error</td>
<td>0.18</td>
<td>2.76**</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Risk of litigation for hospital</td>
<td>-0.10</td>
<td>-1.44 ns</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Risk of disciplinary action for prescriber</td>
<td>0.10</td>
<td>1.21 ns</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Harms professional relationship</td>
<td>-0.09</td>
<td>-1.40 ns</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Risk of disciplinary action for pharmacist</td>
<td>-0.09</td>
<td>-1.24 ns</td>
</tr>
</tbody>
</table>

Table 13 shows the mean scores for the outcome evaluations associated with the behavioural beliefs and the positive consequences were again more important, and rated
more strongly, than the negative ones. The fear of harming the doctor – pharmacist professional relationship was seen as the most undesirable followed by fears for hospital trust litigation. Concerns about disciplinary action were greater for pharmacists than for doctors.

Comparing the behavioural beliefs with the outcome evaluations suggest that pharmacists think that increased awareness of medication safety problems is important but do not agree that reporting errors will necessarily achieve that.

Table 13 Mean scores for the outcome evaluations on a scale from -3 (extremely undesirable outcome) to +3 (extremely desirable outcome)

<table>
<thead>
<tr>
<th>Outcome evaluation</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>OE1 Increases awareness of a problem</td>
<td>2.63</td>
<td>0.66</td>
</tr>
<tr>
<td>OE2 Reduces risk of a similar error</td>
<td>2.83</td>
<td>0.60</td>
</tr>
<tr>
<td>OE3 Risk of litigation for hospital</td>
<td>-1.32</td>
<td>1.18</td>
</tr>
<tr>
<td>OE4 Risk of disciplinary action for prescriber</td>
<td>-0.47</td>
<td>1.49</td>
</tr>
<tr>
<td>OE5 Harms professional relationship</td>
<td>-1.89</td>
<td>0.95</td>
</tr>
<tr>
<td>OE6 Risk of disciplinary action for pharmacist</td>
<td>-1.21</td>
<td>1.38</td>
</tr>
</tbody>
</table>

Table 14 shows however that the value of increasing awareness of medication error problems and not involving prescribers in disciplinary action are both taken into account when deciding whether to report or not.

Table 14 Regression coefficients of outcome evaluations in the prediction of intention to report medication errors * P<0.05 **P<0.01

<table>
<thead>
<tr>
<th>R Adj R²</th>
<th>Predictor</th>
<th>Beta</th>
<th>t</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.29** 0.06</td>
<td>Increases awareness of a problem</td>
<td>0.18</td>
<td>2.28**</td>
</tr>
<tr>
<td></td>
<td>Reduces risk of a similar error</td>
<td>0.07</td>
<td>1.14 ns</td>
</tr>
<tr>
<td></td>
<td>Risk of litigation for hospital</td>
<td>0.04</td>
<td>0.59 ns</td>
</tr>
<tr>
<td></td>
<td>Risk of disciplinary action for prescriber</td>
<td>-0.19</td>
<td>-2.45*</td>
</tr>
<tr>
<td></td>
<td>Harms professional relationship</td>
<td>-0.11</td>
<td>-1.72ns</td>
</tr>
<tr>
<td></td>
<td>Risk of disciplinary action for pharmacist</td>
<td>0.10</td>
<td>-1.25ns</td>
</tr>
</tbody>
</table>
Table 15 shows the mean scores for the control beliefs that make up Perceived Behavioural Control. The error being a near miss, rather than an error where the patient comes to harm, or personally being under time/workload pressures were all rated as making reporting less likely. The use of a simple reporting form and the presence of a medication safety pharmacist, to assist with the completion of the reports, were rated as making reporting more likely.

Table 15 Mean scores for control beliefs on a scale from -3 (much less likely to report errors) to +3 (much more likely to report errors)

<table>
<thead>
<tr>
<th>Belief</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>CB1 Error outcome (Not serious)</td>
<td>-0.68</td>
<td>1.12</td>
</tr>
<tr>
<td>CB2 Error outcome (Near Miss)</td>
<td>-1.26</td>
<td>1.49</td>
</tr>
<tr>
<td>CB3 Pressures (Time)</td>
<td>-1.62</td>
<td>0.58</td>
</tr>
<tr>
<td>CB4 Pressures (Workload)</td>
<td>-1.69</td>
<td>1.36</td>
</tr>
<tr>
<td>CB5 Reporting form (simple)</td>
<td>1.99</td>
<td>0.92</td>
</tr>
<tr>
<td>CB6 Reporting form (electronic)</td>
<td>0.88</td>
<td>1.30</td>
</tr>
<tr>
<td>CB7 Reporting alternative (Telling prescriber error occurred)</td>
<td>0.48</td>
<td>1.25</td>
</tr>
<tr>
<td>CB8 Reporting alternative (Telling pharmacist error occurred)</td>
<td>0.45</td>
<td>1.10</td>
</tr>
<tr>
<td>CB9 Reporting alternative (Recording in notes)</td>
<td>0.25</td>
<td>1.02</td>
</tr>
<tr>
<td>CB10 Anonymity (identifying prescriber in report)</td>
<td>-0.25</td>
<td>0.98</td>
</tr>
<tr>
<td>CB11 Efficacy of others (Medication safety pharmacist available)</td>
<td>1.6</td>
<td>1.18</td>
</tr>
</tbody>
</table>
Table 16 shows the regression coefficients for the control beliefs which reveals that only the seriousness of the error and the availability of a medication safety pharmacist were statistically significant predictors of the pharmacist’s intention to report.

Table 16 Regression coefficients of control beliefs in the prediction of intention to report medication errors * P<0.05 **P<0.01

<table>
<thead>
<tr>
<th>R</th>
<th>Adj R²</th>
<th>Predictor</th>
<th>Beta</th>
<th>t</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.39**</td>
<td>0.11</td>
<td>Error outcome (Not serious)</td>
<td>0.16</td>
<td>2.35**</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Error outcome (Near Miss)</td>
<td>0.05</td>
<td>0.83 ns</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pressures (Time)</td>
<td>0.06</td>
<td>0.73 ns</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pressures (Workload)</td>
<td>0.02</td>
<td>0.24 ns</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reporting form (simple)</td>
<td>0.07</td>
<td>1.06 ns</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reporting form (electronic)</td>
<td>0.05</td>
<td>0.83 ns</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reporting alternative (Telling prescriber)</td>
<td>-0.02</td>
<td>-0.19 ns</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reporting alternative (Telling pharmacist)</td>
<td>0.09</td>
<td>0.96 ns</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reporting alternative (Recording in notes)</td>
<td>0.12</td>
<td>1.78 ns</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Anonymity (identifying prescriber in report)</td>
<td>0.03</td>
<td>0.56 ns</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Efficacy of others (Safety pharmacist available)</td>
<td>0.14</td>
<td>2.19*</td>
</tr>
</tbody>
</table>
Table 17 shows the mean scores for the frequency ratings that match the control beliefs. These indicate that in daily practice being under time or workload pressures and preventing errors from harming patients occur frequently, as well as influencing the likelihood of reporting.

The presence of a medication safety pharmacist in a hospital pharmacy department, which has been suggested to positively influence reporting rates\textsuperscript{68} appears to be a very rare occurrence, whilst telling prescribers and pharmacists that an error has happened occurs often.

**Table 17 Mean scores for frequency ratings on a scale from 1 (never) to 7 (always)**

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Error outcome (Not serious)</td>
<td>4.43</td>
<td>1.3</td>
</tr>
<tr>
<td>Error outcome (Near Miss)</td>
<td>5.75</td>
<td>0.68</td>
</tr>
<tr>
<td>Pressures (Time)</td>
<td>5.83</td>
<td>0.88</td>
</tr>
<tr>
<td>Pressures (Workload)</td>
<td>5.29</td>
<td>1.00</td>
</tr>
<tr>
<td>Reporting form (simple)</td>
<td>3.56</td>
<td>1.26</td>
</tr>
<tr>
<td>Reporting form (electronic)</td>
<td>3.52</td>
<td>2.35</td>
</tr>
<tr>
<td>Reporting alternative (Telling prescriber error occurred)</td>
<td>5.04</td>
<td>1.21</td>
</tr>
<tr>
<td>Reporting alternative (Telling pharmacist error occurred)</td>
<td>5.11</td>
<td>1.4</td>
</tr>
<tr>
<td>Reporting alternative (Recording in notes)</td>
<td>3.75</td>
<td>1.63</td>
</tr>
<tr>
<td>Anonymity (identifying prescriber in report)</td>
<td>4.27</td>
<td>1.46</td>
</tr>
<tr>
<td>Efficacy of others (Medication safety pharmacist available)</td>
<td>2.31</td>
<td>1.88</td>
</tr>
</tbody>
</table>
Table 18 shows that having a simple reporting form, personally telling the prescriber or pharmacist that an error has occurred, and having to identify the prescriber involved in an error are all statistically significant predictors of the pharmacist’s decision to report. The variable about having to identify the prescriber involved in an error was intended to discover if pharmacists were fearful of actually recording the name of the prescriber, who made the error, on the reporting form (i.e. loss of anonymity for the transgressor). Given that this was not considered important in the control beliefs (mean -0.25) it is possible that its presence here has been confused as meaning the frequency of identifying prescribing error per se, which would be the same as control belief 7.

Table 18 Regression coefficients of frequency ratings in the prediction of intention to report medication errors * P<0.05 **P<0.01

<table>
<thead>
<tr>
<th>R</th>
<th>Adj R²</th>
<th>Predictor</th>
<th>Beta</th>
<th>t</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.46**</td>
<td>0.18</td>
<td>Error outcome (Not serious)</td>
<td>0.00</td>
<td>-0.01 ns</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Error outcome (Near Miss)</td>
<td>0.01</td>
<td>0.17 ns</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pressures (Time)</td>
<td>-0.23</td>
<td>-0.30 ns</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pressures (Workload)</td>
<td>0.01</td>
<td>0.07 ns</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reporting form (simple)</td>
<td>0.26</td>
<td>3.90**</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reporting form (electronic)</td>
<td>0.03</td>
<td>0.58 ns</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reporting alternative (Telling prescriber)</td>
<td>0.19</td>
<td>2.74**</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reporting alternative (Telling pharmacist)</td>
<td>0.15</td>
<td>2.14*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reporting alternative (Recording in notes)</td>
<td>0.05</td>
<td>0.82</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Anonymity (identifying prescriber in report)</td>
<td>0.13</td>
<td>2.04*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Efficacy of others (Pharmacist available)</td>
<td>-0.34</td>
<td>-0.58 ns</td>
</tr>
</tbody>
</table>

4.2.2 Summary of results

On the whole, respondents held very strong intentions to report medication errors and the strongest influences on that intention were the expected benefits of reporting (attitude to behaviour variable), the belief that other pharmacists would report (descriptive norm variable) and the presence of factors that would facilitate or inhibit the act of reporting (perceived behavioural control variable).
The pharmacists’ Agenda for Change (AFC) grade (directly) and gender (indirectly) also had a weaker influences over intention, with senior pharmacists being more likely to report medication errors and female pharmacists having a stronger intention to report medication errors because of their normative beliefs about other pharmacists reporting.

As might be expected increasing awareness about medication safety problems and preventing similar harm in the future were considered to be extremely desirable within the hospital setting, with anxiety about damaging the doctor-pharmacist professional relationship the most undesirable. Both increasing awareness of a medication safety problem and not wishing to cause disciplinary action for doctors actually influenced the pharmacist's intention to report or not.

Pharmacists were equivocal about the negative effects of reporting (disciplinary issues/litigation/harming professional relationships) but strongly agreed that reporting prevented harm to patients due to a similar problem in the future which, together with increasing the awareness of medication errors, was found to influence their intention to report. This might suggest that pharmacists don’t believe that reporting itself increases the awareness of a medication safety problem; even if they think that it will reduce the chance of similar harm to another patient in the future.

Time and workload pressures, which seemed to occur with regularity in hospitals, make the reporting of errors less likely but unexpectedly these pressures did not appear to affect the intention of pharmacists to report the error. The fact that commonly patients come to no harm (i.e. a near miss) also made reporting less likely but crucially the seriousness of the outcome of the error did independently influence their reporting intention.

The presence of a medication safety pharmacist was discovered to be very rare in hospitals but was regarded as possibly making the reporting of medication errors more likely and to influence their decision to report an error.

Participants also agreed that a simple reporting form made reporting errors more likely and though such simple reporting forms are rare in hospitals the frequency of their availability has an influence on intention to report (i.e. if a hospital had a simple reporting form pharmacists might have a greater intention to report).

Finally the results support the widely held belief that unreported medication errors occur frequently in UK hospitals as pharmacists described that they frequently intervened to prevent medication errors occurring, and often told pharmacists and doctors about these errors, the frequency of the latter having an influence on their decision to report.
4.2.3 Qualitative responses

53 respondents added information in the general comments section of the questionnaire. These comments were mapped closely to the themes about medication error reporting identified in the focus groups.

Working environment for reporting (n=21)

The most frequent remarks were about the scale of the problem of medication errors and the time/workload pressures involved in a modern NHS hospital.

“I generally report adverse events if I consider them to be clinically significant..... Time pressure is of concern and whereas previously I have been diligent in reporting...my workload has got to the point where I just do not have this luxury. This is just time management on my time - prioritising my workload so I see all new patients/order medicines for them, do urgent TTOs, follow up previous important interventions and check bloods etc.. By the time this is all complete there is unlikely to be time left to go back and do an adverse report. Maybe a shift in our culture to say this is part of our every day tasks instead of an add on task?? “

31 yr old Male Band 8a

“If we were to report all errors/near misses we find in a day I suppose we would all need about 1-2 hours/day of 'reporting errors' time and I cant see that happening” 30 yr old male Band 8a

“Snapshot audit of 15 patients on an admission ward on a Mon morning showed 13 had some sort of change needed to Rx, so chasing all these Drs up personally would take the rest of the day instead of rectifying the problems” 31 yr old female Band 8a

“Reporting of errors is a timely process in an already busy day. The actual task of doing it is not difficult. There are difficulties with regards to identifying the Rxer, often you cant from the signature” 30 yr old female Band 8b

One very astute comment about the workload issue was made by a relatively junior pharmacist and is worth noting.
“I believe that the enormous level of under-reporting in the UK does us no favours when it comes to recruitment/staffing levels and helps keep our time pressures high”
28 yr old male Band 7

The culture of the hospital’s response to reporting incidents and the way that different professional groups may be treated was also mentioned, with interest in comparing attitudes of other groups.

“nurses/pharmacists are severely penalised for any medication errors they make whereas the medics appear to have no form of disciplinary procedure at all and merely shrug it off!”
33 yr old female Band 8a

“reporting errors made by prescribers does not appear to have much effect, pharmacy staff get disciplined, nursing staff more so” 44 yr old male Band 8b

“A comparator of how other healthcare professionals would report would be of interest”
36 yr old male Band 8b

“Nursing staff will have a different perspective to pharmacy colleagues therefore it is worth considering their point of view” 30 yr old male Band unknown

Anxieties about reporting (n=8)

A number of pharmacists mentioned the current criminal court case around dispensing errors and its likely effect on reporting behaviour and others reported personal fears about litigation and disciplinary proceedings as a consequence of reporting errors.

“Consequence of reporting the error would be very dependent on circumstances that led to it occurring i.e. genuine mistake/negligence, and also the culture of the organisation and individual relationships” 30yr old female Band 8b
“Although reporting is essential, it may automatically lead to litigation within the Trust, which is unfortunate, but it should not pose a conflict to the reporter” 39 yr old female Band 8b

“Prescribers making errors seems acceptable - almost expected - unfortunately some are persecuted for it. For a pharmacist, unfortunately, it is seen to be an unacceptable professional failure resulting in disciplinary processes being invoked; letters on file regarding future performance and withdrawal of non-close mentored working” 47 yr old male Band 8a

“The Elizabeth Lee case has made it far less likely that I would formally report a fellow professional, more likely to let them know in person. Also, how to report? Not a clear system to follow” 30 yr old female Band 7

The incident (n=10)

The seriousness of the medication error was considered to be very important when making decisions about reporting given the number of errors actually encountered but not everybody agreed that pharmacists should be selective about reporting.

“Intention to report medication errors is dependent on the seriousness of the mistake. Non-serious medication errors are deemed as 'normal'. There certainly isn't time to report these types of errors. I tend to report errors more of there is a point to prove i.e. if there is no clinical pharmacist cover or shortage of staff” 28 yr old female Band 7

“Obviously we encounter minor medication errors everyday (doses omitted etc.). If we were to fill out incident forms for every single one them we wouldn't do anything else! “ 30 yr old female Band 8a

“One difficulty pharmacists face is knowing when to report an error e.g. should every medication history error be reported” 31 yr old male Band 8b

“Nature of the reporting 'error' is also complex as pharmacists often make interventions to prevent errors ('near miss') but has an error still occurred due to item being prescribed or missed off at prescription. 3. Serious errors (like the one described) - I would always
report, but 'less serious' might depend on time pressures/ability to follow up” 43 yr old female Band 8a

“I very strongly believe that all errors should be recorded, reporting implies submission to a local or national body and this should be clear” 59 yr old female Band 8b

One comment specifically pointed out that dealing with an outpatient error, as described in the survey, was atypical compared with more usual inpatient error identification.

“Reporting errors on prescriptions form clinics is harder because you are not likely to see the prescriber in your daily work i.e. when in the dispensary I would be less likely to speak to the prescriber whereas if I was working on the ward I would be much more likely to have contact with prescriber and explain the error to them” 29 yr old female Band 7

Error reporting system (n=11)

A number of comments were made about the reporting form itself, and electronic reporting systems were not without criticism.

“Error/Clinical incident form complex to complete” 25 yr old male Band 6

“I would say that having an easy to use, efficient and preferably an electronic error reporting tool would greatly increase the number of medication errors reported” 24 yr old male Band 6

“Error forms are a pain, we have an electronic system in the hospital (Sentinel) but I find its long and unclear, slow. Filling manual error forms while you cover the ward is not practical, time pressures would make it impossible to do on a day by day basis” 30 yr old male Band 8a

“Already use electronic recording of error. System used is time consuming and not easy to enter error quickly” 47 yr old female Band 7

There were also suggestions for an NHS wide reporting system and other ideas on how to improve the reporting system.
“I strongly see a need for a universal medication error reporting system. We are migrating to e-reporting to NRLS using Datix, but I have concerns about the quality of the medication data fields. My Trust has a very strong opinion/policy that medication errors may only be recorded through the general Incident Reporting System and I feel this lacks the sensitivity required for medication errors” 45 yr old male Band 8c

“In terms of ease of reporting errors I believe an answerphone is one of the best methods as you can do at any time and give as much or as little info as you wish without the need for paper or an electronic system” 42 yr old male Band 8c

“I think a medication safety pharmacist post could be combined with the in-house teaching post (to Drs by pharmacists on prescribing). The teaching pharmacists view the errors and liaise with ward pharmacists about areas of weaknesses in prescribing/safety. I think it may be very good practice to record normal or minor medication errors in notes as it is quicker than other error report systems and other staff may view benefits/interventions made by pharmacists” 28 yr old female Band 7

**Learning from errors (n=12)**

Both junior and senior pharmacists seem clear that feedback to staff after errors is not good, which in turn limits learning and may not promote further reporting.

“Dissemination /learning from errors reported not great. Don't find out what errors have been made or have applicable training in area where incidents are reported to address source” 25 yr old male Band 6

“Feedback of errors to reporter = poor +also or others that could learn from it = poor - they are big motivators in reporting in my view e.g. Warfarin in death occurs in ITU, the Div of Surgery (where ITU sits) conduct on RCA the rest of the Trust do not hear anything about it. Surgery learn but not necessarily policy writers, DTC members. Chief P’cist. Things are improving as clearer governance structures are in place but without the 2 things written at the top then reporting will be poor” 34 yr old female Band 8d
“A culmination of reported errors (medication) would be beneficial as a feedback tool both to specific professions and across professions. 2. I would always wish to be informed in an identified error to seek at least to learn from my mistakes and would benefit from learning from others”  26 yr old female Band 6

“Other considerations when deciding whether to report an error may include the response that you receive. I never get to find out what happens about any reports that I send in, just an acknowledgment of the report being received. This does not encourage reporting as I am unsure whether it is a waste of time or if reports are acted on. Also prescribers’ attitudes vary greatly, some are appreciative that you brought it to their attention, others are rude and aggressive. This does not affect whether I make the report but does affect whether I inform them personally of the error”  28 yr old female Band 8a

Patients response (n=1)

A single comment was made about patients’ views about pharmacists reporting medication errors.

“I am unclear as what we are supposed to do about talking about errors to patients: Does the Trust want me to? Do they like to be involved? if so, are we going to bombard them with bureaucracy?”  63 yr old male Band 7

Overall the observations from survey participants had resonance with the focus group conclusions and the final comment sums up the views of the vast majority of pharmacists who left comments and is worth stating its entirety as a summary.

“A colleague recently highlighted a national report on error reporting rates, and we are lower than average. We agreed that this was more likely due to under-reporting than true low error rate. Since then, I have consciously tried to report more errors. However, the form is a pain to use, the process which then follows does not seem to feed back to clinical staff, and I started to feel petty about reporting every tiny intervention. I have started to log minor errors that are caught before they reach the patient in a spreadsheet of my own, shared within our department. Bigger errors are recorded in the spreadsheet and on the Trust's Incident Forms. The biggest problems with the system are the unwieldy process and its paperwork, and the lack of pro-active teaching using the errors that have been reported to inform all clinical staff of pitfalls to be wary of”  35 yr old female Band 8a
Chapter 5: Conclusions

5.1 Study strengths

The published literature about pharmacists’ attitudes to reporting medication errors is very limited. This study is the first ever undertaken in UK hospitals and has included both qualitative and quantitative research methods to establish what pharmacists think about reporting medication errors. The inclusion of pharmacists in both arms of the study from large and small, district and teaching hospitals, and with a range of experience, in predominantly clinical roles strengthens the face validity of these findings. It is therefore likely that they would be generalisable to all UK hospital pharmacists, and possibly non UK hospital pharmacists with similar service configurations. The results may not relate fully to community pharmacy where the doctor/pharmacist relationship and teamwork dynamic is quite different, but given the fears about reporting by community pharmacists\textsuperscript{51,52}, efforts to increase awareness of the positive side of reporting, and simplified guidance about what to report and not report would still be beneficial.

The research is also highly relevant given the recent press reports about criminal sentences for pharmacists making dispensing errors\textsuperscript{148}, the change to mandatory error reporting in all NHS hospitals and the General Medical Council’s EQUIP study findings that 9% of all hospital prescriptions have errors.\textsuperscript{15}

The sample size of the survey was large and the response rate was reasonable for a TPB style questionnaire. The methodologies used, the framework analysis in the focus group and the TPB style questionnaire, were both well recognized research models and therefore strengthen the reliability of these findings.

5.2 Study limitations

One possible overall limitation was that the female to male gender ratio for participants in both arms of the study were skewed towards female pharmacists, but this is representative of the UK pharmacist population.\textsuperscript{158}

Participants in the focus groups were not randomly selected but self-selected, after invitation from their departmental clinical pharmacy manager. Therefore it is possible that the sample may have only included pharmacists prepared to give an opinion on the topic
that was in part about not following hospital guidance, when senior departmental colleagues may have also been present. The focus group moderator was aware of these possible concerns and tried to keep pharmacists at ease when potentially difficult scenarios about errors were described.

The total number of pharmacists participating in the focus groups was relatively small but nonetheless with pharmacists from hospitals with different safety cultures it was sufficient to ensure data saturation and to identify key attitudes to reporting, which then informed the design of the TPB survey.

Although the construction of the TPB survey followed international design guidance there are a number of limitations that should be considered. Firstly the survey only tested the intention of pharmacists to report prescribing errors, not administration or dispensing errors. Whilst this is an accepted limitation it was intentional to only use one medication error scenario in an effort to keep the questionnaire as straightforward as possible as TPB questionnaires are accepted as being difficult to complete. During piloting of the survey pharmacists reported that the questionnaire was “clunky” and non intuitive and took a long time to complete. Comments from survey participants also confirmed that the questionnaire was considered somewhat difficult to complete.

In addition the prescribing scenario used was based on an outpatient prescribing error rather than relating to an inpatient one. This is unlikely to have made a difference in attitudes/intention to report as the error could easily have been made whilst the patient was on the ward. It is accepted however that the professional relationship between a pharmacist discovering an error and an outpatient prescriber is likely to be less well-developed than between a ward clinical pharmacist and a doctor, who work together daily in a multidisciplinary team. This could have influenced respondents’ answers to questions about the act of reporting and possibly harming the professional relationship between pharmacists and doctors.

The internal reliability of the TPB constructs, particularly Attitudes to Behaviour, were lower than expected and this may have influenced the results as measures with low reliabilities can mean an underestimate of the TPB's predictive validity.

5.3 Discussion of overall findings

The focus group results showed that UK hospital pharmacists understood that it is part of their job to improve medication safety for patients through reporting errors. The questionnaire, in addition, clearly showed that hospital pharmacists believed that
increasing the awareness of medication safety problems, and preventing similar harms in the future, is extremely desirable and that reducing the risk of similar errors is a very likely outcome from reporting. Their attitude to reporting behaviour had reasonable correlation with their intention to report, and in particular beliefs about the positive effects of reporting (increasing awareness and reducing risk of similar harm) were found to significantly predict their intention to report. The fact that pharmacists in the survey were ambivalent about the belief that increased awareness of a particular problem was the likely outcome from reporting medication errors was particularly telling. It is possible that this reflects the dichotomy of views from pharmacists in the focus groups. The experience of poor feedback and in-action following errors appeared to make pharmacists less confident about reporting future errors, compared with pharmacists who had experienced positive change after errors had been identified. The lack of feedback following errors was consistently identified in the studies reviewed about barriers to reporting, and there is evidence that improved hospital safety culture produces staff who are less negative about barriers to reporting, leading to increased reporting.\textsuperscript{17,23,32,35}

Pharmacists’ beliefs about the negative attitudes to reporting medication errors (risks of litigation for the hospital, disciplinary action for health professionals) were limited in the survey and showed no value in predicting their intention to report, with the exception of the belief that prescriber involvement in disciplinary procedures was undesirable. Overall this is in line with the views of the focus group participants where, apart from one group of pharmacists who had experienced an internal "witchhunt", getting themselves, doctors or the hospital into trouble was not seen as a concern. This is at variance with nursing\textsuperscript{32-34} and in particular medical fears about the effects of reporting on colleagues\textsuperscript{43-45} which may reflect differences in how health professionals view their respective roles in relation to safety and risk management.

One area where the results of the two research methods diverged was the perceived anxiety that reporting medication errors adversely affected the pharmacist - doctor professional relationship. In the focus groups the vast majority of pharmacists related to situations where pharmacists had, or considered, not reporting a prescribing error because of their relationship with the doctor or team involved, or in deference to seniority. In the TPB survey pharmacists were equivocal about reporting harming these professional relationships. One explanation for this may be that the error example used in the survey was very serious, and not a routine omission type of error that would have been considered more “petty”.

In the survey the perceived behavioural control construct had the strongest correlation with intention to report, with multiple themes that pharmacists believed facilitated or inhibited their reporting. Being under time or workload pressures were identified as making pharmacists less likely to report medication errors but these pressures did not predict the overall intention to report. Pharmacists in the survey reported frequently being under time or workload pressures which were also themes identified through the focus groups, due in part to the prevalence of prescribing errors in hospitals. Pharmacists conceded that the endemic nature of medication errors in hospitals probably led to a “reporter apathy” culture, which in turn led to an acceptance of not reporting. This is a very important barrier to reporting medication errors that appears unique to hospital pharmacists as it does not feature heavily in studies investigating medical and nursing attitudes to reporting errors.

Another key barrier to reporting medication errors identified in both studies was the outcome of the error for the patient. Pharmacists in the survey were less likely to report the error if the patient had not received the incorrect drug, i.e. a near miss, and the seriousness of the error influenced the intention of pharmacists to report. The severity of an incident has been shown to strongly influence whether doctors and nurses report and error or not and could be a very important factor in identifying how to improve the reporting of medication errors. In the focus groups severity of the incident appeared to be the primary concern for hospital pharmacists considering reporting a medication error. However it was clear that for any error, at any given time, pharmacists had different thresholds for reporting and that complex subjective assessments were made based on: actual versus potential harm; the drug involved; repetition or negligence by an individual; repetitive system errors made by multiple health professionals. There was universal agreement however that those simple prescribing errors of omission, discovered as part of the Medicines Reconciliation process, both on admission and discharge, were unlikely to be reported unless serious harm had or was likely to have occurred. It is possible that these decisions about the severity of medication errors serve as a coping strategy for busy hospital pharmacists faced with an excessive number of medicines reconciliation errors on a daily basis. Potentially, hospital pharmacists may need to be given better guidance as to what to report rather than relying on these personal judgements.

The final barriers to reporting medication errors identified were regarding the burden of actually reporting incidents. Pharmacists in the focus groups agreed that general reporting forms were too cumbersome and asked too many irrelevant questions. The survey results
agreed, as simple reporting forms appeared rare in hospitals throughout the sample, but the respondents concurred that a simple reporting form would make reporting errors more likely.

Participants in both studies were unconvinced about the benefits of electronic reporting systems over paper ones. An additional point of interest from the focus groups was the perceived additional time taken by pharmacists to complete an incident form, due to the fact that they were not prepared to fill out the form, and risk upsetting the health professional involved, unless they had found out all the facts about the case. This may seem strange but pharmacists are well known for their attention to detail and are trained to think and operate that way, and so this is a plausible hypothesis for why pharmacists do not like completing error reporting forms. The TPB respondents agreed that the presence of a medication safety pharmacist, to help complete the details of medication error reports, would make reporting more likely and was found to predict intention to report. In fact this perceived behavioural control question about medication safety pharmacists was added to the TPB survey due to the overwhelmingly positive attitude towards medication error reporting displayed in the focus group where such a post existed.

Pharmacists were ambivalent about telling the pharmacist or doctor who had made the error or recording their identity on the reporting form. The recording of medication errors in a patient's clinical notes did also not appear to influence pharmacists’ likelihood of reporting medication errors.

In research including doctors and nurses/midwives the effect of seniority/age on attitudes to reporting was equivocal, however in this study seniority (61.5% of the survey sample had jobs considered as senior posts, Band 8a-9 on the national pay scale) had an independent effect on pharmacists intention to report. This suggested that more senior pharmacists had a stronger intention to report medication errors than their junior colleagues.

Descriptive but not subjective norms were discovered to have a moderate correlation to, and significantly influence, the intention of pharmacists to report medication errors. This suggested that pharmacists have a strong intention to report medication errors due to the belief their peers would do likewise. It does not appear to be due to a desire to please medical/nursing, patients or clinical risk managers, or collective beliefs about whether pharmacists should report or not. Comments from the survey and the focus groups point to the fact hospital pharmacists have never really considered, to date, what patients might think about pharmacists reporting errors or not, and this could be a possible future research target given the success that empowering patients in the NHS has had on improving hand washing by health professionals.\(^{164,165}\) This nevertheless may need careful consideration
given that involving patients may worsen concerns about straining professional relationships.

5.4 Interventions to improve reporting of medication errors by hospital pharmacists

To achieve the third objective of the study the combined results from the focus groups and in particular the TPB survey were used to consider possible interventions to increase the reporting (or reduce under reporting) of medication errors by UK hospital pharmacists. First of all there was a need to briefly review the evidence for changing clinician behaviour.

5.4.1 Over reliance on the TPB model

If only 32% variance of hospital pharmacists’ intention to report medication errors was predicted by TPB predictors then clearly other processes are involved in their overall decision making about whether or not to report. In their review of how to apply social cognition theories to modify clinician behaviours Perkins et al explain that whilst TPB can help to understand behaviour it does not necessarily give the answer of how to change these beliefs or indeed the actual behaviour. They argue, that although TRA/TPB theoretical models are powerful other models are needed that also address the influences of economic, political, organisational and individual factors on health professionals’ behaviour. (see Figure 2)

This concurs with other workers who conclude that intentional control of behaviour is not the whole story and that there is a need to consider other factors that may reduce the impact of intention on behaviour, such as volitional control and habitual control. (Volitional control - people overestimate the amount of control they possess over behaviours. Habitual control - behaviours performed regularly support the development of habits)
Azjen’s suggests that results from TPB models only provide general guidance and do not explain which type of intervention will be the most effective but, as the Attitude to Behaviour and Perceived Behavioural Control constructs were the best predictors of intention to report medication errors, those significant behavioural and control beliefs are the ones that should be targeted to try to improve reporting.

It is also possible that intention, and thus behaviour, can be improved by changing the relative importance of say attitudes, without actually changing attitudes i.e. designing an intervention where hospital pharmacists are encouraged to see the positive side of reporting medication errors.
5.4.2 Evidence for the success of interventions to change clinician behaviour

A limitation to changing clinician behaviour is that there is no guarantee that the intervention will be effective. Although education, audit and feedback, reminders, media campaigns, financial interventions, patient mediated interventions have been used to successfully change patient care\(^{172}\) there is relatively poor evidence to support the best overall strategies to changing clinicians’ behaviour.\(^ {173}\) Even if one knows what contributes to an intention or the behaviour itself\(^ {174}\) one seems to need multifaceted tailored approaches at different levels (i.e the healthcare professional, team, hospital, wider environment).\(^ {172,175}\)

The psychological theory group agreed a set of key theoretical constructs for non-psychology researchers and health service managers to better understand the processes involved in successful and unsuccessful practice change and to help the development of effective intervention strategies.\(^ {176}\) These included 12 domains that explain behaviour change: knowledge; skills; social/professional role and identity; beliefs about capabilities; beliefs about consequences; motivation and goals; memory, attention and decision processes; environmental context and resources; social influences; emotion regulation; behavioural regulation and nature of the behaviour. The authors claim the success of implementing change will be improved by psychological explanation of behavioural change rather than the psychological theoretical models that predict behaviour.

5.4.3 Evidence for improving the reporting of incidents

Very recently there has been increasing evidence that increased incident reporting is associated with a healthy hospital reporting culture\(^ {17}\) and that those hospitals with patient safety programmes perform better overall at adverse event reporting, in terms of a supportive environment, timely distribution and review of incident reports and the range of health professionals reporting.\(^ {177}\)

Braithwaite et al evaluated the introduction of the Australian national electronic reporting system with an online survey of more than 2000 health professionals (nurses 54.5%, doctors 5.5%, allied health professionals 18.5% plus other administrative and IT staff), and provided further evidence that increased reporting is associated with enabling factors, and that decreased reporting is linked to their absence.\(^ {178}\) Participants were asked about reporting frequency, system training, and their experiences of enablers and behaviours to improve reporting which included: accessibility, ease-of-use, security, feedback, workplace reporting culture and overall value of the reporting system. 22.7% of
respondents said they were reporting more, whilst 21.8% of respondents said that they were reporting less since the introduction of the system. Respondents who said they were reporting less were least likely to agree about the value and ease of use of the system. However respondents who said they were reporting more were more likely to believe the system was accessible, easy to use, secure, provide feedback and of overall value.

Evans et al also showed that interventions to reduce the barriers to reporting (through the use of education, simplification of reporting system, feedback about incidents with subsequent positive change) improved incident reporting rates across multiple hospital sites.\(^{179}\) In addition Tuttle et al demonstrated that the introduction of a hospital wide electronic reporting system coupled with a multifaceted educational programme increased the frequency of reported incidents.\(^{180}\)

Other studies have also illustrated that, when accompanied by substantial organisational transformation, voluntary web based reporting systems can lead to better incident reporting.\(^{181,182}\)

### 5.4.4 Evidence for improving the reporting of medication errors

Confidential / anonymous reporting (i.e. name of the reporter withheld) has been shown, on a small scale, to improve medication error reporting by doctors\(^ {183}\) and multiple health professionals\(^ {184}\) whilst, on a larger scale wholesale, multidisciplinary redesign of the medication process has increased medication error reporting rates.\(^ {185,186}\) Most recently Force et al have considered the problem of low reporting of medication errors by nurses and pharmacists in one US hospital.\(^ {187}\) An intensive multidisciplinary educational programme was launched to try to change the perceptions of reporting (i.e. accentuate the positive and not the negative) including the use of thank you letters, with gift cards and lunch passes for reporters, and simplifying the reporting system. The number of reports improved after one year of the programme from 14 to 72 per month.

Peshek et al introduced a voicemail system into one large US hospital where all medication error reports left on the system were then formally reported to the appropriate hospital committee by a dedicated medication safety pharmacist who also then initiated positive changes to the medicines administration systems.\(^ {188}\) One year after its introduction there had been a sixfold increase in the number of near miss medication errors reported each month by pharmacy staff, nurses, doctors and physiotherapists.
5.5 Recommended interventions to improve medication error reporting by hospital pharmacists

As discussed in Chapter 1, the attitudes of doctors and nurses to reporting incidents appear to be generally driven by negative attitudes about why they do not report (barriers), as opposed to positive attitudes about why they should report (benefits).

This study found that, unlike their medical and nursing colleagues, UK hospital pharmacists fully understand that is part of their professional role to report medication errors and hold very strong intentions to report medication errors for the ultimate benefit of improved patient safety. Hospital pharmacists agree with the four perceived barriers to reporting incidents (knowledge, effort, fears, outcomes) to different extents than their professional colleagues, but they also seem to have an additional fifth barrier to reporting, that is size (of the problem). The “endemic” nature of medication errors, with prescribing errors alone occurring in 9% of all hospital prescriptions means that hospital pharmacists, although resolving the errors, just do not report medication errors as often as they would like, and know they should.

The other four barriers, after the size of the problem, are:

Outcome- Pharmacists agreed that reporting medication errors can increase the awareness of medication errors and reduce the risk of similar future errors but there was clear evidence that poor feedback and inaction does not encourage pharmacists to feel confident about reporting.

Fears- The culture of blame was recognised by pharmacists but personal fears about disciplinary action/ litigation were limited and in contrast to the views of nurses and in particular doctors. Their greatest anxieties were about the effects of reporting on their close professional relationships with medical and nursing staff.

Knowledge of what and when to report- Pharmacists were unsure which medication errors to report and all appear to have different personal thresholds for reporting with decisions about whether to report driven primarily by the seriousness of the error (This is inextricably linked with the size of the problem).

Effort- Pharmacists agreed with their professional colleagues that a simpler reporting form would make reporting medication errors more likely.
The key to improved reporting of medication errors by hospital pharmacists therefore appears to be threefold, and in the following order of importance:

1 **Confidence:** Personal confidence to report health professional colleagues and overall confidence that they will see positive outcomes from the reports.

2 **Clarity:** Given the endemic nature of medication errors greater clarity about which medication errors should and should not be reported with the use of targeted reporting.

3 **Simplicity:** Simpler drug specific reporting forms and assistance with the completion of the form by others.

Before explaining these recommendations however there is a need to be clear and pragmatic about what could be achieved locally, within an individual hospital, and what might need national policy change, by the Department of Health or the NPSA, to achieve the aim of improved medication error reporting.

Much has been written about the need to improve patient safety in healthcare and the systemic problems which are not likely to be improved by local organisations and need to be solved by national policies and systems.\(^{189}\) Models to improve patient safety through improving reporting systems have also been proposed with the central theme of education and learning to engage staff.\(^{190}\) Boyle et al have very recently suggested a conceptual model to improve medication incident reporting and learning in community pharmacists.\(^{52}\)

1 **Confidence:**

The primary efforts to improve medication error reporting should be about increasing awareness about the positive effects of a) reporting on system change and b) preventing future harm due to repetitive incidents.

The concept of using incidents in a positive way is not at all new. As far back as 1979 Duran reported that feedback from incidents can encourage staff to help reduce patient harm\(^{191}\) and in 1999 one of the guru’s of patient safety, Lucian Leape, claimed that a lack
of belief that reporting resulted in improvements was the major reason for not reporting errors.\textsuperscript{162} However still now in the twenty first century the importance of feedback about safety problems and their solutions is still considered critical to improve reporting.\textsuperscript{192,193,104,195}

The difference between the focus groups showed that in organisations where pharmacists witnessed positive feedback pharmacists felt more confident about reporting. Intensive multidisciplinary educational programmes to promote medication error reporting have been shown to work in the short term\textsuperscript{185-187} but clearly these types of interventions would have to be introduced locally in hospitals and led enthusiastically perhaps by a Medication Safety team. This team should comprise a lead Medication Safety pharmacist, medical and nursing champions and a clinical risk expert. A good topical analogy about the benefits of continuous education and feedback is the NHS Infection Prevention Programme, in particular the benefits of hand hygiene and prudent use of antibiotics, which have been shown to help reduce Hospital Acquired Infections over the last couple of years.\textsuperscript{196}

Benn and international safety experts have described multiple modes of feedback for improving patient safety (Table 19) and designed a Framework for Safety Action and Information Feedback from Incident Reporting (SAIFIR) which they claim should ensure the development of a “safety conscious and just culture” and therefore promote future reporting of incidents.\textsuperscript{197} These could provide the basis for such a multifaceted campaign to improve feedback about medication error reporting.

Table 19 Five modes of feedback for incident reporting systems with examples of how each may be implemented (Taken from Benn et al\textsuperscript{197})
Increasing the personal confidence of pharmacists to report health professional colleagues is much more difficult. Cohen, the then president of the Institute for Safe Medication Practice, declared that "reporting is fundamental to the broad goal of error reduction and will only occur if practitioners feel safe doing so and it becomes a culturally accepted activity within the healthcare community ....until that culture is embraced by health practitioners reporting will continue to be an untapped resource".\textsuperscript{198} Though such cultural changes may be improved by greater hospital confidence in the benefits of reporting and the introduction of measures to reduce harm\textsuperscript{199}, it is most likely that it will require longer term organisational and national cultural change.

2 Clarity

Given the sheer scale of medication errors and the time/workload pressures for pharmacists in hospitals, greater clarity about which medication errors should, and should not be reported, could be implemented to improve reporting, and more importantly the learning from errors.

This type of targeted reporting may be seen as controversial and, although such a strategy would limit the ability to identify repetitive failure by an individual practitioner or due to a hospital wide system error, it is pragmatically essential. The bottom line is that error reporting is about learning and reducing medication harm and not about establishing the
prevalence of prescribing, dispensing or administration errors (in particular medicines omitted as part of the medicines reconciliation process).

Targeted reporting strategies could be introduced locally (e.g. cyclical reporting of one type of high risk medicine e.g. anticoagulants for 3 months) but it would be more powerful and effective if implemented nationally. The under reporting of medication errors has great parallels with the problems associated with Adverse Drug Reaction (ADR) reporting. The national ADR scheme is nevertheless accepted as an imperfect but very important and reliable early warning system for identifying and preventing reactions (if serious enough to be removed from the marketplace). A comparable medication error reporting hierarchy could be established along similar lines to the MHRA yellow card reporting scheme but still allow for the secondary benefit of reporting, that is to detect incompetence or reckless/malicious practice by a health professional within a local hospital.

**Suggested medication error reporting hierarchy**

Health Professionals should report:

- All serious medication errors for any drugs which are fatal, life-threatening, disabling or incapacitating, result in or prolong hospitalisation, or medically significant

- All medication errors (including near misses) for high risk medicines or medicines under intensive surveillance by the NRLS – (identified by a new symbol in the BNF)

- Any medication errors due to a witnessed repetitive failure by an individual practitioner or because of a system

- All malicious or reckless violation type medication errors (e.g. attempting to intentionally administer an opiate overdose or witnessed prescribing of a toxic drug to a neonate without any attempt to establish patient’s weight/ body surface area)
3 Simplicity

The final answer to improved reporting by pharmacists is the simplicity of the reporting system and interventions should include simpler reporting forms and easier completion of the form.

In the modern NHS electronic reporting systems will inevitably supersede paper ones in all hospitals but pharmacists actually appeared most likely to improve their reporting if the form was designed specifically for drugs. A national electronic reporting form for medication errors already exists\(^\text{200}\) and so a national drive to allow pharmacists to use this system within their hospitals may improve reporting. A good case could be made for a specially tailored medication error form, like the ones already offered for GPs and Anaesthetists.\(^\text{200}\) Any concerns about local hospitals not receiving their own data could easily be eliminated by the ability of confidential bidirectional transfer of the electronic dataset between the NRLS and the hospital site where the error occurred.

The completion of reporting forms is burdensome for all health professionals but pharmacists’ inimitable “detail conscious” nature means that they don’t like completing the forms unless they have found and recorded all the relevant details. The presence of a medication safety pharmacist to help complete the details of medication error reports appeared to be very successful in one of the hospitals that participated in the focus groups and has previously been suggested\(^\text{68}\) and shown to have contributed to improved medication error reporting.\(^\text{188}\) Such a Medication Safety pharmacist could also be the lead pharmacist in the Medication Safety team described above, but alternatively a trained administrative and clerical assistant could enter the details of the error electronically after the details have been collected by the pharmacists or been left on an answer phone.

Another alternative data capture method could be the use of Personal Digital Assistants (PDAs) by hospital pharmacists. There is limited evidence, that PDAs are convenient and easy to use for collecting pharmacy clinical interventions (similar to reporting medication errors)\(^\text{201,202}\) and can actually increase intervention reporting.\(^\text{203,204,205}\) PDAs have been found to be useful for simply and quickly collecting data at the “bed end” for use as a reminder to complete a full intervention form later\(^\text{206}\) and so could be utilised in a model where the medication error report is completed by another person.
5.6 Future Research

This study has raised many questions that could form the basis for further research.

TPB is not the only social cognition model designed to study the behaviour of health professionals and other models which include the effect of habit and trying could be researched to see if the results of this study were replicated.

Observational studies to further explore the reporting behaviour of hospital pharmacists need to be undertaken. This may prove difficult and might be best carried out covertly whilst concurrently studying other less controversial activities e.g. Medicines Reconciliation.

Controlled studies need to be performed to demonstrate if a single or a package of, interventions as described above can show a sustainable improvement in reporting rates by hospital pharmacists.

The views of patients about the reporting of medication errors by pharmacists (or any health professionals), or indeed self reporting of medication errors, is an interesting aspect of reporting that might be worthy of further investigation. This is particularly relevant in 2010 as patient empowerment is very contemporary and patients are encouraged to report ADRs and demand health professionals wash their hands as part of the NHS plans to improve hand hygiene in hospitals.
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Appendix 1

Invitation letter to participate in focus groups

Dear Hospital Pharmacist

**Attitudes to reporting medication errors by hospital pharmacists**

I would like to invite you to participate in a research study exploring the attitudes to reporting medication errors by hospital pharmacists. I am carrying out this study, as part of an MPhil, with Dr Darren Ashcroft at the University of Manchester’s School of Pharmacy and Pharmaceutical Sciences.

Briefly, participation in the study will involve a single focus group with 6-7 other pharmacists from your department, lasting no more than 1 hour. The focus group will be arranged to take place at a time and place that is convenient to you and conducted in a private location.

Further details about the study are given in the attached leaflet, which I would encourage you to read before making up your mind.

The study involves reflection on why hospital pharmacists do or do not report medication errors and it is hoped that participants will find this advantageous, especially due to the importance of lifelong learning and reflective practice. The purpose of the focus group is not intended to judge your behaviour but to give you an opportunity to talk through your beliefs about reporting medication errors. Following the focus groups we intend to design a questionnaire that we can then send to all hospital pharmacists in the North West NHS region about their attitudes to reporting medication errors.

If, after reading the participant information leaflet, you have any other questions or clarifications, please do not hesitate to contact me. If you are interested then please fill in the form attached and return it to your principal clinical pharmacist. This questionnaire provides us with background information so that you can be contacted. All information that you provide will remain strictly confidential.

Thank you for your time

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Pre-focus group questionnaire

Attitudes to reporting medication errors by hospital pharmacists

I am willing to take part in the focus group for this study

Name  ..................................................................................

Post/AFC band  ....................................................................

How long in post (approximately) ..........................................................

Department  ..............................................................................

Address  ..............................................................................

Contact tel. number ...............................................................

Email  ....................................................................................

Bleep  .....................................................................................
Appendix 2

Attitudes to reporting medication errors by hospital pharmacists

Participant Information Sheet (Focus groups)
You are being invited to take part in a focus group. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully to decide whether or not you wish to take part. Ask us if there is anything that is not clear or if you would like more information.

The purpose of this research is:
To examine the attitudes of hospital pharmacists towards reporting medication errors.
To identify how to maximise the capture of medication error reports after understanding the reasons for non-reporting

Why have I been chosen?
You have been asked to participate because you are a hospital pharmacist who regularly provides pharmaceutical care to inpatients and we want to know what makes you decide whether to report or not the medication errors that you discover on a daily basis.

Do I have to take part?
No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your working conditions or rights, in any way.

What will happen to me if I take part?
The focus group will last approximately one hour and will be audio-recorded with your permission. The focus group will be facilitated by a researcher working on the study.

What are the possible disadvantages and risks of taking part?
Although the study focuses on the ways we might be able to increase the reporting of medication errors by pharmacists, it is possible that you may discuss or describe real patient medication errors which may be sensitive; or which may cause you discomfort, embarrassment or upset in front of your peers or more senior pharmacist staff members. We do not wish to cause you discomfort and you may refuse to answer questions or discuss issues at any time, and without giving a reason.

You should also be aware that members of the research team will be operating within their respective codes of professional practice. Therefore should any unreported errors come to light that led to serious patient harm we are obliged to report this to the appropriate personnel in the trust.

Will my taking part in this study be kept confidential?
All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you will have your name removed so that you cannot be recognised from it. With your agreement an audio recording will be made of the focus group. The recording will be transcribed and all names or other aspects which may identify the people involved will be removed and replaced with a code. Only the research team will have access to a key to the codes. In this way all transcripts will be made anonymous and your participation in the study will be kept confidential. The audio recordings will be securely stored in our research base. If things you have said are quoted in presentations, publications or reports, care will be taken so that you cannot be identified.
What will happen to the results of the research study?
The results of this study will be published as a report and in academic journals. Findings may also be reported in presentations given at professional or academic conferences. Details of publications or presentations and copies of reports will be obtainable from the research team, please tell them if you would like to receive a copy of the findings at the end of the study. You will not be identified in any publication.

Who has reviewed this study?
This study has been reviewed by a local Research Ethics committee

Who is funding the research?
The research is being carried out as part of an MPhil

Contact details for the research team
Please feel free to contact me if you have any concerns or questions.
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Thank you for taking the time to read this
Appendix 3

Focus Group Interview Schedule: Attitudes to reporting medication errors by hospital pharmacists

Little is known about what pharmacists think about incident reporting of medication errors. The purpose of this focus group is to explore your experiences of reporting medication errors and your attitudes towards reporting and barriers to not reporting. Confidentiality is assured at all times and information analysed or reported from this interview will not enable anyone to recognise you. The interview will last approximately 50-60 mins and will be taped unless you are opposed to this. The tapes will be kept securely for five years after the study is completed then destroyed.

Do you have any questions before starting the interview?

Part ONE
Background [brief]

Can you tell me your current grade and the number of years that you have been qualified as a pharmacist?

Part TWO
Attitudes to medication error reporting [in depth]

Prompts will be used to obtain more in-depth information as necessary

- What does incident reporting / medication error reporting mean to you?
- What system exists in your hospital for reporting medication errors

Prompts: Does it work well?
Are there any problems with it?
Do you have a pharmacy intervention monitoring scheme as well?
Do you record incidents in the medical notes?
What do you think is an ideal reporting system?

• Are you clear what to report?

  Prompts: Any differences between near misses and actual incident?
  Does the severity of the incident make any difference? Use example
  Are you expected to report all medication errors?
  What dictates whether you actually do or don’t report a medication
  error you come across?

• What do you think is the primary purpose of reporting medication errors?

  Prompts: If we don’t report errors how do we spread the message that
  occurred and work out how to reduce likelihood of happening again?
  Should it not be for the greater good?

• Are you happy to report medication errors?

  Prompts: Any fears and if so what of?
  Any differences between self-reporting and reporting others?
  Any cultural issues?
  Issues about anonymity?

• Can you give me any positive or negative examples of reporting?

  Prompts: Any changes made (or not made) / lessons learnt because of an
  incident?

• What do you think patients’ views would be about whether pharmacists report
  medication errors?

  Prompts: Are you motivated to report for the benefit of patients?

• How often do you report medication errors?

• Why is that hospital pharmacists don’t report medication errors very well?

• Are there any other barriers to reporting medication errors?

  Prompts: Any physical barriers e.g. time to fill out or ease of form

Concluding part

Is there anything else you would like to talk about? Or anything you would like to
go back to or add?
Switch off the tape recorder

I would like to thank you for your time. This interview has been extremely valuable to the research. When the study is completed a summary of the findings will be sent to you if you wish. In the meanwhile please feel free to contact me if you have any questions or other issues would like to discuss.

Post interview

A thank you letter is to be posted to the participant.
## Appendix 4: Initial Thematic Framework

<table>
<thead>
<tr>
<th>Theme</th>
<th>Sub Theme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Culture</td>
<td>Management style</td>
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<tr>
<td></td>
<td>Individual</td>
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<tr>
<td></td>
<td>Job role to report and/or deal with errors</td>
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<td></td>
<td>Blame versus no blame culture</td>
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<tr>
<td></td>
<td>Bureaucratic</td>
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<td></td>
<td>Inter professional differences</td>
</tr>
<tr>
<td>Fear</td>
<td>Personal (job/reputation)</td>
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<td></td>
<td>Other professionals: individual or multidisciplinary team</td>
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<td></td>
<td>Senior versus Junior</td>
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<tr>
<td>Work environment</td>
<td>Bureaucracy</td>
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<td></td>
<td>Workload</td>
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<td></td>
<td>Time pressures</td>
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<td></td>
<td>Relationship: individual versus team</td>
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<tr>
<td>Forms</td>
<td>Time</td>
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<td></td>
<td>Complexity</td>
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<tr>
<td></td>
<td>Process</td>
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<tr>
<td></td>
<td>Dataset (medication versus other error)</td>
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<td></td>
<td>Paper versus electronic</td>
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<td></td>
<td>Aonymous</td>
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<td></td>
<td>Confidential</td>
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<tr>
<td></td>
<td>Confusion</td>
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<tr>
<td>Incident</td>
<td>Actual versus near miss</td>
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<td></td>
<td>Severity</td>
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<td></td>
<td>Internal or external to department</td>
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<td></td>
<td>Medication involved</td>
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<td>Dose involved</td>
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<td></td>
<td>System versus individual error</td>
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<td></td>
<td>Justification (role versus individual action)</td>
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<td></td>
<td>Repetition (same mistake versus same person)</td>
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<tr>
<td>Learning</td>
<td>Dependent on individual</td>
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<td></td>
<td>Dependent on department</td>
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<td></td>
<td>Dependent on multidisciplinary team</td>
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<tr>
<td>Feedback</td>
<td>Positive</td>
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<td></td>
<td>Negative</td>
</tr>
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<td></td>
<td>In-action</td>
</tr>
</tbody>
</table>
Patients
- Improve safety
- Improve care
- Priority (patient care comes first)
- Self reporting
- Expectation

Improvement
- Form filing
- Clarity (what/ when to report)
- Targeted reporting
- Anonymity
- Patient reporting
## Appendix 5: Final Thematic Framework

<table>
<thead>
<tr>
<th>Theme</th>
<th>Sub Theme</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environment</td>
<td>Management</td>
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<tr>
<td></td>
<td>Job role</td>
<td>7</td>
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<td>Blame culture</td>
<td>4</td>
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<td>Inter professional differences</td>
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<td>Workload pressures</td>
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<td>Direct communication</td>
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<td>Anxieties</td>
<td>Personal</td>
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<td>Professional relationships</td>
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<td>Incident</td>
<td>Severity</td>
<td>23</td>
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<td>Internal or external</td>
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<td>Drug</td>
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<td>System error</td>
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<tr>
<td></td>
<td>Justification</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Repetition</td>
<td>3</td>
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<td>Personal judgement</td>
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<td>Omission errors (MR)</td>
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<tr>
<td></td>
<td>Negligence</td>
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<td>System</td>
<td>Time</td>
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<td>Dataset</td>
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<td>Paper versus electronic</td>
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<td>Anonymity</td>
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<td>Form confusion</td>
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<td>Severity scale</td>
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<td>Learning</td>
<td>Change in practice</td>
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<td>In-action</td>
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<tr>
<td></td>
<td>Improve safety/care</td>
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</tr>
<tr>
<td></td>
<td>Reporter confidence</td>
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<tr>
<td></td>
<td>Positive feedback</td>
<td>6</td>
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<tr>
<td></td>
<td>Preventing recurrence</td>
<td>7</td>
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<tr>
<td></td>
<td>Identify safety problem</td>
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<td>Patients</td>
<td>Beliefs</td>
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<tr>
<td>Topic</td>
<td>Score</td>
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<td>-----------------------------</td>
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<tr>
<td>Relationships</td>
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<tr>
<td>Empowerment</td>
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<td>Improvements</td>
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<td>Form simplicity</td>
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<td>Targeted reporting</td>
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<td>Anonymity</td>
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<td>Technology</td>
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<td></td>
</tr>
<tr>
<td>Feedback</td>
<td>9</td>
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<tr>
<td>Drug specific</td>
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### Appendix 6: Table of Themes and Sub themes

#### Environment

<table>
<thead>
<tr>
<th>Tail</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blame culture</td>
<td>Well, it’s supposed to be a no-blame but … you still think that someone’s gonna get in trouble for it cos you have to put down people’s names and things.</td>
</tr>
<tr>
<td>Blame culture</td>
<td>we’ve had doctors who’ve ended up with prescribing rights removed…nursing staff dismissed</td>
</tr>
<tr>
<td>Blame culture</td>
<td>There’s still a stigma associated to ..forms. You just think it’s not a quid pro quo type of thing, is it, it’s just happened and we’re just supposed to be documenting something has happened as opposed to vying off against one another with how many forms we can fill it.</td>
</tr>
<tr>
<td>Blame culture</td>
<td>Associate badness with the form.. As in it’s a critical analysis of them, when it could’ve just been a multitude of things when happened, but by a multitude of departments, and we’re just documenting that and that’s all it is, but people still think, it’s a form, my God, someone’s gonna come down from up on high and shoot me.</td>
</tr>
<tr>
<td>Workload pressures</td>
<td>Time constraints. I mean it’s more important to get your prescription out to the patient than to sit down and write a report.</td>
</tr>
<tr>
<td>Workload pressures</td>
<td>you regard it as a time issue that adds to your workload.</td>
</tr>
<tr>
<td>Workload pressures</td>
<td>… I think it’s workload (barriers)</td>
</tr>
<tr>
<td>Workload pressures</td>
<td>I don’t know whether that actually gets done as much as it should do, because like who has time when you’re in the dispensary…</td>
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<tr>
<td>Workload pressures</td>
<td>Being too busy at times. I know that shouldn’t be an excuse but …</td>
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<tr>
<td>Workload pressures</td>
<td>We should be but are there enough hours in the day?</td>
</tr>
<tr>
<td>Workload pressures</td>
<td>it just seems like another thing to do when you’ve got more pressures and more things to do, so I tend to not do them.</td>
</tr>
<tr>
<td>Workload pressures</td>
<td>I probably won’t report them today either,</td>
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</table>
just I won’t have the time to do it today

Workload pressures Cos if we reported every time something was missed off a patient’s drug history we’d probably make a report about every patient…well, you’d have no time to do anything else.

Workload pressures …report all medication errors? I mean we’d grind to a halt here. So I don’t think in reality they expect us to report everything, cos we actually wouldn’t provide a service.

Workload pressures even though it’s there to implement change and, to possibly implement change, you just know that, especially now over the last couple of months, I mean we were speaking earlier, it’s been so busy, you know it’s shortages of staff.

Workload pressures If you filled in an incident form every single time you’d made an intervention because somebody had made a mistake you’d be filling in...

Workload pressures I think we accept quite a sort of background level of minor errors that maybe we shouldn’t do

Workload pressures I don’t know whether it’s due to fear though, I think it might just be due to a general apathy, possibly.

Job role that’s why I’m here, supposed to be picking up these things

Job role trouble with prescribing errors is that unless they’re so serious that they really could result in harm, you tend to reckon that’s what your job is.

Job role I work as part of a clinical team and I would be assumed to fill in the forms, not so much that we are policing the area, but that is recognised as one of the roles that I carry out

Job role if it’s a medication error the sister or the doctor will come and find me, and I think they just presume, you know, we have the discussion, ‘Shall I fill in the IRI or are you gonna do it?’

Job role obviously they’re orthopaedic surgeons …. they just don’t take very good medication histories, I would under-report quite a lot because it happens all the time, and that’s, to me that’s part of what my job

Job role don’t think that we report them as much cos
<p>| <strong>Job role</strong> | you see it as part of your job to be dealing with this will and be a safety mechanism for the prescribers |
| <strong>Inter professional differences</strong> | the clinicians won’t fill out like a clinical incident forms about prescribing errors or things like that, they will fill out clinical incident forms because x-rays weren’t available |
| <strong>Inter professional differences</strong> | the nursing staff generally think that they’re not for drugs really, because it’s a non-specific form about any incident, clinical or not, fair enough, ……some of that, I think, is patient fell out of bed then there can’t be any apportioning of blame to anybody other than the patient for wriggling around in the bed. I think that’s where they’re quite happy to fill them out, whereas I had to fight my ward because they had a sixty milligram isosorbide tablet, and somebody had gone to give it three mornings in a row and a patient had said, three mornings in a row |
| <strong>Inter professional differences</strong> | when we get the Trust figures pharmacy always have loads and loads of errors,…, it makes us look dreadful, but it’s just because we’re go was notod about reporting them ….whereas everybody else doesn’t, and so we look much worse |
| <strong>Inter professional differences</strong> | I did have an incident where the sister on my ward asked me why I’d filled one in, cos I said it could work both ways, which I did report to my seniors here, because I felt she was saying I shouldn’t be filling them in |
| <strong>Inter professional differences</strong> | though I wasn’t the only person that made a mistake…but the nurses on the ward didn’t get anything like that…. |
| <strong>Inter professional differences</strong> | think there is certainly a perception and probably not an unwarranted one, that the way medical staff are dealt with, treated, approached, when it comes to when an error has happened is a lot different….but I think there is a very, or there seems to be, a light touch approach when it comes to medical staff |
| <strong>Inter professional differences</strong> | I think that the doctors think, see incident forms as punitive. Very definitely Because they’ll say, ‘Oh, you’ve done that, I’m going to fill an incident …’ |</p>
<table>
<thead>
<tr>
<th><strong>Inter professional differences</strong></th>
<th>the doctors will say, ‘This hasn’t happened, therefore I’m going to, I will fill an incident form in.’</th>
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</thead>
<tbody>
<tr>
<td><strong>Inter professional differences</strong></td>
<td>P1 “Oh, this is missing medication, it’s potentially serious, we need to know what may or may not have happened to it, please fill in an incident form before you come down and pick up the duplicate.’ P2 Well, normally they actually find it. If you say ‘Fill in an incident form.’</td>
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<tr>
<td><strong>Inter professional differences</strong></td>
<td>nurses ringing down saying….well, you made a mistake.’… ‘And I’m filling in an incident form.’.. ‘Well, I’ll have to fill in an incident form then.’ And it’s like, ‘I’m telling you that so that you’ll change your mind</td>
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<tr>
<td><strong>Inter professional differences</strong></td>
<td>There are certain people in the Trust... who threaten to do incident forms. Some sisters</td>
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<tr>
<td><strong>Direct communication</strong></td>
<td>there are better ways of dealing with things, that still achieve the same end. Like yesterday.... they could’ve filled a incident form in about that, but instead of which we’ve dealt with it, we’ve sorted it, the consultant is informed, the policy’s going to be reviewed, the patient’s, you know, had the treatment that they need, even though it’s not in the guidelines, and .. there’s none of the witch-hunt, kind of nobody’s cross or upset about it and everybody’s like ‘Oh, thanks a lot, we’re gonna sort this out now.’ And that means that the problem is resolved but we didn’t fill an incident form in even though we could’ve.</td>
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<tr>
<td><strong>Direct communication</strong></td>
<td>I’ve always been more successful and I feel much better when I speak to someone and do it that way</td>
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<tr>
<td><strong>Direct communication</strong></td>
<td>I try and do it more verbally on the ward I try and speak to people and sort it out that way..</td>
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<tr>
<td><strong>Management</strong></td>
<td>different managers will have different styles and some managers kind of throughout the organisation will be very supportive and empathetic and understanding and other ones’ll be, well, that guy doing that, and it’s almost like you’re made to feel so small that, like and that will colour your future kind of interaction with kind of incident forms. I think kind of like that’s a major challenge to try and get over.</td>
</tr>
<tr>
<td><strong>Management</strong></td>
<td>we should and I know that x, you know, is</td>
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</table>
always on our cases to report them, because essentially that proves our service warranted and needed.

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<thead>
<tr>
<th>Management</th>
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<tr>
<td>P1 I would always feel confident that as an individual professional I would be supported, certainly by the pharmacy system, I would hope by the Trust system as well, to follow that through, rather than being a lone ranger. I think as a locum, when I used to locum as a junior pharmacist, you’d pick errors up that GPs made regularly and the dispenser would say, ‘Oh, he always does that.’ Do you know what I mean? That kind of thing, and I think, in a way, they’ve probably not tackled incident reporting as well as we have in hospital, have they.</td>
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<tr>
<td>P2 I suppose in the hospital environment it’s where I’m comfortable, it’s where I work, I know how I can help change, bring change about. I know fill an incident report form, that that, yeah, it can be negative but nine times out of ten I’m hoping it’s going to be a positive outcome. (in the community with) a GP, I suppose, I don’t know, it’s outside my comfort zone.</td>
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<tr>
<td>Management</td>
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<tr>
<td>I suppose the people high up in the organisation don’t know of all these errors, do they. They don’t know, do they. They should come round with a pharmacist for the day and see what, how many errors we pick up but don’t report …</td>
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**Anxieties**
<p>| Seniority | As a band 6 or band 7 it’s very intimidating when you’re working with senior doctors, to be filling out forms, when you’re just looking like you’re picking up errors. |
| Seniority | I was a junior, (laughs) and you do maybe feel less confident. |
| Seniority | I just say, ‘I’m gonna complete one anyway.’ And I don’t ask them for permission any more, I just do it. I can see why a more junior graded pharmacist would have hesitation. |
| Seniority | I made .. an unfortunate error of suggesting to a senior doctor that he fill out an incident report on something that had happened on a ward and had my head bitten off. |
| Seniority | I also think it is about maintaining a professional....some of the pharmacists have had an extreme difficulty with consultants and nurse managers saying you shouldn’t fill out, like cos it’s almost some people would see that as a black mark against their department. |
| Personal | But somehow that’s not the attitude that’s taken. There’s a sort of witch-hunt surrounding it; Who did this? Who did that? And it can really affect you and your confidence and how you just feel about everything, if you know that you’ve made a serious error, you know, and it’s being investigated, it’s horrible. |
| Personal | But I still think that things need to be reported but they also need to be dealt with sensitively. |
| Personal | Well, concerned about errors cos you don’t want to be in trouble yourself, to be quite honest about this. |
| Personal | I said to you right at the outset, a concern, personal concern , I think that’s the biggest barrier. |
| Personal | it did feel like a witch-hunt and I really, really was really upset about the way it was handled. I was sort of almost ostracised and made to swap wards and wasn’t allowed to go anywhere without an accuracy checking technician and stuff, I really did feel like it was a witch-hunt. |
| Professional relationships | … or to get, or to get any other member of staff into trouble for anything. |
| Professional relationships | Yes, sometimes somehow you do feel like |</p>
<table>
<thead>
<tr>
<th>Professional relationships</th>
<th>you’re getting people in trouble</th>
</tr>
</thead>
<tbody>
<tr>
<td>if it’s me and I’m filling one in about a doctor, I tend to … tell them that I’m doing it, but not as a kind of, ‘I’m filling an incident form.’ But actually saying, ‘Obviously it’s really important that this doesn’t happen again and if you didn’t know then that means lots of other people didn’t know about this and so I have to fill this form in to make sure that this gets identified by the Trust, so that it doesn’t happen and other people get warned about this. And it’s not against you</td>
<td></td>
</tr>
<tr>
<td>Professional relationships</td>
<td>I don’t like the idea of causing bad working relationship between people, sometimes I think by like shouting and throwing incident forms everywhere that you could create an atmosphere, a little bit of not working together as much</td>
</tr>
<tr>
<td>Professional relationships</td>
<td>P1 it’s just that when you go and say, ‘I’m gonna be filling in an incident form about such and such.’ There’s kind of a look as if to say, ‘You’re a traitor.’…. ‘You’re meant to be on our side, you work on our ward.’</td>
</tr>
<tr>
<td>Professional relationships</td>
<td>what’s gonna happen when you fill out an incident form. Because for us, because it’s drummed into us, we know that means they’re actually gonna look at that process ….whereas for the ward staff if they like … there’s a repercussion, like sort of what we’ve already said, but .. it’s not a fear of what’s gonna happen, it’s just a feeling that the wrong thing’s gonna happen or a misunderstanding’s gonna happen.</td>
</tr>
<tr>
<td>Professional relationships</td>
<td>if you’re, you’ve got a new house officer and they make a mistake and it’s because of their inexperience, you’re probably more likely to sit down and say, ’You’ve put this medication on the wrong person, what can we do about it?’ And then if they do it again you fill out an incident report, but possibly on the first one you’re less likely to because you’re building a professional relationship and also you have an inexperienced colleague who you can educate.</td>
</tr>
<tr>
<td>Professional relationships</td>
<td>you actually want the multidisciplinary team to be working well you’re kind of jeopardising the whole thing by starting playing solo</td>
</tr>
<tr>
<td>Professional relationships</td>
<td>if you’re working in a fairly discrete clinical</td>
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</table>
team, pharmacists have, I think, historically, had difficulty finding a role within a team, finding acceptance of people accepting pharmacists’ roles, and I think sometimes you may be a little cautious about wanting to jeopardise that, particularly if it’s a team that you work closely with.

**Professional relationships**

I think pharmacists are still maybe a bit nervous, unnecessarily, that they feel their role in the team is jeopardised. I know I’ve sometimes thought, you know, if I do that, I’ve done well to get myself valued by the doctors on the ward, and then when you actually do it you actually find that the opposite’s the case, and they actually do respect your opinion more than you probably thought they did.

**Professional relationships**

I would feel more comfortable if it was a team I worked in, but I don’t think the fact that it would be someone else, you know, say for example I was working a weekend or I was on-call, I wouldn’t feel hindered in reporting that, on the basis I would feel I would be jeopardising what I was doing for the patient, on the basis that someone could quite easily make that mistake … you know, we need to get it right for the patient.

**Professional relationships**

I think it’s misused in a lot of ways, in a sense that … they try and flag up incidence, in a sense that they’ll be having a go at someone, and you have to be very careful in how you word things because it’s supposed to be neutral, and it is supposed to be a report rather than a complaint so I think you have to be quite careful.

**Professional relationships**

I find it quite difficult with the relationship I have with the doctors and nurses on the ward also. It’s sometimes deemed as a personal dig if you report it. And I’ve said to them time and time again, ‘It’s not a personal dig I just have to document it. It’s a form of documentation.’ I try to sell it in that way, but … but it’s fed back to the team and it’s flagged up, you know, ‘So and so reported.’ But it’s, ‘So and so dobbed on you.’ Sort of thing.

**Professional relationships**

It’s understandable … I mean they’ve reported me before… but I took that as a personal dig, and I didn’t mean to and I
<table>
<thead>
<tr>
<th>Professional relationships</th>
<th>(I had) a bad reaction to that, so it kind of has put me off reporting it cos it does turn it into a huge great big mess so I kind of wanna view it as my last resort.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional relationships</td>
<td>usually I have a really good relationship with my ward sister, but recently I had like a bit of an altercation with her, because I’d said, ‘Please, we really need to start sorting out some of these missed doses.’ ‘We’re very busy. You don’t know what it’s like, you’re not a nurse.’ It was a bit out of character, she must have been very busy but it does kind of put you off from tackling similar issues.</td>
</tr>
<tr>
<td>Professional relationships</td>
<td>I think it’s the barrier (uncomfortable reporting drs and nurses), the hurdle of sort of, that’s why I don’t report most of the time. And I don’t know how you’d overcome that.</td>
</tr>
<tr>
<td>Professional relationships</td>
<td>I know someone that reports a hell of a lot, and the wards aren’t particularly happy with them), there’s a lot of trouble...and I think one of the nurses actually went up to her, cos she reported them, you know, when she was transferred over, and one of the nurses was like, ‘I know you like your reporting system, but I don’t understand what we’ve done wrong.’</td>
</tr>
<tr>
<td>Professional relationships</td>
<td>I’d be happy, but I’d always, I think, involve the people I’m reporting so then it’s not a shock.</td>
</tr>
<tr>
<td>Professional relationships</td>
<td>It depends on your personality. I don’t like, I’m not a particular fan of conflict and so I don’t like having to cause huge like situations on the ward, when I’m saying, ‘Why wasn’t this dose given?’ I’m being sort of the policeman for a situation...think would put me off from reporting.</td>
</tr>
<tr>
<td>Professional relationships</td>
<td>It was a prescribing error, so the doses were ten times the amount that they should’ve been but the nurse still gave the correct dose but never got the doctor to change it. I reported that... but the sister called me and asked me, ‘What happened? Why have you reported it?’ And she got her back up straight away.</td>
</tr>
<tr>
<td>Professional relationships</td>
<td>just the getting people’s backs up and not...</td>
</tr>
</tbody>
</table>
really helping your working relationship with people

**Professional relationships**
It's a telling off, you know, a public telling off, in a way

**Professional relationships**
….It's gonna really demoralise them and they're probably doing their best in an imperfect situation

**Professional relationships**
I'm gonna have to sit there and fill out about sixty boxes, but also people involved as well and what impact will have on them and try and find out, before I go wading in, exactly what's gone on and it is a proper incident as opposed to

**Professional relationships**
not knowing the full detail of exactly the entire incident … but if you don’t know, you don’t wanna lay the blame at somebody, so to speak, if they’ve really not been involved and if you don’t know the full

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### Incident

**Omission errors (MR)**
Especially when you’re sort of talking about things like the medicines reconciliation, because … Three years ago even, as long as a drug cardex looked clinically all right, it didn’t have weird interaction or anything on it, then it was fine, we never checked up whether it was medication that patients should be having. So we’ve created a whole new set of prescribing errors that we didn’t have a few years ago.

**Omission errors (MR)**
we advise them that they’ve missed off quite a few of the regular medications on a regular basis, and I wouldn’t fill in an incident form for those. To me that’s run of the mill, that they just don’t take very good medication histories, so we do that.

**Omission errors (MR)**
Cos if we reported every time something was missed off a patient’s drug history we’d probably make a report about every patient...

**Internal or external**
If we got a dispensing that said ‘Metformin MR’ and the box was plain with an MR label on a ward we would fill in a Trust form cos we’d found that. But when the doctors prescribed plain and we later find
out that they’re on MR we don’t fill out an incident form for that, which is, that’s exactly the same error.

**Internal or external**
P1 errors that come through dispensary are never reported.
P2 No, never. I don’t think anybody, I’ve never heard of anyone reporting anything in dispensary.

**Severity**
Patient Harm: I suppose then you would report that, but more typically that’s not the case, it’s more it’s the potential, you see the potential for it.....Contact the prescriber, they change it, it isn’t the subject of a report.

**Severity**
Obviously if the patient’s come to harm it would have to be reported cos they’ve come to harm.

**Severity**
or like when you think oh, when you’re relieved that the patient hasn’t had it

**Severity**
Caused harm or could have:

**Severity**
If something has been missed out, you know, omitted by accident.

**Severity**
I’ve managed to get the doctor to change it before anything could happen to the patient. I feel, .. I just didn’t report it, it wasn’t an incident

**Severity**
incident where something’s happened, not potential incidents, just something has happened.

**Severity**
those were the ones that were potentially drastically serious, yes. And I wouldn’t report minor, that were unlikely to harm the patient

**Severity**
like unless something’s happened and it’s caused harm you don’t see it as an incident and it’s not like worth creating a lot of hassle for something that hasn’t actually caused any harm or done anything

**Severity**
It makes me wonder if the patient actually got anything before. So my first question is, ‘Did the patient get anything?’

**Severity**
I think if it’d actually been an actual harm to the patient or a significant, what I thought was a significant near miss,

**Severity**
If it was something that a patient was given and it was wrong then I would like to say I would report it. I don’t know. That is something I should, would view as something that’s suitable for reporting. Or if it was a near miss but the potential for
harm to the patient was high if it had been given, then I’d report that.

**Severity**  
I mean I always think of things in terms of could it prolong their stay in hospital or could it … similar to, I suppose, the adverse drug reactions really, where, you know, if it resulted in or prolonged hospital admission or … caused them some damage of some description.

**Severity**  
not fair to the person who’s been unfortunate enough to make the serious error. Cos you are pillorying them and you’re ignoring someone else who might have made three times as many errors that were minor

**Severity**  
it really does just depend on the seriousness of the incident,

**Severity**  
I go on severity. Like today I had a penicillin allergic patient given Augmentin and it turns out she wasn’t penicillin allergic but to me that could’ve been really serious and could’ve resulted in definite patient harm if not death Report kind of incidents that either were, like happened and were severe or quite serious near misses. Like I class that as quite a serious near miss

**Severity**  
if it had the potential to be, to cause patient harm or it was serious or it was something that was happening a lot then I’d report it. If it was just something like….was no stock of paracetamol …I wouldn’t fill it in because I wouldn’t see that as potentially being serious.

**Severity**  
. I think every time it comes to severity, you’re doing it for the patient, aren’t you…so those ones, the severity, all driven by this is a particularly serious event that you can’t not report it. you shouldn’t make any difference, all patients should be cared for absolutely, but if you think about it being your relative, even the most minor medication error becomes hugely significant

**Severity**  
I tend to only report the really, really bad ones

**Severity**  
Not the routine ones, I wouldn't do those, it’s only the shocking ones …Well, I suppose if you examine it they all are. They’re all completely wrong and they’re
<p>| Severity | The clerking in doctor had written the medication into the notes and then that had been transcribed by somebody subsequently and the transcription was completely wrong. |
| Severity | ....think it does have an impact on what you do report. I probably wouldn’t report the minor ones either |
| Severity | Severity overrides everything, I think, in my case |
| Drug | Like serious ,like if a dose is completely wrong |
| Drug | it depends, that depends on the drug |
| Drug | that means that you’re making a witch-hunt of people who’ve made a mistake with a particular drug, rather than for the people who’ve made exactly the same mistake with a different drug. I mean .. and that’s what I think’s, that’s why you should report them, no matter how minor. |
| Drug | But methotrexate 2.5 and methotrexate 10 is exactly the same relationship as atenolol 25 and atenolol 100 but the results of muddling them up aren’t the same, but it’s the same error, so really you should be reporting them as an error type. That’s what I always feel .. I wouldn’t report the atenolol but really you should because it’s exactly the same thing, isn’t it. |
| Drug | if I dispense the wrong strength of ketovite ..really even if you’ve given it to a tiny baby it wouldn’t have mattered, but because it was vancomycin it could’ve ..given somebody like permanent renal failure |
| Drug | I reported a five milligrams per kilogram of gentamicin three times a day |
| Drug | I won’t report things like senna stat, cos I think,...but I’ll report things like if a digoxin stat isn’t signed for, cos did the patient get the dose or did they not? And two days later is the potential that the patient could then be given that stat, two days later when they’re already loaded |
| Personal judgement | So maybe I’m kind of thinking, oh, they can’t do much about that. Whereas I should be letting someone else think that or decide what can be done and what actions can be taken, rather than me deciding on my own. |</p>
<table>
<thead>
<tr>
<th><strong>Personal judgement</strong></th>
<th>I think you just leave it to your own professional judgement…. it’s a hard thing to quantify or qualify</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Personal judgement</strong></td>
<td>the classic is everybody’s got different thresholds for reporting different things…It probably varies on the day of the week and it varies on your mood ..and it may be less on a Sunday than on a Monday</td>
</tr>
<tr>
<td><strong>Personal judgement</strong></td>
<td>.comes down to that subjective assessment of what’s the consequence or could’ve been the consequence</td>
</tr>
<tr>
<td><strong>Personal judgement</strong></td>
<td>I think also it lies with clinical judgement as well. So there are .. you know, important omissions and they’re there for a reason ..like missing an antiepileptic would be very important whereas missing a statin or something…</td>
</tr>
<tr>
<td><strong>Personal judgement</strong></td>
<td>because it’s your bug-bear you’ve kind of blown it out of all proportion and sort of you think it’s much worse than it is or better</td>
</tr>
<tr>
<td><strong>Repetition</strong></td>
<td>I don’t know how I would define significant, but something that I’d maybe seen a trend of, that might make me start thinking, ‘This is a trend I’m seeing, unless I start reporting this nobody else is going to see this.’</td>
</tr>
<tr>
<td><strong>Repetition</strong></td>
<td>Cos if you know a doctor who, on a regular occasion, makes the same error and if you don’t fill out an incident form they’re never gonna get pulled up, whereas if you do fill an incident form then they might.</td>
</tr>
<tr>
<td><strong>Repetition</strong></td>
<td>P1I mean it doesn’t matter how serious it is if they keep on doing it, it makes you want to report it cos they’re not learning. P2 But you don’t know they’re repeating, you don’t know if they’re doing it again and again if you’ve not reported it.</td>
</tr>
<tr>
<td><strong>System error</strong></td>
<td>when I’m in the dispensary if the system we’ve got in place has fallen down then .. and the whole system’s kind of gone down rather than it just being one individual’s fault, kind of thing, if the whole system’s at fault then I would be more inclined to report something then</td>
</tr>
<tr>
<td><strong>System error</strong></td>
<td>I do believe that you can actually change things by reporting…I think I probably am tending more towards system errors….than an individual person has got mixed up and missed off a drug or made a sort of error in prescribing something that’s not minor</td>
</tr>
<tr>
<td>Type</td>
<td>Description</td>
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<tr>
<td>System error</td>
<td>The poor patient had brought all their meds into the hospital and we’d lost them. So like they had, they needed to dispense sixteen medicines because of a breakdown in their system, and to me that’s a classic one that you would report because your department would benefit from it, the patient would benefit from it</td>
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<tr>
<td>Justification</td>
<td>I think if you think something’s gonna come back at you as well and you kind of want, I know it’s not the attitude to have but if you know something’s going to come back at you, well, I want an incident report form done, one, to put my side of the case forward and it’s documented and it’s down and it’s there.</td>
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<tr>
<td>Justification</td>
<td>if we know that there’s a focus on the impact that we have on nights we will report it. Like if we think it’s going to be observed you’re more likely to say, ‘Fill out an incident report than I rang doctor cos the patient’s penicillin allergic.</td>
</tr>
<tr>
<td>Justification</td>
<td>I would often go by what the patient was like as well, if I know they’re an obstructive….it’s defensive because you know they’re gonna cause a problem, they’re gonna probably bring in PALS or liaison people, so you do, again, you cover your back.</td>
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<tr>
<td>Negligence</td>
<td>if there’s any sort of suspicion that it might be negligence….but you go through the process in your mind, thinking, is this just an honest omission or is this dangerous?</td>
</tr>
<tr>
<td>Negligence</td>
<td>I just had a totally unacceptable junior doctor working on my ward once, who I, after a number of incidents, I ended up writing to say I really didn’t think he was competent, and despite training and all the rest of it it ended up he didn’t get assigned</td>
</tr>
<tr>
<td>Data set</td>
<td>And cos then you have to follow it all up so it is a lot of work, you have to find all the bits.</td>
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<td>-------------------------------------------------------------------------</td>
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<tr>
<td>Data set</td>
<td>The trouble is it’s the same form for everything, isn’t it.</td>
</tr>
<tr>
<td>Data set</td>
<td>balance between what data-set is workable, because pharmacists being pharmacists, give us a form, there’s sixty boxes on it, we’ll attempt to fill sixty boxes because that’s what we do</td>
</tr>
<tr>
<td>Data set</td>
<td>if you’ve forgotten a little bit of the detail and you can’t complete the form, then you sort of.. oh well….I’m not too familiar with the form, I’m not sure exactly what’s needed, so I need that mental list in my head of all the information that’s needed, so I can, like I say, jot it down and then do it when I have ten minutes later</td>
</tr>
<tr>
<td>Data set</td>
<td>The form’s not user-friendly, particularly for medication</td>
</tr>
<tr>
<td>Data set</td>
<td>Medical equipment and you have to write the serial numbers, there’s just too much irrelevant guff on the form for medication errors.</td>
</tr>
<tr>
<td>Data set</td>
<td>makes me think of bureaucracy and that you’ve got to fill out lots and lots of details that you think</td>
</tr>
<tr>
<td>Data set</td>
<td>it could be much simpler if you just said you don’t need to relate it to a patient, , you just need the basic detail cos you can then work out … this happened at this time</td>
</tr>
<tr>
<td>Data set</td>
<td>I mean a lot of it’s not needed that it asks for, patient’s email addresses, that’s not needed. How many ninety year olds have those, an email?</td>
</tr>
<tr>
<td>Data set</td>
<td>on the electronic form there’s certain sections that you haven’t got answer in that drop-down list that’s relevant and you want to leave it blank or put ‘other’ and there isn’t an option to do that,… field that you kind of get stuck on sometimes, and there’s not really an answer there but it won’t let you proceed.</td>
</tr>
<tr>
<td>Data set</td>
<td>Some of it is, if you look at our form, there’s spaces for names of the people who did it, and names of the witnesses….Why do you</td>
</tr>
</tbody>
</table>
need a witness? What you gonna do to me that you need a witness?

| Data set | because of the time and the effort and the complicatedness of the form that we don’t tend to fill in as many |
| Data set | I’m gonna have to sit there and fill out about sixty boxes, but also people involved as well and what impact will have on them and try and find out, before I go wading in, exactly what’s gone on and it is a proper incident as opposed to .. |
| Form confusion | P1 If it’s like a serious one I’ll do both but I tend to find I do the pink one. P2 Well, if it’s a serious one surely you should just be filling in a clinical incident. |
| Form confusion | I do think though there is a lack of understanding of the procedure and that on the, cos I get a lot of incident forms given to me, or I used to anyway, by ward, pharmacy ward staff where they shouldn’t have come anywhere near pharmacy, they should’ve just been filled in and given to the ward manager and people don’t realise... So I do think people shy away from the process cos they don’t understand it a bit.. |
| Form confusion | If you’ve got a really high gentamicin level because someone’s dosed it incorrectly, then I would probably go IR1 wise, because that could be a teaching issue, it’s not a pharmacy issue as such, it’s a teaching issue for doctors |
| Form confusion | And then it’s not supposed to be in pharmacy anyway, you know, or possibly not, it’s possibly supposed to be given back to the ward manager |
| Time | not knowing the full detail of exactly the entire incident … Because you think, I’m gonna have to go back and look through all the notes, blah-blah-blah, and again it’s probably a time thing but if you don’t know, you don’t wanna lay the blame at somebody, so to speak, if they’ve really not been involved and if you don’t know the full…. |
| Time | ..you just don’t have the time to sit down and do every single one of them, so do you batch them all together and go, ‘I saw fourteen incidences on my ward today of patients not getting medication over the weekend.’ You don’t have the time, the |
effort or possibly the inclination to actually do that.

**Time**

because of the time and the effort and the complicatedness of the form that we don’t tend to fill in as many

**Time**

time

**Time**

Cumbersome...there’s a lot of bits and pieces to fill in, which I can appreciate that you need to be able to analyse the situation, but I find it quite time consuming

**Paper vs electronic**
certainly probably would be easier to do a paper based record but I don’t think you, you wouldn’t record all the stuff that people needed

**Paper vs electronic**
I find it quite easy, yeah. I quite like the online system...I think you have to be familiar with the format and exactly what the online system is asking, so you have to gather all the information and all the data there and then, otherwise your patient’s whisked off out of the hospital or for whatever reason you can’t go back to see the notes. But once you’ve got that I think it takes about ten minutes, if the computers are working properly and the internet’s working properly

**Paper vs electronic**
I think the online, online’s the way to go. Like other places I’ve worked I’ve had like, honestly, the A3 size things.. It’s essentially the same sort of questions it asks, and there’s a red, amber, green, and if it’s red this needs to be reported directly to your head of department and things. But that, I find that ridiculous, that’s just like long-winded and total waste of paper.

**Paper vs electronic**
Can you be bothered to go and get the stationary cupboard key and go to the stationary cupboard to get some more forms when there aren’t any in the file, etc.

**Anonymity**
You don’t put names, but they’ll know. They’ll know who reported you....

**Anonymity**
You put patient details...for the people following it up. I mean they have to be able to follow it up in case, well, yes, to investigate it they need to know

**Anonymity**
No, it doesn’t ask for their details.(dr involved)....but if the same error’s occurring by the same doctor then you might possibly want to flag up that doctor... think you can find out anyway, with
### Severity scale

<p>| | |</p>
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<tbody>
<tr>
<td>P1</td>
<td>Well, severe is essentially patient harm.</td>
</tr>
<tr>
<td>P2</td>
<td>I think if the potential for serious patient harm was there as well I’d put it as severe.</td>
</tr>
<tr>
<td>P1</td>
<td>See, I’ve always been told that it’s not.</td>
</tr>
<tr>
<td>P2</td>
<td>But I would still class it as severe.</td>
</tr>
</tbody>
</table>

### Learning

<p>| Improve safety/ care | A tool to improve the management of patient care, to improve the quality of what we do and improve the experience of the patients going through the system |
| Improve safety/ care | Improve future practice. |
| Improve safety/ care | The principal concern…is always for the patient, that’s at the front of your mind in everything that you do |
| Improve safety/ care | I think they do protect patients in the long run. |
| Improve safety/ care | Improve the patient safety and care |
| Improve safety/ care | I’ve noticed, the ethos around, you know, reporting the errors, is all about improving people’s working lives and patient processes |
| Improve safety/ care | Improve practice and ensure patient safety. |
| Identify safety problem | The useful thing that I find from the incident reporting is that we can identify trends, you know, in a general area, rather than just saying we do something badly, we can pinpoint why, where and when we do things badly, and start trying to focus on maybe smaller parts of the process rather than just being overwhelmed. |
| Identify safety problem | The error reporting begins to bring it to a clear focus for you and helps drive forward whatever changes you’re trying to put in place |
| Identify safety problem | Essentially it’s there, isn’t it, for changes, and to flag up trends or any preventable sort of errors in medication, be it like prescribing or administration |
| Identify safety problem | Identify an area of risk? |
| Preventing recurrence | I think you’ve not to think about it as getting into trouble, because it is supposed to look at things for preventing the incident happening in the future. |
| Preventing recurrence | To prevent it from happening again. |</p>
<table>
<thead>
<tr>
<th>Preventing recurrence</th>
<th>opportunity to learn, opportunity to share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preventing recurrence</td>
<td>It’s so that systems can be changed so that it doesn’t happen again, that’s the idea, isn’t it.</td>
</tr>
<tr>
<td>Preventing recurrence</td>
<td>Obviously it’s really important that this doesn’t happen again and if you didn’t know then that means lots of other people didn’t know about this and so I have to fill this form in to make sure that this gets identified by the Trust, so that it doesn’t happen and other people get warned about this</td>
</tr>
<tr>
<td>Preventing recurrence</td>
<td>, because someone was very ill because of what happened and you have to make sure it doesn’t happen again.</td>
</tr>
<tr>
<td>Preventing recurrence</td>
<td>I think it does influence change, in a sense. Because if you did report a missed dose and it was something really important, some antiepileptics or antibiotics or something, and a patient could’ve come to real harm from it, then it is fed back to the ward sister and it is fed back….they’re then gonna go and find the people, aren’t they, and do something about it, cos they don’t want to have more reports coming in about their staff members under their leadership.</td>
</tr>
<tr>
<td>Positive feedback</td>
<td>ones are coming back to me and we are, I’ve got to feed them back to the weekly staff meetings</td>
</tr>
<tr>
<td>Positive feedback</td>
<td>often has a chat with people to see what could we do differently, how could we improve it?</td>
</tr>
<tr>
<td>Positive feedback</td>
<td>feed back to paediatrics</td>
</tr>
<tr>
<td>Positive feedback</td>
<td>on a monthly kind of basis, we actually get discussion amongst the clinicians, nurses and pharmacy department</td>
</tr>
<tr>
<td>Positive feedback</td>
<td>it’s also the mind-set of the department that you’ve got. I mean here we’re very pro….We don’t see it as a vilification but up on the wards you might see it, might have a different mind-set towards actually doing incident forms, depending on where you are, the manager might be</td>
</tr>
<tr>
<td>Positive feedback</td>
<td>I remember x making a suggestion about maybe what I should’ve done and you know, I took that onboard, so we did used to learn</td>
</tr>
<tr>
<td>Reporter confidence</td>
<td>I think we’ve done a good job in explaining the benefits of why we’re doing it, it’s not just to come and hit you with a big stick, you know, and tell you what you’re doing</td>
</tr>
<tr>
<td>Reporter confidence</td>
<td>Yeah. Cos here, since I came here from the Trust I was working at, here they do reflective learning so you’ll, if you’ve made an error or you’ve been part of an error, whatever, it’ll come through on email and they’ll say, ‘This is the error, these are the details, can you fill out a reflective learning.’ And that, to me, was a huge change, cos we would never, when I worked at the other Trust we never got told when we made an error unless it was, it was something that people may sit and talk about behind your back, especially when I was a junior pharmacist, if you were on-call and you made an error and you’d walk in and there’d be a bottle of something labelled wrong on a desk, and you thought, oh, yeah, that’s got my initials on it. But no one ever spoke to you about it. And I think that’s a huge difference here.</td>
</tr>
<tr>
<td>P2</td>
<td>It encourages you to find the reasons why. It doesn’t have, ‘because you’re an idiot.’ On the list of reasons why the mistake was made, it’s ‘Was it busy?’ ‘What else was going on?’ ‘What pressures were on you?’ And you start looking at the way you work, so I think it’s done well.</td>
</tr>
<tr>
<td>Reporter confidence</td>
<td>I can see why a more junior graded pharmacist would have hesitation but I think we would offer them enough support within the department, either directly through line manager or through medicines safety department, to try and encourage them to complete forms wherever they feel it’s appropriate, and if they had any hesitation or doubt they would come to us, discuss it, and then we would go and support them to complete the necessary forms. So I think we give support at an early stage for people.</td>
</tr>
<tr>
<td>Reporter confidence</td>
<td>It was really designed to get over the cultural barriers that existed at that time, to gain confidence in the reporting system. Because we knew, from evidence of other industries, that if you didn’t put in place a confidential and anonymous system the chances of people believing that it wasn’t gonna be a punitive system were very high, therefore you had to implement something</td>
</tr>
</tbody>
</table>
that was like that, and that’s what we did. And it did exactly what it said it would do, gained the confidence of people

<table>
<thead>
<tr>
<th>Change in practice</th>
<th>Well, we do things to change practice, to stop the thing happening again, but they’re usually more laborious, like (making something like) a controlled drug and all that sort of thing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in practice</td>
<td>post was created on the back of incident reporting around anticoagulation errors</td>
</tr>
<tr>
<td>Change in practice</td>
<td>It’s to show that we’re needed and then we get more funding for more pharmacists Which is actually a reason that we’ve been told. That’s true . . That’s what we’ve been told, report as much as you can because it shows the job that we’re doing.</td>
</tr>
<tr>
<td>Change in practice</td>
<td>we have now got a much better relationship with the medical staff as trainers and tutors, after a fairly large prescribing error. They then saw us as a source of information that they weren’t using and we’ve become much more involved in induction and actually doing a bit of teaching of prescribing.</td>
</tr>
<tr>
<td>Change in practice</td>
<td>I’ve seen processes change in pharmacy because of incident forms,</td>
</tr>
<tr>
<td>Change in practice</td>
<td>we’ve got a massive, or we’ve got a major pedigree of like changing things in terms of prescribing, as a result of people flagging issues up and like the issues could be flagged up in a multitude of ways but a clinical incident form might be one of the ways that are used to kind of like flag that up</td>
</tr>
<tr>
<td>Change in practice</td>
<td>after everybody had finished talking nothing had changed, and we started filling in an IR1 for every patient that had gone twenty four hours without these things, and then it changed. It changed practice straight away, because it gets reported at a Trust level and people from very high heights start jumping on people, so it was necessary. It was unfortunate but it did work.</td>
</tr>
<tr>
<td>Change in practice</td>
<td>throughout last year there’s lots of things that’ve been amended as a result of issues that’ve been flagged up</td>
</tr>
<tr>
<td>Change in practice</td>
<td>I’ve filled in a form, and then (safety pharmacist) has maybe come back to me and said, ‘This needs to be taken further, we’re having this happen time and time again.'</td>
</tr>
<tr>
<td>Inaction</td>
<td>I think that's a major, like a major deterrent to doing it, if you don’t think anything’s gonna happen why waste your time filling one out? If you don’t think anyone’s gonna read it.</td>
</tr>
<tr>
<td>----------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Inaction</td>
<td>if I came across that doctor the only way I would’ve known this was a problem would be if they’d happened to mention it to me on more of a social chit-chat thing, rather than any kind of formal feedback, and I do think that’s a problem.</td>
</tr>
<tr>
<td>Inaction</td>
<td>‘Thank you very much for sending this to risk management.’ And then you get nothing back, you get nothing else.</td>
</tr>
<tr>
<td>Inaction</td>
<td>when you did get feedback in pharmacy about it you remembered to do it, whereas now you don’t get feedback you kind of, but every now and then reminded to quax I’ll do like seven in a day and then I will have forgotten it then by the next day.</td>
</tr>
<tr>
<td>Inaction</td>
<td>I don’t know how it works afterwards, I don’t know how much, does a team come and look at the notes and look at the patient cardex for them? I don’t know how it’s followed up really. I know they’re emailed out to loads of people, I’m not sure what the follow up procedure is….you never get feedback on ones you’ve reported yourself.</td>
</tr>
<tr>
<td>Inaction</td>
<td>I mean obviously you have things that happen on ward level and down here somewhere, and it’s all fed back to the ones up top, so they’ll know what’s going on across the hospital, but we don’t necessarily unless we discuss amongst ourselves</td>
</tr>
<tr>
<td>Inaction</td>
<td>No positive feedback (because of incidents reported)</td>
</tr>
<tr>
<td>Inaction</td>
<td>if you know that nothing’s gonna be done about it really there’s gonna be no benefit from reporting and .. you don’t</td>
</tr>
<tr>
<td><strong>Empowerment</strong></td>
<td>I’ve encouraged patients to do complaints about things, you know, especially if it’s something that I agree with them it shouldn’t have happened, I say, you know, ‘I would encourage you.’ They’re like, ‘I’m gonna write a complaint.’ You say, ‘Well, I wish, you know, that would be good because then we can make sure this doesn’t happen to anybody else.’</td>
</tr>
<tr>
<td><strong>Empowerment</strong></td>
<td>I think that involving the patients is the key towards the next stage of change, involving them with the medicines and making sure that they have a voice and speak out when something’s going wrong.</td>
</tr>
<tr>
<td><strong>Empowerment</strong></td>
<td>medicines errors are becoming more recognised now, we’re having this, about empowering the patients with (thromboprophylaxis) you know, you get these posters now in your GP’s surgery ‘Are you washing your hands?’ business. Okay. Not every patient will do it, but some will and it only takes a few to kind of kick start the system.</td>
</tr>
<tr>
<td><strong>Empowerment</strong></td>
<td>Actually challenging, empowering the patients to speak up or their relatives to speak up on behalf of the patients….I think we need to do more to encourage them to report to us to then take further onwards, because that will then lead to further improvements in practice</td>
</tr>
<tr>
<td><strong>Empowerment</strong></td>
<td>at the outset of it the nurse ended up being suspended and was off for so many months and then had to come back and be retrained, and I felt that the system failed in that, because it took too much of a preference to the patient’s views</td>
</tr>
<tr>
<td><strong>Beliefs</strong></td>
<td>P1 I think some of the things they wouldn’t really think of as being errors P2 ‘Ooh, it’s all bureaucracy, isn’t it, and you have to do so much paperwork.’… So I think there would possibly be a bit of an understanding of the fact that we should all be out there washing people (or dispensing their tablets) and not flinging bits of paper.</td>
</tr>
<tr>
<td><strong>Beliefs</strong></td>
<td>I think they’re very sympathetic to human error</td>
</tr>
<tr>
<td><strong>Beliefs</strong></td>
<td>P1 They would want us to report them, but whether they think that we actually do, I don’t know.</td>
</tr>
<tr>
<td>Beliefs</td>
<td>P2 I think the perception is that we have a lot of cover up and a lot of covering each other’s backs.</td>
</tr>
<tr>
<td>Beliefs</td>
<td>they probably don’t have a view on that, what they probably want to do is to know that if anything happens that’s untoward, some learning falls from that.</td>
</tr>
<tr>
<td>Beliefs</td>
<td>I think they would view the fact that, yeah, you are policing their prescribing, you are scrutinising what other people are doing, they have got a complex list and you’re just keeping an eye that everything’s right. I think those patients would,</td>
</tr>
<tr>
<td>Beliefs</td>
<td>P1 I reckon they’ll think we should do. P2 I think they’ll view that as our responsibility.</td>
</tr>
<tr>
<td>Beliefs</td>
<td>It would depend on the actual individual situation...So I think our patients would be quite keen..... and trying to think of it as a patient, and with my mother who’s on a lot of medication, I would hope that the person involved would report it and I would hope that the public would think the same. Wouldn’t know cos I’ve not actually asked them, but I would hope that would be the case</td>
</tr>
<tr>
<td>Relationships</td>
<td>I think that it’s different with my patients because we know them quite well, we have quite a small group of patients and they come in a lot’ They’d say, ‘Oh yes.’ If I went and said that such and such a nurse has made a mistake with your medication so I’m going to fill in a form about it, she’d say, ‘Oh no, don’t.’ I think it would be because they feel like they have a relationship with that professional and they don’t want to get them into trouble</td>
</tr>
<tr>
<td>Relationships</td>
<td>would someone want a community pharmacist to report a medication error about their GP...I think patients have, I think it depends who made the error, you know, if a nurse made the error then they’d throw the key away, if it was a doctor had written a medication error they would be very, I think the opinion would be very different, I think they’d be very much like, ‘No, no, can’t do that, he’s a doctor.’</td>
</tr>
<tr>
<td>Relationships</td>
<td>I think it depends, cos where I work as a locum …they will openly say they don’t trust their GP, and they’ll say, ‘The GP’s given</td>
</tr>
</tbody>
</table>
me this, what do you think?’ So I think it’s, I think it works both ways. I think it’s about the individual relationships

### Improvements

| Feedback | ensure that these things are dealt with sensitively. That managers, or whoever has to handle it are told this, that’s the way they have to deal with it. |
| Feedback | I suppose another way as well is to sometimes try to make a general point about something by announcing it at a meeting … Pointing out it’s happened, ‘Can you be careful that don’t do this sort of thing because … just be careful when you’re dealing with this …’ |
| Feedback | Communication. Knowing that what you’re doing is actually being seen, read, heard by someone, and something is actually being done about it.. And trying to get rid, trying to promote the open and learning, you know, so that people don’t have this antiquated idea that we’re actually out to get them, that we’re actually trying to do it for the benefit of not only the patient but their ward at the same, or their area at the same time. |
| Feedback | Feeding back and saying, ‘The team seems to have been making more errors recently.’ So you’re not actually apportioning blame to any one person but, you know, you live and die by the team |
| Feedback | system failures, professional solutions..if you look at most of the errors that happen are breakdown in system and if you actually get your healthcare professionals to work together and analyse and promote it it’s like sometimes the best solutions come from the least expected source, |
| Feedback | incident post-box and like once a week the ward round for the last half hour would take all the incidents out of the post-box and the consultant would, with some discussion within a multidisciplinary team, say ‘This is what’s happened on our ward, what do you think we can do about it?’ Because it’s not about like kind of us solving all the issues |
it’s about the kind of multitude of people involved coming up with, ‘Oh, why don’t we try this? Why don’t we try that?’ It was almost, that gets through the communication, it encourages, it empowers, it promotes learning. We do that now…

Feedback

I think definitely easy way of reporting is the main thing to helping.. Trying to change the threatening attitude of, ‘I’m going to fill in an incident report form about you.’ Changing the attitude, that we know that we’re learning from what we’re doing and that also if you do fill in a form, whatever, you know that you’re making a difference.

Feedback

plan was that you actually have about ten different letters, so you get them randomly so it’s not the same letter that you get every time

Feedback

That’s the bad thing about it, cos you don’t, all you get is a letter saying, ‘Thank you very much, we’ve received your form.’

Drug specific

P1 introduce a drug specific one here though….
P2 Which I think will be better.

Drug specific

internal pharmacy form….is something that you could use pretty quickly. You know, I can usually fill one of those in in ten minutes, whereas obviously an IR1, because it is a more formal form takes longer to fill in because you have physically got to find out quite a bit of information to fill it in correctly.

Drug specific

we’ve developed..a kind of shorter, more concise forms to pharmacists to report specifically medicines related errors…. just makes reporting them a bit easier for the people who are doing the reporting.

Form simplicity

P1 I think other hospitals, certainly in the past, have just got it on an answer machine, so you pick up the phone and say, ‘This has happened.’ Put the phone down and, well, there’s your data-set, you’ve got as much as somebody will give and you can then, you can get a lot more reporting because it’s so, so easy and it’s anonymised,
P2 I don’t think that would be appropriate for the really big, like we had chemotherapy on the ward given by the wrong route
<table>
<thead>
<tr>
<th><strong>Form simplicity</strong></th>
<th>if it was easier and quicker I would report a lot more</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Form simplicity</strong></td>
<td>I would say one of the big factors is probably ease of use. And trying to make the processes as easy as possible and robust as possible</td>
</tr>
<tr>
<td><strong>Form simplicity</strong></td>
<td>best way of reporting is like the quickest, simplest, scribble it down on a scrap of paper.</td>
</tr>
<tr>
<td><strong>Form simplicity</strong></td>
<td>..whether you could have a paper, one side of A4, that you could stick in your own ward folder, so you could carry it round with you, just photocopies of it, which contains all the basic bare information that you need, so that you could quickly, when you’re on a ward, scribble in the necessary information and then when you’d got ten minutes you go and sit at a computer and type it up from the bit of paper on to the system.</td>
</tr>
<tr>
<td><strong>Technology</strong></td>
<td>And if you could tie it into the patients’ electronic patient record so that it was part of their records as well.</td>
</tr>
<tr>
<td><strong>Technology</strong></td>
<td>I think it’d be better if it was electronic so that you could just get onto it through the intranet on any computer anywhere.</td>
</tr>
<tr>
<td><strong>Technology</strong></td>
<td>It’d be better if it was electronic</td>
</tr>
<tr>
<td><strong>Technology</strong></td>
<td>P1 But if you had the form that we fill out on the computer …</td>
</tr>
<tr>
<td><strong>Technology</strong></td>
<td>P2 …It might be easier</td>
</tr>
<tr>
<td><strong>Technology</strong></td>
<td>We’re looking quite a lot towards more sort of technologically appropriate means of doing it, to try and make it easier</td>
</tr>
<tr>
<td><strong>Anonymity</strong></td>
<td>P1 I think you’d get more people actually reporting if you made it less official, cos it just seems really, really big when you do it</td>
</tr>
<tr>
<td><strong>Anonymity</strong></td>
<td>P2 But you can’t follow it up unless you know who’s involved, and the whole thing does involve following it up, doesn’t it …If you didn’t have to put your name to it as a reporter, that’s open to abuse as well, isn’t it .I don’t think it would improve the quality though because you just wouldn’t know, wouldn’t be able to follow anything up</td>
</tr>
<tr>
<td><strong>Anonymity</strong></td>
<td>I think as well if you had the option not to fill in people’s names, if it was obviously a process error and they were just unlucky in that they were the one that made the error</td>
</tr>
<tr>
<td><strong>Targeted reporting</strong></td>
<td>:I do feel we should actually report everything, I don’t,…cos it’d be such an onerous task we should maybe do it a week</td>
</tr>
<tr>
<td>Targeted reporting</td>
<td>Probably should do it (reporting all errors) one week every two or three months, just so that you do have a picture, or a baseline.</td>
</tr>
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<td>--------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Targeted reporting</td>
<td>I think when we focused on anticoagulation to try and prove the point for your post, I think we got something like thirty reports in the space of ten days, just on anticoagulation alone, cos we focused on that specifically.</td>
</tr>
<tr>
<td>Targeted reporting</td>
<td>if you reported every single thing that was technically an error you’d, like you say, you’d have a big pile, and it would be good, (you’d have accurate?) reporting, but you wouldn’t be able to see the wood for the trees. I know we’ve, in the past year or so we’ve kind of focused on ….</td>
</tr>
<tr>
<td>Targeted reporting</td>
<td>people can become a bit snow-blind to kind of multiple reports of lots of things going on without any clear focus about what you’re trying to do to improve it. So targeting certain sub-sections of a Trust for monitoring a specific target is one area, but then deciding what you are gonna report and not gonna report is key.</td>
</tr>
<tr>
<td>Targeted reporting</td>
<td>We know it’s an audit, we know it’s once a month. That’s more manageable than a daily sort of reporting scheme.</td>
</tr>
<tr>
<td>Targeted reporting</td>
<td>, I know it’s only one day or maybe once every two weeks or something. But I think that would flag it up more, maybe.</td>
</tr>
<tr>
<td>Targeted reporting</td>
<td>I personally know I’m more inclined to do it if I know it’s something that’s flagged up for a day, you know, like I’ve mentioned. I think I work better like that. It’s marketed, sort of thing.</td>
</tr>
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</table>
Appendix 7

A survey of the attitudes to reporting medication errors by hospital pharmacists

Faculty of Medical and Human Sciences
The University of Manchester

This survey forms part of a research study that has received ethical approval from the National Research Ethics Service (NRES reference number 08/H1003/230)
This survey takes approximately 10-15 minutes to complete.

Introduction
The purpose of this survey is to find out the views of hospital pharmacists to reporting medication errors and focuses on a prescribing error scenario.
Anecdotal and research evidence suggests that hospital pharmacists do not always report medication errors. We would like to gain a better understanding of what influences the decision to either report or not report a medication error. We hope to use this knowledge to identify recommendations as to how under reporting might be reduced, through either psychological interventions, technological interventions or organisational changes.

The structure of the survey
• **Section 1** presents the scenario which is then followed by a series of questions that attempt to find out your reaction to aspects of the scenario. Note that the scenario used and questions asked assume that you have taken a decision path you may not feel you would usually choose. This reaction should be reflected in your responses;
• **Section 2** asks you for some demographic information and details about your experience and grade. We would like this information in order to make statistical comparisons and to ensure that our group of respondents is representative of hospital pharmacists in general.
• **Section 3** is a space in case you wish to make any comments, either about the issues discussed in the survey or about the survey itself.

Please note that the survey is anonymous – we do not ask for your name, and your responses will be treated in confidence.

How to fill the survey in
Responses are to be recorded using the scale indicated beneath each question. For example, if you consider other clinical pharmacists to have a slight influence on the way that you work then you might circle 2 on the scale as shown below.

![Survey scale](Q1)

**Doing what pharmacist colleagues in my hospital think I should do, matters to me**

Not at all | Hardly | A little bit | Moderately | Considerably | Very much | Absolutely
--- | --- | --- | --- | --- | --- | ---
1 | 2 | 3 | 4 | 5 | 6 | 7

Q1

Note that the questions are divided into groups, each of which uses the same scale. The first question in each group will show the full scale, which should then be used for the remainder of the questions in that group.
If you have any questions about this research, then you are welcome to contact us using the details provided on the final page.

Thank you for taking part in this study.

**Section 1: The Scenario**

You have just finished your morning visit to your ward and you now need to attend a departmental meeting followed by a teaching session all afternoon. During your ward visit you discovered a medication error which may have caused this hospital admission. A patient had been prescribed Azathioprine 250mg instead of Azithromycin 250mg.
following an outpatient visit 6 weeks ago and has now presented with severe neutropenic sepsis. You decide to report the medication error via the hospital reporting system but you also make an entry in the clinical notes and contact the original prescriber and pharmacist involved to make sure they understand what has happened.

Reporting medication errors increases the awareness of a particular medication safety problem for Health Professionals
1 Strongly Disagree, 2 Disagree, 3 Slightly Disagree, 4 Neutral, 5 Slightly Agree, 6 Agree, 7 Strongly Agree

Increased awareness of a particular medication safety problem for Health Professionals would be
1 Extremely undesirable, 2 Undesirable, 3 Slightly undesirable, 4 Neutral, 5 Slightly desirable, 6 Desirable, 7 Extremely desirable

Reporting medication errors reduces the risk of harm to another patient due to the same problem in the future
1 Strongly Disagree, 2 Disagree, 3 Slightly Disagree, 4 Neutral, 5 Slightly Agree, 6 Agree, 7 Strongly Agree

Reducing the risk of harm to another patient due to the same problem in the future would be
1 Extremely undesirable, 2 Undesirable, 3 Slightly undesirable, 4 Neutral, 5 Slightly desirable, 6 Desirable, 7 Extremely desirable

Reporting the medication error would lead the trust to be involved in litigation.
1 Strongly Disagree, 2 Disagree, 3 Slightly Disagree, 4 Neutral, 5 Slightly Agree, 6 Agree, 7 Strongly Agree

Trust involvement in litigation would be
1 Extremely undesirable, 2 Undesirable, 3 Slightly undesirable, 4 Neutral, 5 Slightly desirable, 6 Desirable, 7 Extremely desirable

Reporting the medication error would lead the prescriber who made the error to be involved in disciplinary procedures.
1 Strongly Disagree, 2 Disagree, 3 Slightly Disagree, 4 Neutral, 5 Slightly Agree, 6 Agree, 7 Strongly Agree

Prescriber involvement in disciplinary procedures would be
1 Extremely undesirable, 2 Undesirable, 3 Slightly undesirable, 4 Neutral, 5 Slightly desirable, 6 Desirable, 7 Extremely desirable

Reporting the medication error would harm the professional relationship between the pharmacist reporter and the prescriber who made the error
1 Strongly Disagree, 2 Disagree, 3 Slightly Disagree, 4 Neutral, 5 Slightly Agree, 6 Agree, 7 Strongly Agree
Harming the professional relationship between the pharmacist reporter and the prescriber would be
1 Extremely undesirable, 2 Undesirable, 3 Slightly undesirable, 4 Neutral, 5 Slightly desirable 6 Desirable, 7 Extremely desirable

Finding and reporting the medication error would lead the pharmacist who did not originally spot the outpatient error to be involved in disciplinary procedures.
1 Strongly Disagree, 2 Disagree, 3 Slightly Disagree, 4 Neutral, 5 Slightly Agree, 6 Agree, 7 Strongly Agree

Pharmacist involvement in disciplinary procedures would be
1 Extremely undesirable, 2 Undesirable, 3 Slightly undesirable, 4 Neutral, 5 Slightly desirable 6 Desirable, 7 Extremely desirable

Pharmacist colleagues in my hospital would think I should report the medication error.
1 Strongly Disagree, 2 Disagree, 3 Slightly Disagree, 4 Neutral, 5 Slightly Agree, 6 Agree, 7 Strongly Agree

Doing what pharmacist colleagues in my hospital think I should do, matters to me
1 Not at all, 2 Hardly, 3 A little bit, 4 Moderately, 5 Considerably, 6 Very much, 7 Absolutely

Medical and nursing colleagues in my hospital would think I should report the medication error.
1 Strongly Disagree, 2 Disagree, 3 Slightly Disagree, 4 Neutral, 5 Slightly Agree, 6 Agree, 7 Strongly Agree

Doing what medical and nursing colleagues think I should do, matters to me
1 Not at all, 2 Hardly, 3 A little bit, 4 Moderately, 5 Considerably, 6 Very much, 7 Absolutely

Patients would think that I should report the medication error
1 Strongly Disagree, 2 Disagree, 3 Slightly Disagree, 4 Neutral, 5 Slightly Agree, 6 Agree, 7 Strongly Agree

Doing what patients think I should do, matters to me.
1 Not at all, 2 Hardly, 3 A little bit, 4 Moderately, 5 Considerably, 6 Very much, 7 Absolutely

Clinical risk managers at my hospital would think I should report the medication error.
1 Strongly Disagree, 2 Disagree, 3 Slightly Disagree, 4 Neutral, 5 Slightly Agree, 6 Agree, 7 Strongly Agree

Doing what the clinical risk managers of the hospital think I should do, matters to me.
1 Not at all, 2 Hardly, 3 A little bit, 4 Moderately, 5 Considerably, 6 Very much, 7 Absolutely

Most pharmacists would................................................................. report the medication error described in the scenario.
1 Never, 2 Very rarely, 3 Rarely, 4 Occasionally, 5 Often, 6 Very often, 7 Always
Most pharmacists would consider reporting the medication error described in the scenario to be………………..  
1 Extremely undesirable, 2 Undesirable , 3 Slightly undesirable, 4 Neutral, 5 Slightly desirable 6 Desirable , 7 Extremely desirable

If the outcome of the medication error was not serious would you be…………….. to report medication error  
1 Much less likely, 2 Less likely, 3 Slightly less likely, 4 Neutral , 5 Slightly more likely, 6 More likely, 7 Much more likely

How often is a medication error not serious?  
1 Never, 2 Very rarely, 3 Rarely , 4 Occasionally, 5 Often , 6 Very often, 7 Always

If a pharmacist intervened with the outpatient clinic prescription and the patient never received the Azathioprine would you be…………….. to report medication error  
1 Much less likely, 2 Less likely, 3 Slightly less likely, 4 Neutral , 5 Slightly more likely, 6 More likely, 7 Much more likely

How often does a pharmacist intervene to prevent a medication error reaching the patient?  
1 Never, 2 Very rarely, 3 Rarely , 4 Occasionally, 5 Often , 6 Very often, 7 Always

Being under time pressure would make reporting medication errors …  
1 Much less likely, 2 Less likely, 3 Slightly less likely, 4 Neutral , 5 Slightly more likely, 6 More likely, 7 Much more likely

How often are you under time pressure?  
1 Never, 2 Very rarely, 3 Rarely , 4 Occasionally, 5 Often , 6 Very often, 7 Always

Excessive daily workload would make reporting medication errors …  
1 Much less likely, 2 Less likely, 3 Slightly less likely, 4 Neutral , 5 Slightly more likely, 6 More likely, 7 Much more likely

How often is your daily workload excessive?  
1 Never, 2 Very rarely, 3 Rarely , 4 Occasionally, 5 Often , 6 Very often, 7 Always

Having a simple error reporting form would make reporting errors….  
1 Much less likely, 2 Less likely, 3 Slightly less likely, 4 Neutral , 5 Slightly more likely, 6 More likely, 7 Much more likely

How often is the reporting form simple to complete?  
1 Never, 2 Very rarely, 3 Rarely , 4 Occasionally, 5 Often , 6 Very often, 7 Always

Having an electronic reporting form would make reporting errors…  
1 Much less likely, 2 Less likely, 3 Slightly less likely, 4 Neutral , 5 Slightly more likely, 6 More likely, 7 Much more likely
How often is the reporting form electronic?
1 Never, 2 Very rarely, 3 Rarely, 4 Occasionally, 5 Often, 6 Very often, 7 Always

Ensuring that the prescriber involved was personally told that the medication error happened would make my reporting of errors....
1 Much less likely, 2 Less likely, 3 Slightly less likely, 4 Neutral, 5 Slightly more likely, 6 More likely, 7 Much more likely

How often do you personally let a prescriber know that a medication error has occurred?
1 Never, 2 Very rarely, 3 Rarely, 4 Occasionally, 5 Often, 6 Very often, 7 Always

Ensuring that the pharmacist involved was personally told that the error happened would make my reporting of errors....
1 Much less likely, 2 Less likely, 3 Slightly less likely, 4 Neutral, 5 Slightly more likely, 6 More likely, 7 Much more likely

How often do you personally let a pharmacist know that a medication error has occurred?
1 Never, 2 Very rarely, 3 Rarely, 4 Occasionally, 5 Often, 6 Very often, 7 Always

Recording the medication error in the patient's clinical notes would make my reporting of errors....
1 Much less likely, 2 Less likely, 3 Slightly less likely, 4 Neutral, 5 Slightly more likely, 6 More likely, 7 Much more likely

How often do you record medication errors in the patient's clinical notes?
1 Never, 2 Very rarely, 3 Rarely, 4 Occasionally, 5 Often, 6 Very often, 7 Always

Having to identify the prescriber involved in the error would make reporting errors .......
1 Much less likely, 2 Less likely, 3 Slightly less likely, 4 Neutral, 5 Slightly more likely, 6 More likely, 7 Much more likely

How often do you have to identify a prescriber involved in an error?
1 Never, 2 Very rarely, 3 Rarely, 4 Occasionally, 5 Often, 6 Very often, 7 Always

Having a medication safety pharmacist to help complete the details of medication error reports would make my reporting of errors....
1 Much less likely, 2 Less likely, 3 Slightly less likely, 4 Neutral, 5 Slightly more likely, 6 More likely, 7 Much more likely

How often do you have a medication safety pharmacist available?
1 Never, 2 Very rarely, 3 Rarely, 4 Occasionally, 5 Often, 6 Very often, 7 Always
How likely is it that you would report the error described in the scenario?
1 Very Unlikely, 2 Unlikely, 3 Fairly Unlikely, 4 Neutral, 5 Fairly Likely, 6 Likely, 7 Very likely

How strong is your intention to report medication errors in future?
1 Very Weak, 2 Weak, 3 Slightly Weak, 4 Neutral, 5 Slightly Strong, 6 Strong, 7 Very strong

Section 2: Personal and Professional Details

What is your age? ..................... years

What is your gender? (Please circle)

Male     Female

What is your Agenda for Change Band  (Please circle)
6    7    8a    8b    8c    8d    9
Locum

For how many years have you worked as a hospital pharmacist (including pre-registration year)?
.............................. years

What is your primary role? (Please circle one)

Clinical     Dispensary     Purchasing

Technical Services     Medicines Information     Other (please specify).........................

What type of hospital do you work at? (Please circle)

Teaching     District general     Specialist eg Paediatrics

Other (please specify).............................
Section 3: General Comments

You may use this space to provide any comments you wish to make, either about this survey or about any issues that it has raised.

Please return the completed survey using the envelope supplied as soon as possible, and at the latest by 12th June 2009. The supplied envelope includes our Freepost address and thus the postage is free to you or your host institution. If the envelope is missing from then the survey can be returned by hand writing the Freepost address on an envelope. The Freepost address is:

Steve Williams
FREEPOST MR9661
School of Pharmacy and Pharmaceutical Sciences
The University of Manchester
Stopford Building, 1st Floor
Oxford Road, Manchester
M13 9PT
Thank you again for your time

If you have any queries about our research then you are welcome to contact Steve Williams either by telephone (0161 275 2342) or by e-mail s.williams@manchester.ac.uk
Email text to be sent to pharmacists by principal clinical pharmacist

Email subject: Research study assessing attitudes to reporting medication errors by hospital pharmacists

Email text:
Dear colleague

Please find attached information from a pharmacist researcher at the University of Manchester assessing the attitudes to reporting medication errors by hospital pharmacists. Please read the covering letter and information leaflet about the study first and then decide if you would like to participate.
If you wish to participate you have a choice of two ways to anonymously complete the questionnaire:
   Either
   i) I will be distributing paper copies of the questionnaire which can be posted back to the researcher using prepaid envelopes
   Or
   ii) The questionnaire will also be made available for online completion via a secure web link used by the University of Manchester.

Any questions about the study do not hesitate to contact Steve Williams Consultant Pharmacist in Medicine & Medication Safety

s.williams@manchester.ac.uk
Appendix 9

Attitudes to reporting medication errors by hospital pharmacists

Participant Information Sheet (Questionnaire)
You are being invited to take part in a questionnaire. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully to decide whether or not you wish to take part. Ask us if there is anything that is not clear or if you would like more information.

The purpose of this research is:
To examine the attitudes of hospital pharmacists towards reporting medication errors.
To identify how to maximise the capture of medication error reports after understanding the reasons for non-reporting

Why have I been chosen?
You have been asked to participate because you are a hospital pharmacist who regularly provides pharmaceutical care to inpatients and we want to know what makes you decide whether to report or not the medication errors that you discover on a daily basis.

Do I have to take part?
No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your working conditions or rights, in any way.

What will happen to me if I take part?
The questionnaire should only take 15mins to complete. If you chose to complete it on paper please return to the University, using the pre-paid envelopes provided, and if completing it online just follow the instructions on the screen to ensure that it has been sent.

Will my taking part in this study be kept confidential?
All information which is collected about you during the course of the research will be kept strictly confidential. If things you have said are quoted in presentations, publications or reports, care will be taken so that you cannot be identified.

What will happen to the results of the research study?
The results of this study will be published as a report and in academic journals. Findings may also be reported in presentations given at professional or academic conferences. Details of publications or presentations and copies of reports will be obtainable from the research team, please tell them if you would like to receive a copy of the findings at the end of the study. You will not be identified in any report/publication.

Who has reviewed this study?
This study has been reviewed by a local Research Ethics committee

Who is funding the research?
The research is being carried out as part of an MPhil
Contact details for the research team
Please feel free to contact me if you have any concerns or questions.

Steve Williams
Consultant Pharmacist in Medicine & Medication Safety
School of Pharmacy and Pharmaceutical Sciences
1st Floor Stopford Building
University of Manchester
Oxford Road
Manchester
M13 9PL
Tel: 0161 2752374
Email: s.williams@manchester.ac.uk

Thank you for taking the time to read this
Appendix 10

Study ID Number:

Attitudes to reporting medication errors by hospital pharmacists

CONSENT FORM

Please initial box

I have read and understand the Information Sheet dated 24/09/2008 and have had the opportunity to ask questions which have been answered to my satisfaction.

I understand that I do not have to take part. If I do take part I may withdraw at any time, without giving a reason.

I agree to take part in a focus group and to it being audio taped.

I understand that my contribution in the focus group will be anonymised in all transcribed material and I agree for my anonymised direct quotations to be used in the study.

I understand that the information I have given in this study may be used in the future as part of further work on this subject. I understand that it will not be possible to identify me from this information and no further contact will be made with me.

I understand that my taking part in the study and the content of the focus group will be kept confidential.

I agree to take part in this study.

I would/would not* like to receive a summary of the results of the study (*please delete as appropriate).
Name of Participant: _____________________
Date: ________________
Signature: _____________________

Name of Researcher: _____________________
Study ID Number: _____________________
Date: ________________
Signature: _____________________

Age: ________________
Gender M/F: ________________

Years working in hospital pharmacy: ________________
Grade: ________________

Area of hospital pharmacy working in present: ________________

CONTACT DETAILS FOR SUMMARY OF RESULTS

I would prefer to receive the results by (please tick one):

Post: [ ]

Email: [ ]

Postal address:

………………………………………………………………………………………………………………………
………………………………………………………………………………………………………………………
………………………………………………………………………………………………………………………
………………………………………………………………………………………………………………………

Email:

………………………………………………………………………………………………………………………
Appendix 11

Ethics committee approval letter

National Research Ethics Service
South Manchester Research Ethics Committee
Room 191
Gateway House
Piccadilly South
Manchester
M60 7LP
Tel: 0161 237 2288
Fax: 0161 237 2383
Email: cynthia.carter@northwest.nhs.uk

Dr Darren Ashcroft
Clinical Reader in Medicines Usage
and Safety & Director of Centre for Innovation in Practice
University of Manchester
School of Pharmacy and Pharmaceutical Sciences
Stopford Building
M13 9PT

30 December 2008

Dear Dr Ashcroft

Full title of study: Attitudes to reporting medication errors by hospital pharmacists
REC reference number: 08/H1003/230

The Research Ethics Committee reviewed the above application at the meeting held on 11 December 2008. Thank you for attending to discuss the study.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

The Committee gave a favourable opinion as it was considered that there were no outstanding ethical issues other than to make minor amendments as follows:

1. To include in the Participant Information sheet (PIS) details about the process for managing conflict and disclosures in the focus groups

2. In the Consent form to consider making the items seeking consent to audio tape and use direct quotations be made more explicit with simple statements such as

   • I agree for my participation in the focus group to be audio taped

   • I understand that my contribution will be anonymised in all transcribed material

   • I agree for my anonymised direct quotations to be used in the study

3. To forward a copy of the final questionnaire to the Committee for review at the appropriate time

This Research Ethics Committee is an advisory committee to North West Strategic Health Authority

The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England
Ethical review of research sites

The Committee agreed that all sites in this study should be exempt from site-specific assessment (SSA). There is no need to submit the Site-Specific Information Form to any Research Ethics Committee. The favourable opinion for the study applies to all sites involved in the research.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission at NHS sites ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk

Approved documents

The documents reviewed and approved at the meeting were:

<table>
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<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
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<tr>
<td>Participant Consent Form: Focus Group</td>
<td>1</td>
<td>24 September 2008</td>
</tr>
<tr>
<td>Participant Information Sheet: Questionnaire</td>
<td>1</td>
<td>24 September 2008</td>
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<tr>
<td>Participant Information Sheet: Focus Group</td>
<td>1</td>
<td>24 September 2008</td>
</tr>
<tr>
<td>Letter of invitation to participant</td>
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<tr>
<td>Questionnaire: Survey of attitudes</td>
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<td>14 November 2008</td>
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<tr>
<td>Interview Schedules/Topic Guides</td>
<td>1</td>
<td>24 September 2008</td>
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<td>Protocol</td>
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<td>05 November 2008</td>
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<td>11 November 2008</td>
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<td>Participant study record sheet</td>
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<td>Letter of invitation to participant</td>
<td>1 - Questionnaires</td>
<td>24 September 2008</td>
</tr>
</tbody>
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Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.
After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

With the Committee’s best wishes for the success of this project

Yours sincerely

[Signature]

Dr Philip G Haji-Michael
Chair

Enclosures:
- List of names and professions of members who were present at the meeting and those who submitted written comments
- "After ethical review – guidance for researchers SL-AR2"

Copy to:
- Dr Karen Shaw, Research Governance, University of Manchester
- Dr Andrew Maines, R&D office for UHSM NHS Foundation Trust
- Mr Steve Williams, Consultant Pharmacist in Medicine & Medication Safety, UHSM NHS Foundation Trust