Safety Science 105 (2018) 114–120

Contents lists available at ScienceDirect

Safety Science

journal homepage: www.elsevier.com/locate/safety

Understanding procedural violations using Safety-I and Safety-II: The case of community pharmacies

Christian E.L. Jones[a,b,*], Denham L. Phipps[a,b], Darren M. Ashcroft[a,b]

[a] NIHR Greater Manchester Patient Safety Translational Research Centre, The University of Manchester, Williamson Building, Oxford Road, Manchester, M13 9PL, United Kingdom

[b] Drug Usage and Pharmacy Practice Group, Division of Pharmacy and Optometry, School of Health Sciences, University of Manchester, Stopford Building, Oxford Road, Manchester M13 9PT, United Kingdom

ARTICLE INFO

Keywords:
Pharmacy
Compliance
Patient safety
Qualitative research
Primary care

ABSTRACT

Objective: Procedural violations are known to occur in a range of work settings, and are an important topic of interest with regard to safety management. A Safety-I perspective sees violations as undesirable digressions from standardised procedures, while a Safety-II perspective sees violations as adaptations to a complex work system. This study aimed to apply both perspectives to the examination of violations in community pharmacies.

Design: Twenty-four participants (13 pharmacists and 11 pharmacy support staff) were purposively sampled to participate in semi-structured interviews using the critical incident technique. Participants described violations they made during the course of their work. Interviews were digitally recorded, transcribed verbatim and analysed using template analysis.

Setting: Community pharmacies located in England and Wales.

Results: 31 procedural violations were described during the interviews revealing multiple reasons for violations in this setting. Our findings suggest that from a Safety-II perspective, staff violated to adapt to situations and to manage safety. However, participants also violated procedures in order to maintain productivity which was found to increase risk in some, but not all situations. Procedural violations often relied on the context in which staff were working, resulting in the violation being deemed rational to the individual making the violation, yet the behaviour may be difficult to justify from an outside perspective.

Conclusions: Combining Safety-I and Safety-II perspectives provided a detailed understanding of the underlying reasons for procedural violations. Our findings identify aspects of practice that could benefit from targeted interventions to help support staff in providing safe patient care.

1. Introduction

Procedural violations (when procedures are purposefully deviated from or bypassed) are known to occur in a range of work settings (English and Branaghan, 2012, Hale and Swuste, 1998, Hale and Borys, 2013), including healthcare (Phipps et al., 2008, Phipps et al., 2010, Alper et al., 2006). Although they are usually not intended to cause harm, and indeed are sometimes made with explicitly good intentions, violations have been noted as a potential threat to patient safety.

For example, Amalberti et al. (2006) suggested that violations that are allowed to become routine work practice may lead to the "migration" of work towards or across nominal safety boundaries. Previous studies have suggested that violations are linked to the presence of latent factors, particularly concerning individual and collective beliefs about the applicability of rules to one's work (Phipps et al., 2008, Phipps et al., 2010, McDonald et al., 2005).

Individuals within a work system have often been judged as "liabilities" whose behaviour may lead to accidents (Hollnagel, 2015). The provision of detailed rules is often intended to minimise opportunities for human error by limiting the freedom of choice in responding to a given situation (Hale and Swuste, 1998). Violations from this perspective represent a deviation from the "correct" way of working and introduce an element of risk to practice.

The notion that violations are largely negative behaviours is consistent with the philosophy of 'Safety-I', where safety is based on the absence of incidents and accidents. This approach to safety has traditionally been the dominant view in healthcare, with procedures often being used as an attempt to protect against adverse events. As Table 1

* Corresponding author at: Division of Pharmacy and Optometry, School of Health Sciences, University of Manchester, Stopford Building, Oxford Road, Manchester, M13 9PT, United Kingdom.

E-mail address: chrissy.jones@manchester.ac.uk (C.E.L. Jones).

https://doi.org/10.1016/j.ssci.2018.02.002
Received 16 February 2017; Received in revised form 5 January 2018; Accepted 2 February 2018

Table 1
An overview of the Safety-I and Safety-II approaches (Hollnagel, 2015).

	Safety-I	Safety-II
How is safety attained?	By preventing as many things as possible from going wrong	By enabling as many things to go right
How is healthcare viewed as a work-system?	Healthcare is a linear system constructed of identifiable components	Healthcare is a complex and adaptive system
How is safety achieved in healthcare?	Highly detailed procedures exist that instruct staff on exactly how to work safely	Safety is maintained by the initiative and expertise of healthcare professionals
How do staff deal with risk?	Reactively	Proactively
How are staff typically viewed by management?	Blamed for adverse events	Recognised for their role in helping things to go right most of the time
How do staff learn in practice?	By looking back at what has already gone wrong using incident reporting and investigations and by updating current procedures or introducing new procedures to restrict the work of healthcare staff	By reflecting on how things were able to 'go right' in practice and possessing the flexibility to decide on the safest way to work when appropriate
How are procedural violations judged?	Violations are frowned upon. Complying with procedures is the safest way to work	Violations are expected and understood as sometimes being necessary for ensuring the correct care is provided to patients

shows, the Safety-I approach to risk management may be contrasted with the 'Safety-II' approach, which places safety in the context of the variation in working conditions found in complex work systems (Hollnagel, 2011).

A Safety-II perspective views violations primarily as staff attempting to manage system complexity (Nemeth et al., 2004, Woods et al., 2012, Dekker et al., 2013). In other words, the notion of Safety-II emphasises the need for staff to negotiate variability, diversity, limited resources, specialisation and ad-hoc teams in the course of their work, whilst attempting to follow procedures that do not account for these sources of complexity (Dekker et al., 2013).

Sujan et al.(Sujan et al., 2016) proposed that system variability results in most things "going right" in healthcare settings. One approach to focusing on success is known as "positive deviance" (Lawton et al., 2014). Staff may sometimes deviate from procedures during their practice, however, their positive deviance can lead to an improvement in the system rather than a risk (Lawton et al., 2014). Hence, it cannot be assumed that safety is always achieved by strict adherence to procedures as implied in the Safety-I approach (Hollnagel, 2015). However, Safety-I cannot be overlooked; within the context of Reason's Swiss Cheese model, violations can lead to "holes" within a system, and although these actions often 'go right', harm may occur under circumstances that exploit enough of the system holes (Reason, 2000).

Whilst previous studies have focused typically on Safety-I and Safety-II as separate approaches (Sujan et al., 2016, McNab et al., 2016), it has been suggested that combining these philosophies may be required to manage safety (Hollnagel, 2014). Hollnagel et al. (2015) argue that both Safety-I and Safety-II are characterised in the everyday work of clinicians, as they combine working within the scope of rules by working flexibly, depending on factors such as the nature of the work, the experience of the staff, the organisational climate, management and patient pressures (Hollnagel, 2015). Focusing only on what goes right as suggested by the Safety-II and positive deviance perspectives (Kelly et al., 2016) does not present a representative view of how safety is manifested in practice (Hollnagel, 2012b). At times, staff may use flexibility to work efficiently, which can lead to a lack of thoroughness (Hollnagel, 2009). Exploring how and why things go wrong is an important part of understanding how safety can be improved (Hollnagel, 2012b).

The current study explores the application of both Safety-I and Safety-II perspectives to understanding procedural violations in the community pharmacy (CP) setting. As in other settings, CP imposes a range of demands on its management and front-line workers; for example, meeting both commercial and patient care objectives (Phipps and Ashcroft, 2011, Jacobs et al., 2011), given the growing increase in number of prescriptions dispensed in community pharmacy settings (Prescribing and Medicines, 2017). CP has been described as a complex system, where medicines management relies on staff managing social and technical factors within their workplace (Phipps and Ashcroft, 2011; Phipps et al., 2017; Jacobs et al., 2011). Staff must also manage relationships with patients and multiple healthcare providers across community and hospital care. Furthermore, recent government initiatives in the UK have encouraged patients to visit their CP for acute illnesses which may help to relieve pressure on general practices and Accident and Emergency departments (Morecroft et al., 2015, Murray, 2016). Previously, CP staff have been observed to violate procedures for selling over the counter (OTC) medicines (Watson et al., 2006). Their behaviour has been framed as a result of latent conditions such as a lack of training, understaffing or time pressure (Watson et al., 2008).

The aim of this study was to understand the reasons why staff choose to violate procedures from a Safety-I and Safety-II perspective. In doing so, we aimed to understand how Safety-I and Safety-II approaches could be combined to support staff in providing safe care by learning both from when things go wrong and from when things go right in practice (Hollnagel, 2015).

2. Methods

2.1. Study design and setting

The study used a qualitative design, involving one-to-one interviews with CP staff regarding the nature and antecedents of procedural violations in practice. The sampling frame was CP staff in England and Wales. Ethical approval was granted by the University of Manchester Research Ethics Committee (Ref 14352).

2.2. Data collection

Participants were invited to participate in a semi-structured interview, based on the critical incident technique (Flanagan, 1954, James et al., 2008). Given that discussing violations could be considered a sensitive topic, participants spoke with the interviewer on a one to one basis as opposed to speaking within a group where confidentiality could not be guaranteed. Participants were informed prior to the interview that any declaration of patient harm that had not already been disclosed within the workplace would be raised with their line manager.

Each participant provided informed written consent. All participants were asked prior to interview to identify occasions where they had violated procedures at work (Lewis et al., 2014). Then, specific violations were explored in detail during the interview. Each participant was asked about the nature of the violations, the circumstances leading to the violations, why they acted this way, what alternative courses of action were apparent, and the perceived advantages and disadvantages to violating.

Interviews lasted from 30 min to 90 min and were conducted in a private place of the participant's choice. Each interview was digitally recorded and transcribed verbatim.