

A SYSTEMATIC REVIEW OF THE INCIDENCE, TYPES & CAUSES OF DISPENSING ERRORS IN COMMUNITY PHARMACY

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Background

Dispensing is a process that requires a pharmacist to transcribe and check the prescription written by the prescribing health professional and then pick the medication and document the process (WHO). The process of good dispensing involves a series of steps which are; Receiving and validating the prescription, understanding and interpreting the prescription, preparing and labeling medicines to be dispensed to the patient, making a final check, recording action taken, issuing medicine to the patient with clear instruction and advice(1)

Medication dispensing is the essence of pharmacy practice, and errors that occur during the dispensing process are a major concern for the pharmacy profession. (2&3)

Dispensing errors refer to the discrepancy between medicines prescribed and medicines received by the patient or as a discrepancy between the written order and the completed prescription (4).

The incidence of MDEs in community pharmacies in the UK and the USA ranges from 0.04% to

24%(2) In the literature, MDEs rates in hospitals varied between countries (0.015%–33.5%)(5)

Dispensing errors are defined as “a discrepancy between prescriber’s interpretable written orders and the filled prescription including written modifications made by the pharmacist under contact with the prescriber or in compliance with pharmacy policy (6).

Introduction

Community pharmacists nowadays are urged to provide a wide variety of professional activities that are essential in the health care system. Since medications are prescribed, there is a consequent risk of human errors. Several different studies have shown that the pharmacist’s interventions can help to improve patient safety as a source of drug information (7) and they have the potential to make a huge impact in reducing the incidence of the risk associated with dispensing and self-medication errors.

Dispensing error is defined as “a discrepancy between a prescription and the medicine that the pharmacy delivers to the patient or distributes to the ward on the basis of this prescription, including the dispensing of a medicine with inferior pharmaceutical or informational quality” (8).

Different studies have investigated the factors behind dispensing errors. A study performed in Saudi Arabia reported that the major identified factor for dispensing errors were pharmacist assistants followed by a high workload and these errors can be mainly reduced by improving doctor’s handwriting and reduce the load of working (AL-arifi, 9). Misreading the prescription and confusing similar names or packaging were the main causes of dispensing errors in the UK (National Patient Safety Agency, 10). Other previous studies reported that pharmacy design, interruptions and other pharmacy environmental factors play an important role in increasing the incidence of dispensing errors (11).

According to the English-based National Patient Safety Agency¹ (NPSA), of the 72,482 medication incidents reported by all healthcare settings and across all stages of the medication process, from prescribing through to preparation/dispensing to administration and monitoring, 4,872 (almost 7%) originated from the dispensing process within community pharmacies (National Patient Safety Agency, 2009). Furthermore, previous research suggests that dispensing errors² occur at a rate of 0.04%-3% in community pharmacy (11&12). Community pharmacists are well placed to play a pivotal role in maintaining and ensuring patient safety. However increasing workload as a result of role expansion from the contractual changes of 2005 as well as organisational pressures to meet targets and various other human and environmental factors may adversely affect pharmacist performance and thus increase the likelihood of errors occurring (13&14). The consequences for the pharmacist after the occurrence of a dispensing error can vary from an investigation by the employer or the local National Health Service (NHS) body to civil or even criminal proceedings. For the patient however, the consequences of the dispensing error can vary from no harm caused, to severe harm, and in some cases, death.

The Role of Community Pharmacy:

Pharmacy is considered the third largest health profession globally (15). In England, it has been claimed that around 1.6 million people visit a community pharmacy every day, of which 1.2 million do so for health-related reasons (16). It has been estimated that community pharmacies see over 90% of the UK population annually (Anderson, 2000). This is partly attributable to its accessibility (89% of the population in England can access a community pharmacy within 20 minutes) and convenience (community pharmacies have longer opening hours and work on a no-appointment basis). Thus community pharmacy is ideally placed to play a key role in promoting health and ensuring safety (15&16). However, at present community pharmacy is not well integrated into the healthcare domain, which means that its position as a health profession is not being utilised to its full potential (17, 18&19,20)

In the UK, community pharmacies operate as privately owned businesses, providing NHS pharmaceutical services as independent contractors (21&22). In England and Wales, these services are provided under the 2005 community pharmacy contractual framework, whereas slightly different arrangements apply to Scotland and Northern Ireland (21). In England and Wales, services are divided into three tiers; essential, advanced and locally-commissioned enhanced services. The provision of essential services is the minimal requirement of the contract, and thus these are provided by all contractors.

Dispensing continues to remain the predominant feature of the pharmacist's role (23). This may be attributable to a sustained increase in the number of prescriptions dispensed in community pharmacy in England annually (24). It could be argued that the workload associated with a high prescription volume presents as a barrier in allowing pharmacists to spend time on other clinical activities. This may be reflected in the steady uptake of the Medicines Use Review (MUR) – an advanced service, and locally commissioned enhanced services, which have only ever been minimal (19). Such increase in the levels of service provision suggests that pharmacists may be coping with a larger work burden. Previous research has suggested a negative influence of workplace factors such as high workload, stress, lack of resources and reduced job satisfaction on the performance of individuals (23,13, 25,26). If developments in the practice of community pharmacy are associated with negative influences of workplace factors on performance, the ability of pharmacists to deliver services safely may be compromised, in particular the dispensing of medicines (27). In recent years, there has been a growing interest in the study of dispensing errors, however, most studies have attempted to quantify the rate of dispensing error occurrence and identify the causes and types of errors. Research to date has been unable to provide a robust assessment of the role that community pharmacists play in ensuring accuracy and clinical appropriateness during the dispensing process, as well as the changes that pharmacists may be making to their dispensing practices in order to manage additional work.

Activities of the community pharmacist:

There has been a substantial change in the nature of community pharmacy during the last century (28). At the beginning of the twentieth century, pharmacists' duties primarily lay in the dispensary where they utilised their knowledge and skills in the compounding and preparation of medicines and this continued up until the industrialisation of the pharmaceutical industry in the 1970s (29,28). After this, whilst dispensing continued to be the core function of the pharmacy profession, the process of dispensing was deskilled to simple, repetitive tasks (28). In response to the Nuffield Report of 1986, which suggested that pharmacists' skills could be better utilised, health policy began to emerge which promoted the delegation of dispensing to appropriately trained staff in attempt to free up the pharmacist's time for the provision of pharmaceutical services (28). In the last decade, government policies, as well as advocacy from professional bodies within pharmacy, have further attempted to shift and extend the pharmacist's role away from dispensing-focussed activities towards patient-centred care (30). However a comparison of two work sampling studies from 1993 and 2013 (30) used an observational, fixed-interval work sampling technique to record the activities of ten community

pharmacists in London. Trained observers recorded the activity of each pharmacist every minute for four hours each day over the course of two weeks and classified the activity into one of eighteen predetermined categories.

The Dispensing process

The industrialization of pharmaceutical products, which began after the Second World War, resulted in the increased availability of pre-formulated and pre-packed medicines, reducing the use of pharmacists' technical skills of compounding and formulating (31,28). Thus over time, the dispensing process has been deskilled to a series of simple manipulative tasks requiring little intellectual input from the pharmacist, thereby reducing the time taken to dispense a prescription (28).

The modern dispensing process is a combination of mechanical and judgmental components involving several distinctive stages (33,32). Mechanical components of dispensing are those that are technical in nature and include the assembly, labeling and supply of medicines as well as the appropriate record keeping of these processes (33). The assembly stage involves selecting the correct product, in the correct dosage form, strength, and quantity as requested by the prescriber. In the vast majority of cases, original packs are supplied; however, where the quantity requested is different to that contained within the original pack, blister packs need to be cut, unit doses counted or liquids poured such that the quantity supplied to the patient (or his/her representative) matches the quantity ordered on the prescription.

Finally, in the patient counselling stage, the pharmacist provides advice and information relating to the safe and effective use of the medicine. Having considered the stages involved in the dispensing process, it is important to note that in the case of harm arising as a result of an error, the pharmacist would share responsibility with the prescriber, even if the error originated in the prescribing process. This is because it would be viewed that the failure of the pharmacist to exercise proper professional judgement during the dispensing process allowed the error to be carried through the dispensing stage and reach the patient (29).

Dispensing error: A dispensing error can be described as an error that occurs during the dispensing process which is unrecognised before the drug reaches the patient (24,35). In previous research, a variety of terms have been used to describe dispensing errors. These include content errors which comprise all errors involving incorrect content such as incorrect drug, strength, form, added or missing dose units and expired medication, and labelling errors, which comprise incorrect drug name, form, strength, quantity, dosage instructions and patient name. Similarly, an error that takes place during the dispensing process but does not reach the patient can be defined as a 'near-miss' (24,35). Slight variations of these definitions exist. It is noteworthy that a substantial proportion of the literature is focussed on medication errors in general - that is any error which occurs from the point of prescribing to the point of supplying the medicine to the patient – as opposed to having a direct focus on dispensing errors in the pharmacy setting (36). Furthermore, there is an inconsistency in the terminology whereby some studies use the term 'medication error' as one that is related to the incorrect supply or administration of medication whilst others have also included adverse events/errors and medical errors (36).

The consequences of a dispensing error

Before reviewing the types and causes of dispensing errors, the consequences after a dispensing error, both for the pharmacist and the patient, will be discussed. In order to inform the discussion, a brief overview of the English legal system as well as the structure of pharmacy regulation will be presented. This will be followed by some of the highprofile cases which shape the pharmacy profession today, and are likely to impact future development.

A-The English Legal System: The basic structure of the English legal system is founded upon two main divisions; statute law and common law. The key difference between these is that statute law is enacted through the parliament in the form of legislation or statutes via Acts of the Parliament which form primary legislation whereas common law is not (37, Slapper and Kelly, 2015).

Acts of particular relevance to pharmacy practice include the Medicines Act 1968, the Misuse of Drugs Act 1971 and the Poisons Act 1972. Any Regulations and Orders subsidiary to the Acts also come under statute law and collectively form Statutory Instruments and are secondary legislation (37). The main difference between primary legislation and secondary legislation is that the former is examined and debated in the House of Commons and the House of Lords and is then forwarded to Royal Assent. Secondary legislation on the other hand does not require debate in the Houses or royal assent before being passed. Whereas statute law is the written law created by the parliament in the form of legislation, common law is the unwritten law that has been created through the judicial decisions that have been made in the past (Slapper and Kelly, 2015). Common law is case-centred and judge-centred, meaning that decisions made on previous cases form a precedent and can be used to help make decisions on similar cases in future, thereby allowing a discretionary ad-hoc, pragmatic approach (Slapper and Kelly, 2015). A basic difference between criminal and civil law is that criminal law is founded upon the assumption that the act of offence constitutes the mental (*mensrea*) and physical (*actus reus*) elements, whereby an intention to commit the wrongdoing is present as well as the physical act itself (Slapper and Kelly, 2015). Civil law does not require the presence of intent or ‘the guilty mind’. It is essential to appreciate this key difference in order to be able to identify the routes taken to address the actions of the pharmacist in the case of dispensing errors. Moreover, a difference also lies in the ‘burden of proof’ required for criminal and civil cases. ‘Burden of proof’ means the level of evidence required to prove the facts of the case (Slapper and Kelly, 2015).

In strict liability offences, proof of the *menses* or ‘guilty mind’ is not a necessary requirement. In relation to pharmacy, a mere dispensing error would be considered a criminal offence, even though there was no intention to do anything unlawful or if no harm was caused as a result. This was seen in the case of *Pharmaceutical Society of Great Britain v Storkwain Ltd.* (1986). In this example, the pharmacist was unaware that the presented prescriptions were forged, and as such made the supply of drugs. Despite appeal against the decision made in the Court of Appeal, the House of Lords confirmed the decision (37).

B-Negligence: The tort of negligence is derived from civil law and concerns the civil liability or legal obligations arising from the ‘wrongs’ or ‘tort’ of one individual towards another. An aggrieved party can sue for compensation of damages that resulted from the ‘wrong’ of the third party (37). Of the various types of tort under civil law, the ‘tort of negligence’ is most often seen in cases of professional negligence (37).

Negligence as an established tort originates from the House of Lords ruling in the case of *Donoghue v Stevenson* in 1932, in which a claim was made against a drinks manufacturer when a decomposed snail was found in a bottle of ginger beer (38). This case enabled the courts to develop the concept of ‘duty of care’, which now forms the basis of clinical negligence cases. The courts must weigh and balance the facts of the case in order to identify whether the defendant could reasonably foresee that the claimant is likely to be injured or suffer harm by his or her actions or conduct. In order to establish negligence, that claimant must prove the following:

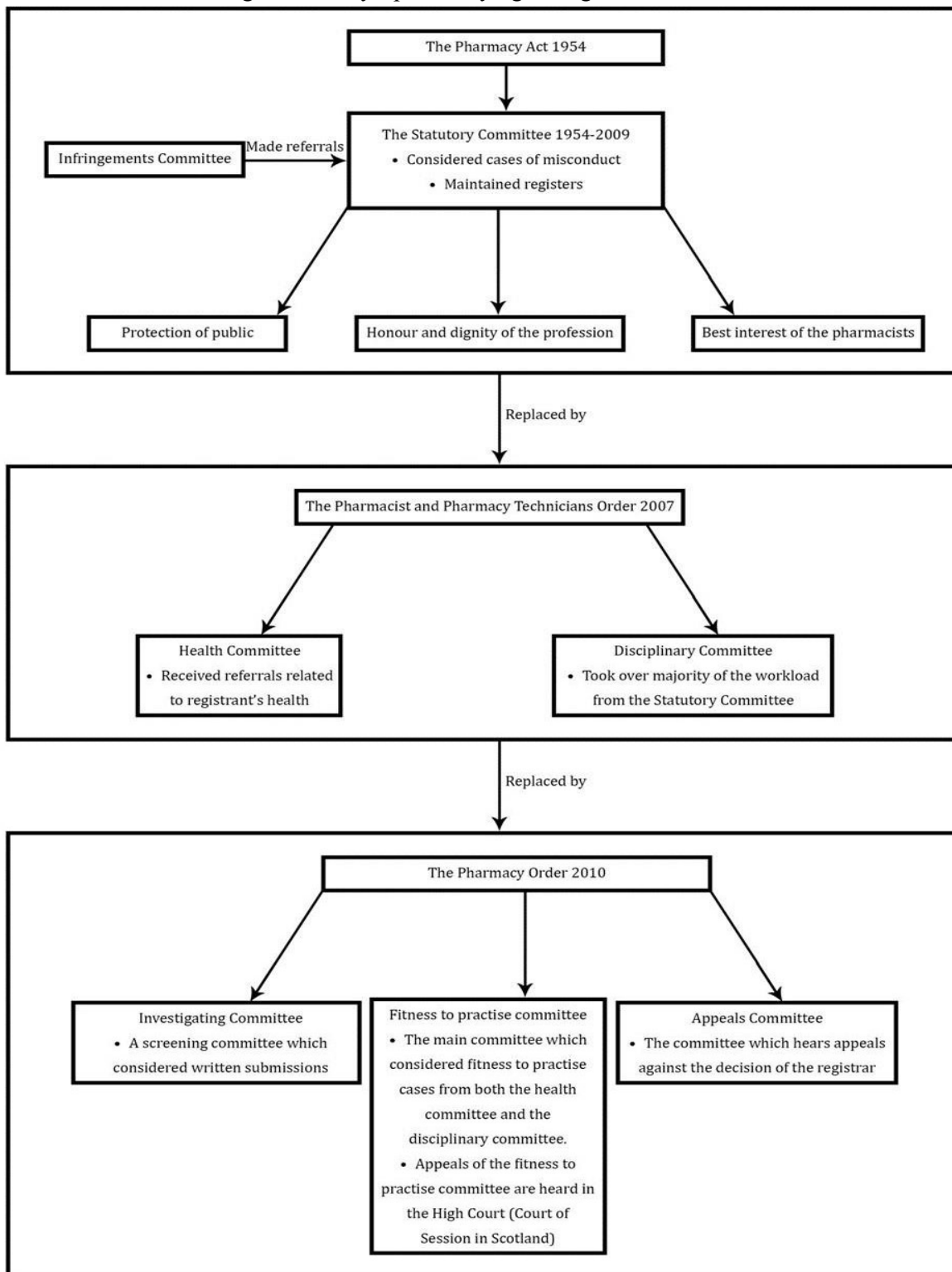
- 1-The defendant owed him a duty of care.
- 2-The defendant was in breach of that duty.
- 3-That he/she suffered damages as a result of that breach.
- 4-That the damage was reasonably foreseeable in all the circumstances(39).

The structure of Pharmacy Regulation:

The European Community Directive 2001/83/EC and the Medicines Act 1968 provide the overall legislative framework surrounding the safe and effective use of medicines for human use (37). Much of the Medicines Act 1968 has been amended and is now largely superseded by The Human Medicines Regulations 2012 (37). The legislation is enforced through the professional regulatory body for pharmacy – the General Pharmaceutical Council (GPhC) (37). The Royal Pharmaceutical Society of Great Britain (RPSGB), which was formed in 1841, remained the representative and regulatory body for the pharmacy profession until 27th September 2010. Subsequently, in order to establish a consistency in the core functions across the regulators of other health professions, the regulatory responsibility of the RPSGB was passed to the GPhC and the representative function was passed to an independent body; the Royal Pharmaceutical Society (RPS) (37,40).

Regulation of pharmacists in the past has been of a reactive nature, whereby the regulator took action when the event had taken place, rather than a proactive nature which would prevent issues arising (40). However, the Pharmacy and Pharmacy Technicians Order 2007 initiated a shift away from reactive regulation by enabling the Disciplinary Committee to issue an interim order. In such cases, a registrant’s health is deemed to be a risk to the public, even when an actual incident related to patient or public safety has not have taken place (40). The establishment of the three statutory committees under the Pharmacy Order 2010 has further attempted to shift regulation to a proactive basis in order to effectively enhance patient safety (40).

Figure 1 History of pharmacy regulating committees



The consequences after a dispensing error;

The consequences after the occurrence of a dispensing error can vary from response to an investigation by the employer or the local NHS body, a civil or, in the most serious cases, criminal proceedings. The route taken depends on the degree of harm caused. For the majority, the error will be identified before any harm is caused and no further action will be taken (40). However in cases where the dispensing error has resulted in some degree of harm to the patient, the patient can pursue a civil claim to gain some form of financial compensation and/or report the matter to the professional regulator, the GPhC(40). Most of the dispensing incidents reported to the GPhC do not progress to criminal or civil proceedings due to the 'Threshold Criteria', which is based upon the seven principles as set out in the GPhC's 'Standards of Conduct, Ethics and Performance' (40). The GPhC stipulates that these standards be complied with by all pharmacists. The threshold criteria are designed to allow minor cases to be dealt with advice and guidance through the inspectorate. It is only these serious or potentially serious cases, which have failed to demonstrate adherence to the seven principles that are referred to the Investigating Committee(40). If an appeal is made against the decision of the statutory committee, the case may progress to the legal court system and be heard in the High Court(40). In the instance that the degree of harm is so severe that the patient dies, a criminal investigation may be necessary before referral to the pharmacy regulator (40). The pharmacist may be charged with gross negligence manslaughter or for breach of pharmacy legislation such as the Medicines Act 1968, the Human Medicines Regulations 2012, the Poisons Act 1972 and the Misuse of Drugs Act 2001(40).

The Pharmacists' Defence Association

The case of Elizabeth Lee, which became a catalyst for a national effort amongst the pharmacy profession to decriminalise dispensing errors, was defended by the Pharmacists' Defence Association (PDA). The Pharmacists' Defence Association is a not-for-profit organisation which aims to look after the needs of the individual pharmacist in an increasingly hostile environment where employee and locum pharmacists make up most of the profession. Established in 2003 from The Pharmacy Insurance Agency (PIA), the PDA claims to be more than just an indemnity insurance provider as it seeks to advise, support and protect its members in their employment and professional activities. Since employment patterns have undergone considerable change in comparison to what they were when many of the representative pharmacy organisations were established, the PDA recognises itself as the only organisation that looks out for the needs of the individual pharmacist rather than the interests of the employer. As well as providing pharmacists with indemnity insurance cover, the PDA is actively involved in lobbying for the interests of the individual pharmacist and the development of the profession. Currently, the PDA has 26000 registered members of which 12000 work in community pharmacy.

Taxonomy of dispensing errors

At present, there is no taxonomy of dispensing errors (34). This poses a great difficulty in categorising errors as there is no universally accepted or validated method for classifying

dispensing errors and, as such, this lack of uniformity is a barrier in the efficient analysis of the presently available research material.

Researchers have used numerous methods of characterizing medication errors. According to (41), errors can be classified according to the stage at which the error occurs in the patient care pathway. These range from errors that take place at the prescribing stage through to dispensing and administration. However, it must be acknowledged that although, there has been an increasing focus on the occurrence of dispensing errors in the pharmacy setting in recent years, most of the presently available literature concerns prescribing errors(36). This may be appropriate as one study suggests that the likelihood of an error occurring is most frequent at the prescribing stage of the patient care pathway (35).

As previously mentioned, errors can arise at any stage of the pharmaceutical care pathway, from the prescribing of the medication through to the administration stage. Due to the fact that the process of dispensing medication falls into the latter part of the medication pathway, it presents an opportunity to identify and correct errors that originated during the prescribing process. The corollary of this is that a failure by a pharmacist to detect a prescribing error would be categorized as a dispensing error (41). This would also be the case in the event of a failure to detect a manufacturing error or if the counselling provided to the patient regarding the use of the medication was inadequate (41).

Another method of classifying dispensing errors that has been used by various researchers is to categories according to the stage of the overall dispensing process in which the error took place.(42) identified these as two major categories namely label errors and content errors whilst (35)suggests the use of prescribing, transcription and dispensing errors, where transcription is the intermediate stage that involves the transfer of data from the prescription to the label. Results from this Danish study found that, of the errors that take place within the community pharmacy setting, transcription errors were most frequent however variations in practice between the UK and Denmark means that these results may not be applicable to the UK (35) however, classified errors according to whether the error was identified within the pharmacy (prevented dispensing incident) or after the medication had left the pharmacy (unprevented dispensing incident); an approach also adopted by the NPSA. According to a comprehensive literature review of international dispensing error research, the rate of prevented dispensing incidents and unprevented dispensing incidents in the UK ranged from 0.22-0.48% and 0.04-3.32% respectively (34). Supply of the wrong drug, strength, form, quantity and labels with incorrect directions constituted the most common type of both prevented and unprevented dispensing incidents(44) grouped errors into two categories, labelling errors and content errors. Each error was also assigned a degree of clinical significance which was determined by a panel of judges. Excluding the wrong quantity as a content error,(12) found that a wrong content error occurred in 0.7% of all dispensed items and the majority of these errors were considered to be of moderate clinical significance. However wrong content errors that included the wrong quantity as a content error occurred in 1.7% of all dispensed items and the majority of these were considered to be of minor clinical significance.

Aetiology of dispensing errors:

Understanding human error using psychological and human-factors perspectives in an attempt to minimise human error in healthcare (45, 46, 47,48,49). Before discussing the causes of dispensing errors, the theoretical basis of human error and the application of human factors and ergonomics as an approach to identifying and minimising dispensing errors will be discussed.

Dispensing is a process that carries an inherent risk of errors as the incorrect supply and administration of pharmaceutical products which are potent and powerful in nature, can be harmful or fatal to patients (40). Over the last decade, policy documents such as the NPSA's 'Seven steps to patient safety for primary care', as well studies examining the causes of errors in healthcare, reflect a growing interest in

A-Human Factors and Ergonomics: Human Factors and Ergonomics (HFE) is a scientific discipline concerned with the understanding of the interactions among humans and other elements of the work system (46) The nuclear and aviation industries are safety critical industries that have successfully applied HFE to engineer reliable systems for minimising human error; for example, in the USA, the statistical chance of dying when travelling by scheduled flight is less than 1 in 3 million (50). However application of HFE in designing and maintaining the safety systems in healthcare has seen slow progress (53). The Institute of Medicine's (IOM) report 'To Err is Human' published in 2000 initiated a renewed interest in the application of HFE to improve patient safety within healthcare (51). A HFE approach to designing work systems was reflected in the NPSA's 'Design for patient safety: A guide to the design of the dispensary environment' (47). However, the NHS remains one the few safety critical organisations that does not have a specialist human factors group in the form committees and courses which can overlook and guide the application of HFE as an attempt to improve patient safety (52).

B-Human Error: Over the last two decades, as the focus on the study of error, in particular in safety critical domains, such as the aviation and nuclear industries grew, so too did the number of proposed definitions of error. Reason's definition of human error however, is one that is widely cited, which defines an error as 'a generic term to encompass all those occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome, and when these failures cannot be attributed to the intervention of some chance agency (54). Other definitions vary around that of (50), which describes an error as 'an unintended act or as an act that does not achieve its intended outcome'. However, a clear, comprehensive and universally accepted definition of human error does not yet exist.

The human failure component is apparent in almost all major safety incidents. According to Feyer and (54), almost 90% of workplace accidents are estimated to have human failure as a cause, thus reinforcing the inevitability of the occurrence of human error. Although the likelihood of human error occurring can never be completely eliminated, it can be reduced by improving systems through, for example, improvements in training, reductions in workload and the alleviation of stress (54,56). Leading error experts have proposed models of error to provide a theoretical basis of the nature of errors in attempt to aid the understanding of the

fundamental factors and mechanisms at play when an error takes place. Reason's model of human error is one that has gained widespread recognition within healthcare organisations and has previously been applied to investigate prescribing error (57).

Reason's Model of Human Error

(54) proposes two approaches to understanding human error; the person approach and the system approach. Each will be discussed in detail below.

The person approach places a focus on individual factors and assumes the individual as responsible for the error. The unsafe acts that produce errors are considered failures in the mental processes of the individual which results in inattention, forgetfulness and moral weakness. Based on Rasmussen (1983)'s model of human performance, (58) categorizes the errors made by individuals into three types:

Skill-based errors – The action made is not what was intended. These are also referred to 'slips' and 'lapses'.

Rule-based errors or 'mistakes' – The intended action is made but does not achieve its intended outcome due to incorrect application of the rule.

Knowledge-based errors or 'mistakes' – The intended action is made but does not achieve its outcome because the individual is faced with a situation beyond their knowledge or skills thus resulting in a misinterpretation of the problem.

Technical Factors

Increased workload, staffing, interruptions, types of dispensing systems and software, pharmacy design and light and sound conditions have all been cited as factors influencing the occurrence of dispensing errors (59,60, 61, 62,63).

Workload: Workload within community pharmacy has been a topic of considerable interest, particularly after the introduction of the pharmaceutical contract of 2005 (13,64). In recent years a considerable increase in workload within the UK has been observed (64). It is thought that this may be due to two reasons; first, the demand for pharmaceutical services has increased, and second, the role for pharmacists has expanded (64). Findings of a comprehensive review of international literature on dispensing errors found that the most commonly cited cause of dispensing errors was high workload (34). However, at present what constitutes high workload is ill-defined, and there appears to be an inconsistency in the measures of workload used in the literature (65).

Interruptions and Distractions

Interruptions and distractions commonly disrupt the work activity of pharmacists and compromise the attention that a pharmacist pays to a given task. Previous research suggests a positive association between interruptions and disruptions and dispensing errors (66,67). It is

thought that interruptions interfere with human cognitive processes that are linked to memory and decision-making (Emmertson and Rizk, 2012, Lea et al., 2015). However at present there is a lack of evidence to confirm a causal relationship between interruptions and dispensing errors (Grundgeiger and Sanderson, 2009). The incidence of distractions and interruptions is thought to have increased in UK community pharmacy noticeably after the introduction of the community pharmacy contractual changes of 2005 (50). Given the absence of evidence relating to the quantitative estimates of interruptions in community pharmacy prior to the contractual changes, it is assumed that an apparent increase in interruptions after the contractual changes may be associated with increasing workloads and role expansion, whereby pharmacists are performing a wider range of tasks. Possibly the most widely cited study examining interruptions during the dispensing process is that of Flynn et al. (69) where fourteen pharmacists were videotaped as they dispensed prescriptions in the presence of an observer who checked the dispensed prescriptions to identify any errors. The results revealed that distractions occur at a rate of 8 per hour, and interruptions occur at a rate of 6 per hour. The study also found that there was no significant direct effect of interruptions and distractions in individual prescriptions. However, when the total number of interruptions over half an hour increased, a significant effect on the occurrence of errors was observed (69). A possible explanation for this may be that the diversion of attention as a result of the interruption or distraction created a short break from the work, which resulted in the pharmacist to review their work upon returning to the task. Continued interruptions over half an hour, however, deteriorated the accuracy of pharmacist dispensing, by reducing the pharmacist's attention. These findings concur with other research which suggests that interruptions do not always have a negative effect on error occurrence and medication safety. Whilst interruptions can have a negative impact on pharmacists by creating a disruptive effect on human cognitive processes (thereby increasing mental workload), interruptions can also reduce error occurrence by allowing detection of errors upon resuming to the task after the interruptions (68, 69,67).

Negative effects of interruptions are thought to occur due to an increased cognitive workload as a result of task disruptions and interruptions (67,69). Studies investigating the impact of subjective workload on error occurrence indicated that external task demands (e.g. interruptions, divided attention and being rushed) were associated with an increased perceived likelihood of error occurrence. On the contrary, Holden et al. (2010) found that internal task demands that require higher levels of concentration and mental effort were not associated with an increased perceived likelihood of error occurrence.

These findings suggest that gaining an understanding of the impact of interruptions on human cognition and mental effort are a key step in identifying effective strategies to overcome errors that are associated with interruptions, multi-tasking and disruptions.

Look-alike sound-alike drug names and packaging

Orthographic (look-alike) and phonetic (sound-alike) similarities in drug names and/or similarities in packaging of medicines have been cited as a major contributory factor to dispensing errors (11). Around one in four medication errors is said to involve look-alike

sound-alike (LASA) drug names and/or similarities in packaging . A prospective study examining the occurrence of dispensing errors in thirty five community pharmacies found that drug selection errors accounted for 60% of all dispensing errors (11). The study also found that almost 17% of all dispensing errors were attributed to similar drug names and almost 8% attributed to similarities in packaging (11). Given the significance of LASA drug names and similar packaging on the occurrence of dispensing errors, strategies to reduce errors associated with LASA drug names and packaging could prove to be an effective approach in reducing the occurrence of dispensing errors.

It is thought that the presence of similar looking or similar sounding drug names within a visual field distorts the cognitive processes involved in selecting the correct product, thereby increasing the chances of a drug selection error (70). With so many LASA medicines in pharmacies, drug names can often be misidentified as a result of misreading the drug name (71). LASA drug names are frequently found within a neighbourhood of LASA drug names, often on pharmacy shelves or in lists in dispensing software (71). When this neighbourhood is dense (when there are a greater number of competing similar names), the presence of other LASA drug names interferes in the identification and selection of the correct drug name (Emmerton and Rizk, 2012). Similarities in packaging, hand-written prescriptions, inadequate lighting and interruptions further confound the correct identification of LASA drug names (71).

Sound and Lighting:

Sound levels and lighting can also have a direct impact on the performance of individuals (Buchanan et al., 1991, Flynn et al., 1999). The findings of a study carried out in a high-volume dispensing military outpatient pharmacy, where pharmacists were subject to various intensities of lighting conditions and observed for errors, found that illumination at 146 foot-candles (foot-candles is a measure of light intensity used mainly in the United States) considerably reduced dispensing error rate compared to the baseline of 45 foot-candles of illumination (Buchanan et al., 1991). The relationship between sound and occurrence of dispensing errors however, is difficult to characterise (69). Flynn et al. (69) found that two aspects of sound influenced the occurrence of dispensing errors; the nature of the sound and the loudness. The study found that certain types of noises, for example unpredictable sounds and controllable sounds, can reduce dispensing errors. This may be attributable to an arousal effect of the unpredictable and controllable stimuli which can enhance the concentration and thereby improve performance. However, increases in the loudness of sounds resulted in a substantial increase in the rate of dispensing errors to a certain level beyond which loudness did not influence the rate of dispensing errors (69). Thus error occurrence is not directly related to ambient sound.

Physical environment of the dispensary

Pharmacy design, which refers to the spatial design and layout of the dispensary (72) and types of dispensing systems, which refers to manual or automated dispensing, have also been cited as being associated with the occurrence of dispensing errors. Over 80% of the dispensing errors reported to the NPSA via the National Reporting and Learning System (NRLS) are those made when selecting an item from a shelf of stock. 'Selection errors' most often involve the wrong strength or formulation of the intended medication or the wrong medication. Poorly designed

dispensary environments and layouts augment the likelihood of an individual making an error. Open type designs, where the pharmacist and the dispensary space is greatly visible to the patients, can hinder privacy and as such can deter pharmacists from concentrating and consulting literature for safe dispensing (72). Studies looking into the impact of various types of dispensing systems are scarce at present and those that do exist originate from secondary care. The rate of both prevented and unprevented dispensing incidents was considerably lower with Automated Dispensing Systems (ADS) as compared to manual dispensing. ADSs can be used for computer-controlled storage and dispensing of medications and can be helpful in eliminating content error types as the product selection stage of dispensing is carried out by dispensing robots, whereas manual systems were associated with a variety of content errors. Furthermore, automation at the labelling stage of dispensing through the use of Patient Medication Record (PMR) or Electronic Transfer of Prescriptions (ETP) linked systems can be helpful in reducing dispensing errors. Across the medication processing pathway, errors are most frequent at the transcription stage thus reduction of labelling errors through the use of PMR and ETP linked dispensing systems may be a useful approach in reducing error occurrence.

Work stress and pressures, and working conditions

In the past, little effort was made to determine the levels of stress in community pharmacy, the causes of work stress and how it may be associated with the occurrence of dispensing errors. As mentioned in section 1.2 the role of community pharmacists has changed in the UK and internationally, with community pharmacists now providing a range of additional health services (73). Previous research suggests that community pharmacists perceive higher levels of workload as a result of increasing dispensing volumes and provision of additional services. As a consequence, anecdotal evidence and research suggests that community pharmacists experience higher levels of work stress compared to their counterparts in hospital pharmacy as well as the general working population.

Large-scale survey (n=1080) conducted by revealed that 58% (n=762) of community pharmacists felt stressed at work, whilst 24% reported working longer hours since the introduction of the contractual changes. However, it is unclear if the increasing levels of stress in community pharmacy are related to role overload or role conflict. The most common factors associated with work-stress are increasing workloads, target-driven working environments, interruptions, long working hours, lack of rest breaks and inadequate staffing. Furthermore, at present, it remains unclear whether increasing levels of work-stress and pressures adversely impact patient safety and the occurrence of dispensing errors. A large-scale survey conducted by (73) found a significant association between perceptions of high workloads and self-reported occurrence of dispensing errors. Work-life balance, nature of job and work relationships were identified as stressors impacting the physical health of community pharmacists, whilst role overload and resources and communication were identified as stressors impacting psychological health. Poor working conditions and long working longer hours were factors that transpired in the two major dispensing error cases; that of Elizabeth Lee and more recently the case of Martin White. With minimal research looking at working hours in

community pharmacy, it is difficult to ascertain a causal link between long working hours and dispensing error occurrence. A survey conducted by the Pharmacists' Defence Association that yielded a response from 1,621 community pharmacists revealed a prevalence of long working hours in community pharmacy. 38% of respondents reported that they worked between 35 and 48 hours per week, whilst 7% reported working over 48 hours per week. Furthermore, the survey revealed a culture of longer working days with 65% of respondents working between 8 and 10 hours (excluding breaks) and 4% working longer than 10 hours per day. In addition to lengthy working hours, the survey revealed a high incidence of a lack of rest breaks taken during the working day; 71% of respondents reported working through the day without taking a rest break of which 50% did so because they were required to by their employers whilst 24% opted not to take a rest break out of necessity. Deteriorating working conditions is a concern often raised by community pharmacists in qualitative studies exploring the impact of increasing levels of workload in community pharmacy. However, the findings of the survey conducted by the Pharmacists' Defence Association raise concerns about unsafe working conditions in community pharmacy and their potential association with dispensing error occurrence

Staffing and skill-mix: Very little research has investigated the adequacy of staffing levels and skill mix in community pharmacy, and whether this is having an impact on the occurrence of dispensing errors. Whilst insufficient numbers of dispensary support staff and inadequately trained support staff are commonly cited contributory factors in studies investigating dispensing errors in community pharmacy, there is yet no evidence to support that these factors may be influencing the occurrence of dispensing errors. Since the introduction of the community pharmacy contractual changes, increasing levels of workload have raised concerns over staffing levels and skill mix in community pharmacy. Research exploring perceptions of increasing workloads in community pharmacy suggests that staffing levels have failed to keep up with demand arising from increasing levels of workload, thereby adding a work burden to overworked community pharmacists and hindering role expansion, (The Pharmacists' Defence Association, 2006). Skill mix and distribution of roles amongst community pharmacy support staff is also an under-researched area (74). According to the level of training attained, there are three categories of dispensary support staff: Medicines Counter Assistants (MCAs), dispensing/pharmacy assistant and pharmacy technicians and accuracy checking technicians (ACTs) (Bullock et al., 2016). Below are definitions for these roles. Whilst there is a paucity of evidence concerning community pharmacy support staff, their numbers, roles and distribution across various pharmacy settings, the evidence that there is suggests that community pharmacy support staff have not expanded their roles in order to meet the workload demands arising from increasing prescription volumes and provision of clinical services (Mullen, 2004). Despite willingness on the parts of community pharmacists to delegate tasks associated with the dispensing process to members of pharmacy support staff, work-sampling studies suggest that pharmacists continue to perform dispensing tasks that can be carried out by suitably trained dispensary support staff such as dispensary assistants or ACTs. Research conducted by a significant association between the number of dispensary support staff and the number of clinical services provided by the pharmacy; pharmacies with a greater number of technicians provided more clinical services than those without suggesting that making full use

of the skill held by support staff is an essential step towards enabling pharmacists' role expansion. At present, due to a dearth of evidence regarding skill-mix in community pharmacy, it remains unclear whether the level of training attained by dispensary support staff involved in the dispensary of prescriptions is an important factor contributing to dispensing errors. Furthermore, more research is needed to identify strategies that can utilise the skill mix of dispensary support staff to better manage community pharmacy workload as a means of error reduction.

Social factors; Social factors of the sociotechnical components of work systems in pharmacy and healthcare comprise the relationships and attitudes of individuals in the system towards each other and to the work itself. These include factors such as communication, trust in other staff members and attitudes towards reporting dispensing errors. In community pharmacy, the form of communication most commonly associated with dispensing errors is poor handwriting, although this form of communication has been much reduced by the increasing use of computer-generated prescriptions. Poor handwriting as a source of error has been cited in numerous studies (11,35). The illegibility and ambiguity associated with poorly written prescriptions then results in the pharmacist making interpretations (Knudsen et al., 2007b). This increases the likelihood of error being carried forward from the transcription stage to the dispensing stage. In instances where a pharmacist attempts to overcome ambiguity by gaining a verbal clarification from the prescriber, various other barriers exist that hinder effective communication. These include the challenge of getting past the 'gatekeeper' (a role most commonly fulfilled by receptionists in GP surgeries), inter-professional barriers in communication influenced by a perceived disparity in professional power between GPs and pharmacists, as well as time constraints. Relationships and attitudes of staff are also considered social factors of the sociotechnical system. Whilst increasing staff numbers can reduce pharmacist workload on a technical level, on a social level, assigning more individuals to the same task or responsibility (such as a step of the dispensing process) can result in an increased reliance upon others to carry out the task. This may result in an individual to assume a task has been completed by another member of staff, when it may not have. Furthermore, an increased degree of familiarity between staff members can contribute to error occurrence in a similar fashion due to the established trust allowing individuals to easily accept one another's judgements.

Individual's factors

Personality traits, gender and state anxiety are also factors associated with an individual that have been shown to have some degree of association with dispensing errors in previous research. In a pharmacy-simulated experiment, examined the state anxiety of 75 undergraduate students after they were subjected to a dispensary task. A measure of participants' state anxiety was measured using The State-Trait Anxiety Inventory; a validated tool widely used to measure state anxiety. The results showed a strong relationship between state anxiety and accuracy of dispensing task with higher levels of anxiety being associated with less accurate performance, thereby producing a greater number of errors. In another pharmacy-simulated experiment, found that personality traits had a modest but significant

association between the accuracy of an individual to identify dispensing errors. Research into personality traits and accuracy of performance in other high-risk jobs also suggests a similar association. Likewise, gender was shown to be associated with accuracy of performance in another pharmacy-simulated experiment which showed women tended to work more slowly and more accurately than men (75).

The cognitive deficiencies of individuals is also an aspect of individual factors that cannot be completely eliminated; the chances of human error will always remain in tasks where humans are involved (Reason, 1990). Human error and performance can be considered two sides of the same coin: mechanisms at play that precipitate an error are the same as those involved in human performance. Whilst human error can never be eliminated, various high risk industries have studied the human error component of incidents and developed ways to minimise its manifestation in systems failures. For example, verbal double-checking procedures, where items are read out aloud from a checklist by one individual and checked by another, are a safety mechanism used by airline pilots as well as healthcare professionals, most notably, radiographers. Various studies within aviation and healthcare safety management have highlighted the propensity for an individual to fail to perform a task despite possessing a belief that they have checked items diligently when they may not have. Findings within these industries as well as findings from human psychology have introduced the socio-psychological phenomenon of 'involuntary automaticity' – which is a reduction in the conscious attention given to a skilled activity when individuals are subjected to adverse operational conditions such as repetition, high workloads, strict time constraints and stress. A study by James et al. (2009) looking into the types, causes and contributory factors of prevented and un-prevented dispensing incidents found that 97% of the prevented dispensing incidents had undergone an accuracy check. Moreover, found that the rate of near-misses was far greater than dispensing error rate and that the highest error rate was for prescription corrections, reflecting that quality control within community pharmacies does play an important role in safety management. Previous research has suggested that whilst accuracy checking is a crucial stage of quality control and error prevention, it is not wholly effective in eliminating errors as 97% of prevented dispensing incidents had undergone an accuracy check. James suggests that this may be due to involuntary automaticity whereby the individual checking may be subject to error-promoting automatism due to repetition of tasks.

Safety culture in community pharmacy

Pharmacies are organisations that inherently face hazards with potentially life-threatening consequences on a daily basis. From selecting the wrong medication, strength or form, to applying the wrong label or handing medication to the wrong patient, pharmacists use their knowledge and skills to avoid errors that can result in harm or injury. As such, healthcare organisations such as community pharmacy should exhibit the attributes of 'High Reliability Organisations' or HROs, such as the military, aviation and nuclear industries. A HRO can be defined as 'organisations that face high intrinsic hazards yet perform successfully because they treat safety systematically'. Although research has been conducted into the concept of safety culture within various organisations, research examining the relationship between the extent of safety culture and the occurrence of dispensing errors in community pharmacy is limited.

Moreover, the guidance and dynamics required to initiate the change for the establishment of a safety culture within this setting is also limited (76). The scope of such research in pharmacy has been confined to prescribing and administration errors, mainly in the hospital setting with minimal work examining dispensing errors in community pharmacy. Moreover, the vast majority of research in this area originates from the United States and as such relatively little information is available on the UK perspective. This adds a further challenge in identifying the causes of dispensing errors in UK community pharmacies and hence making any suggestions to reduce errors.

Measuring Safety Culture and Error Identification;

Safety culture is an important diagnostic tool to assess the quality of care within an organisation and gain a measure of the predictability of error occurrence. Westrum proposed that safety culture in essence describes the levels of sophistication of information flow and handling within organisations and Safety culture is an important diagnostic tool to assess the quality of care within an organisation and gain a measure of the predictability of error occurrence. Westrum (2004) proposed that safety culture in essence describes the levels of sophistication of information flow and handling within organisations and An important aspect in establishing a safety culture is the identification of the causes of error. As is common practice in high risk industries, various analytical tools have been devised to aid the assessment of the vulnerability of systems to errors and enable the identification of potential causes of errors. The critical incident technique has been used in hospital settings to evaluate the causes of dispensing errors (. It involves participants describing their experiences and allows an analysis and interpretation of the individual understands of their environment. Application of this technique identified that errors most commonly occurred at the label generation stage followed by the stock selection phase; a finding supported by other research.

Root Cause Analysis (RCA) takes an analytical approach and identifies the critical causes and contributors to the occurrence of errors and, in the process, provides insights into approaches to managing hazards. Application of RCA in identifying dispensing errors found that handwritten prescriptions, similarities in packaging, names, strengths and dosages, lack of effective control of prescription labelling due to an over reliance on software and other members of staff, and lack of concentration caused by interruptions are the underlying causes of transcription errors.

Reporting of errors

Under the clinical governance requirements of the pharmacy contract, community pharmacies are required to report all incidents that did or could have harmed the patient to the NPSA (Pharmaceutical Services Negotiating Committee, 2017b). The National Reporting and Learning Scheme (NRLS) collects data on adverse events and issues an annual summary report with the statistics. According to data collected since 2003, there has been a slowly increasing trend in reporting errors; however, the overwhelming majority of these reports originate from acute care and hospitals, with reports from community pharmacy being negligible. Ashcroft conducted a survey of 223 community pharmacists and 52 support staff to examine the

likelihood of pharmacists and support staff to report patient safety incidents. The results showed that community pharmacists and support staff are unlikely to report adverse incidents occurring in community pharmacy; however the study fails to indicate the percentage of those who would not report incidents (11).

Outcome of dispensing errors

A-Outcome for patients: Most research looking into dispensing errors in community pharmacy has focussed on studying the incidence, types and causes of dispensing errors. Very little research has been conducted to identify the clinical significance of dispensing errors and the degree of harm caused as a result of errors. An observational study conducted by Franklin and O'Grady in 11 community pharmacies, assessed the clinical significance of errors detected. The majority of errors (67%, n=64/95) were of minor significance, whilst 32% (n=30/95) were of moderate significance and 1% (n=1/95) were of severe significance. Whilst not specific to the community pharmacy setting, or the dispensary process, a majority (82%) of the incidents reported to the NPSA via the NRLS resulted in no harm (National Patient Safety Agency, 2009). It does not present data specific to dispensing errors in community pharmacy or to the dispensing process. Given the paucity of evidence of the clinical significance of dispensing errors, it is difficult to compare and analyse previous literature.

b-To our knowledge, to date, no research study has explored the outcome of dispensing errors for community pharmacists and the impact of dispensing errors on the work and personal life of community pharmacists. Research studies looking into the experiences of community pharmacists with increasing workloads have reflected a growing concern amongst community pharmacists towards unsafe working conditions which can potentially precipitate the occurrence of dispensing errors. However, research studies focussing specifically on the experiences and attitudes of community pharmacists towards dispensing errors within community pharmacy do not exist. Furthermore, there is a paucity of published evidence about the experiences of community pharmacists after a routine dispensing error has been made and the impact of the error on the pharmacists work, personal life and practice the cases of Elizabeth Lee and Martin White (see section 1.10) which resulted in patient death, the occurrence of the dispensing errors had a detrimental effect on the pharmacists' pharmacy careers, as both pharmacists chose never to subsequently work as a pharmacist (PL, 2016). Considering the fact that the cases of Elizabeth Lee and Martin White resulted in a severe outcome, the choice made by these pharmacists to never work as a pharmacist is to some degree understandable. In effect, Elizabeth Lee and Martin Lee, once successful pharmacy professionals, became second-victims of their own error. Not specific to pharmacists, the emotional side effects of a medical error experienced by healthcare practitioners range from shame, self-blame, self-doubt and loss of sleep. Despite such strong effects, it is thought that only one in four healthcare practitioner receives the necessary institutional support to deal with the stress(77). An unanswered need for support for the healthcare practitioner is a symptoms of a pathological organisation in which a poor safety culture means system failure precipitate conditions where errors are incidents waiting to happen. It may be argued that second victimisation stems from a culture of perfection and infallibility prevalent in healthcare, fuelled by fears of humiliation, shame and public

scrutiny and disciplinary action ad punish men. Therefore efforts to create a non-punitive healthcare environments would require a cultural shift as well as a shift in the professional identity of healthcare professionals (77).

Conclusion:

Summary of literature and gaps identified

This literature review has considered the quantitative estimates of dispensing errors, the types and causes of dispensing errors as well as the consequences after an error takes place. It has also highlighted the complexities involved in identifying the causes of dispensing errors as well as the approaches that can be taken to design work systems to minimise error. However, gaps remain in the literature. For example, with regards to the occurrence of dispensing errors within community pharmacy, research has mainly focussed on employing self-reporting or observational methods of data collection, where errors are identified before the medication has been supplied to the patient/representative and thus reflecting potential dispensing errors. Along with the bias associated with self-reporting and observational studies, these approaches to dispensing errors research do not reflect the profile of actual dispensing errors. This literature review also found a paucity of research regarding the outcome of dispensing errors, for patients as well as the pharmacist. At present very little is known about the clinical outcome of dispensing errors for the patients involved and the degree of harm caused. Any data that does exist originates from error reporting schemes not confined solely to the dispensing process, therefore not directly applicable to dispensing errors research. With regards to the outcome of dispensing errors for the pharmacist, there is no previous study that has researched the impact of dispensing errors on the pharmacist's work and personal life, their dispensing practice, or their well-being. Whilst a number of research studies, mainly qualitative, have been conducted to investigate the impact of increasing workloads and stress in community pharmacy, previous literature has not investigated the experiences of community pharmacists during a dispensing error nor have they focussed on the ways in which the working environments of pharmacists can precipitate in dispensing errors

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