King's Patient Safety and Service Quality Research Centre

NHS National Institute for Health Research

NIHR King's Patient Safety and Service Quality Centre

(PSSQ)

Risk Programme

Working Paper 3

THE MANAGEMENT OF RISKS TO PATIENT SAFETY AND SERVICE QUALITY IN PRIMARY CARE: A REVIEW

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March 2010

Introduction[1]

This paper briefly summarises existing literature examining risk management in relation to patient safety and service quality in the primary care context, prior to identifying areas requiring additional research. It follows a preliminary investigation of primary care and non-specialist heath care journals and related texts, rather than an exhaustive review of all potential sources.

This paper uses a relatively restricted definition of risk management, looking only at how risks to patient safety and service quality are identified, analysed, assessed, controlled and communicated. This definition is narrower than those which have suggested that risk management can extend beyond a focus on minimising harm to also encompass the maximisation of positive opportunities (see, for example, the Australian/New Zealand Risk Management Standard 4360:2004 adopted by the Scottish Executive (2005, p.26)), and mainly focuses on risks affecting patients rather than threats to the financial health or reputation of organisations, which have been included within some approaches to risk management (see, for example, East Somerset NHS Trust, 2004, p.4).

Improving the management of risks to patient safety and service quality in primary care is critical for the National Health Service. The majority of clinical encounters occur in primary care (Kostopoulou et al., 2008, p.400; Kuzel et al. 2004, p.333), and as a review by the WHO notes, while occasionally "rare mistakes" may be made "with drastic consequences", the greatest "burden on health systems" arises rather from "the more mundane incidents that have effects that are magnified by frequent repetitions and exposure of a large number of people" (WHO, undated, p.5). Primary care is, if anything, perhaps becoming more exposed to risks to patient safety and service quality with earlier discharge from hospital, increasing prescribing of potentially dangerous drugs by GPs, often more substantial GP workloads, and an "increasing

[1] The author would like to thank Janet Anderson, Naonori Kodate, Naomi Fulop and Juan Baeza for their comments on this paper. All errors or omissions are, however, entirely the author's own responsibility.

fragmentation of services" (Lehmann et al. 2005, p.95; Wilson et al. 2001, p.583).

The risks to patient safety and service quality in primary care differ from those affecting secondary and tertiary care services for two main reasons.

The first relates to the diversity of services offered within primary care. One of the challenges of providing "longitudinal personalised care that is customised to individual beliefs, needs, values, and preferences" is that practices will vary as a result, sometimes deviating from standard operating procedures (Wilson and Sheikh, 2002; Veldhuis et al., 1998), thus potentially increasing the potential for error. Furthermore, such care can be delivered in a variety of settings, and by a variety of different healthcare professionals (Elder and Dovey, 2002, p.928), and can reflect the very diverse circumstances faced by different practices (Ranjit, et al., 2007) and the fact that much of primary care is non-GP led.

The second reason also concerns diversity, but that of the patient body and their health concerns rather than services offered. GPs can encounter a very wide variety of different symptoms, many of which may coexist and interact with existing health problems, and with patients' preferences when it comes to treatment (Wilson and Sheikh, 2002). No area of acute care experiences such a diverse patient intake.

In summary, as Dovey et al. note, the "diversity, scope, and variation in structure and infrastructure [in primary care] may offer more opportunity for error than more highly regulated and procedure oriented hospital based care" (Dovey et al., 2002, p.233).

Despite this, little research has been carried out into risk management in the primary care setting, in comparison with acute care (O'Dowd 2009). This is despite the fact that although primary care may constitute in some ways a less safe environment (due to the factors mentioned above), it may paradoxically be more amenable to the introduction of new measures to

promote safety and quality. This is due to the relatively small and flat (if fragmented) organisational structure within primary care, and the “strong tradition of multidisciplinary teamwork in many practices”, which has been seen as key to fostering a safe culture (Wilson et al. 2001, p.583). Others have however noted that teamwork “does not necessarily follow from professionals working alongside one another” given the effects of structural, historical and attitudinal barriers (Royal Pharmaceutical Society and British Medical Association, 2000, p.5) and, for example, the lack of time devoted to multidisciplinary team meetings in most GP practices (Baeza, 2009).

This rest of this paper is divided into four sections. The first two sections concern, respectively, policies towards and research into salient risks to patient safety and service quality in primary care. The third section considers actions currently being taken within primary care to improve the management of risks. The final part concludes by considering the future of research into patient safety and service quality in the primary care context.

Risk management and primary care: The policy context

Primary care has not, until recently, been targeted by patient safety initiatives. The Institute of Medicine’s report ‘To Err is Human’, often seen as igniting interest in patient safety both in the US and internationally, only briefly referred to family practitioners (in relation to reporting systems - which were less well-developed for family practitioners than in acute care - and performance standards and expectations in relation to patient safety (Institute of Medicine, 1999)).

The British report which followed this, ‘An organisation with a memory’ (Department of Health, 2000), highlighted the lack of knowledge concerning patient safety in primary care and the patchy development of incident reporting in primary care, even going so far as to state that in primary care, incident reporting was “largely ignored” (Department of Health, 2000, p. 54). The report did, however, highlight the value of claims data from the Medical Defence Union and Medical Defence Society, and reports of Adverse Drug

reactions, as useful sources of information about patient safety which related in large measure to general practice. The report also acknowledged the policy pressure for improving risk management in primary care following the Harold Shipman case. An implementation report for taking forward the findings of 'An organisation with a memory' (Department of Health, 2001a) repeated the earlier report's concerns and proposed the creation of a national database of patient safety incidents – the National Reporting and Learning System -, as well as highlighting the challenges of uncovering and dealing with poor clinical practice in primary care, and the fact that the Clinical Negligence Scheme for Trust's requirements for risk management in primary care trusts were only voluntary. These calls were magnified by the Fifth Report of the Shipman Inquiry (2004), which indicated the continuing possibility of PCTs remaining unaware of patient safety incidents concerning GPs on their lists (Shipman Inquiry, 2004, para.12.55).

However, in 2005, the National Audit Office suggested that primary care was still lagging behind other health care sectors in its rates of reporting, despite its inclusion in the new National Reporting and Learning System (National Audit Office, 2005). Nonetheless, significant organisational and professional changes were occurring by this time, which had the potential to significantly affect risk management in primary care. First, primary care trusts had been created, which 'An organisation with a memory' had suggested could improve the degree of organisational support available for incident reporting systems in primary care (Department of Health, 2000). Secondly, the prominence of 'clinical governance' was becoming more marked, as this approach to management and quality improvement was embedded in the NHS. Clinical governance has been conceptualised in many ways (Fulop et al., 2008), generally reducible to the means by which health care organisations are made accountable for both the quality of care and sometimes also its improvement (see for example, Department of Health, 1998). Baker notes that clinical governance has been seen by professional organisations such as the GMC as potentially linked to the use of mechanisms such as significant event audit and risk management. As a result, Baker suggests that "[r]isk management is

therefore clearly defined as a professional activity for a variety of primary care professionals" (Baker, 2005, 10).

Nonetheless, the focus of patient safety programmes at a policy level appears to have remained overwhelmingly on the hospitals sector. Hence, the 'Patient Safety First' campaign, launched in July 2008, focuses on five interventions, of which only two could potentially be seen as relevant for primary care (ensuring a pro-quality and safety culture at the level of Trusts' boards, and reducing harm from high-risk medicines (Feinmann 2009), although most of the drugs mentioned in relation to the latter intervention are not routinely administered in the primary care setting). This is despite the chairman of the English campaign having intimated that work would be undertaken on how the campaign's tools could be altered to make them more relevant for primary care (Hitchen 2008). This lack of focus on primary care has been mirrored in the approach of the Healthcare Commission (now subsumed under the Care Quality Commission), with the ex-chairman stating that he would have liked to have had a "better handle on safety in primary care", but that this was partly prevented by the requirement that the Commission investigate trusts rather than individual GPs. The ex-chairman suggested that many patients failed to understand the specific roles and responsibilities of primary care trusts, as opposed to that of individual GPs, of whom they had a more intuitive understanding (Hawkes 2008).

Overall, despite an increasing focus on risk management at a policy-level, a relatively low level of attention has been focused on this area within primary care.

Common risks to patient safety and service quality in primary care

Five areas have been identified in the literature as posing particular challenges for the safety and quality of primary care: the processes of diagnosis and prescribing; how patients progress between being cared for by different organisations and individuals in primary care (the (dis-)continuity of

care); the impact of work overload on safety and quality; and relational factors such as GPs' relationships with their patients, and relationships and lines of responsibility between different members of staff within practices. All of these can be viewed as relating to individual practitioners' performance but also as resulting from systemic factors such as organisational and institutional structures, inter-organisational relationships, and technological failures.

Diagnostic error

Diagnostic errors account for the bulk of litigation against UK GPs, and, along with delays in referral, often account for a significant proportion of complaints. There is also some evidence that these errors are most likely to be remembered by GPs and seen as serious by them (Kostopoulou et al., 2008, p.400; Mayor, 2007). As Kostopoulou notes, this is perhaps unsurprising given that few other activities undertaken by GPs are likely to have such significant effects. In particular, errors during treatment are estimated as less likely to result in significant threats to patient safety in the primary care context, compared to in acute care (Kostopoulou, 2008, p.1). Unsurprisingly, of errors in diagnosis those most likely to be remembered by GPs are those which have involved the delayed diagnosis of serious life-threatening conditions (Jacobson et al. 2003, p.238).

Incident reporting systems operating in primary care have reported similarly high rates of diagnostic errors resulting in patient safety incidents. Sandars and Esmail's meta-analysis indicated that studies have suggested that errors in diagnosis can account for between 28% and 78% of identified errors in primary care (Sandars and Esmail 2003; see also Fernald et al., 2004). Particularly problematic conditions include "asthma, cancer, dermatological conditions, substance misuse, and depression" (Wilson and Sheikh, 2002 p.585).

Clearly, improving the accuracy of diagnoses is a challenging task in the context of constrained time and resources in primary care. Whilst tools such as protocols, guidelines, other decision support tools and electronic

information systems may improve safety, there is little robust evidence available concerning their efficacy (Wilson and Sheikh, 2002). In particular, little work has been undertaken concerning the impact of using such tools on time-management and work organisation, as with the introduction of many tools in the NHS (Mackintosh and Sandall, 2008). Exhaustive attempts to eliminate all possibilities are simply impossible without “seriously obstructing, continuously interrupting or impractically lengthening the natural reasoning process” (Kostopoulou et al., 2008, p.412). Furthermore, exhaustive investigation could in some contexts generate patient anxiety, procedural risks, extra costs and inconvenience for patients (Jacobson et al. 2003).

Errors in prescribing

After errors in diagnosis, the most common category of errors which lead to litigation are those concerning prescribing (Jacobson et al. 2003, p.238). Particularly problematic drug groups appear to include steroids, anticoagulants, non-steroidal anti-inflammatory drugs, opiates, phenothiazines, hormone replacements, antibiotics, antiepileptics, and some types of antidepressants and oral contraceptives (ibid.; Avery et al., 2002, p.S17; Wilson and Sheikh, 2002; Allahabadia et al., 2009). The increasing use of non-standard treatments, such as herbal remedies, poses additional challenges (Wilson and Sheikh, 2002).

Errors in prescribing can be further subdivided into those which concern failure to recognise or note adverse effects, prescribing inappropriate or incorrect medication, or contraindicated drugs, and mistakes concerning the correct dosage of drugs (Avery et al., ibid).

Clearly these errors concern a variety of different steps in the medical process, potentially involving faulty communication or administration, or a lack of clinician knowledge (Elder and Dovey, 2002, p.930). As a result, there is no simple tool in existence which could universally improve the accuracy of prescribing and the timeliness of acting on signs of adverse reactions. This is further complicated by the fact that there is considerable debate concerning

the definition of prescribing errors, with even experts sometimes disagreeing about whether particular incidents reveal errors or simply differences in judgement or approach (see, for example, Dean et al., 2000; Ghaleb et al., 2005; Lilford et al., 2003).

Nonetheless, a number of studies have suggested that proactive measures can have some effects, such as “educational outreach, the use of computerised prompts, and active intervention by pharmacists” (as opposed to ‘passive’ measures which simply involve the distribution of information) (Avery et al., 2002, p.S18). Such proactive measures are often facilitated by coordinating structures such as PCTs (Baeza, 2009). Many studies have specifically promoted the use of prompts within computerised prescribing systems to indicate possible hazardous combinations (either of different drugs with each other, or with a specific drug and the characteristics of the patient) (ibid., p.S20).

However, as Wilson and Sheikh note, prompts quickly become assimilated into the natural order of things, with many doctors simply ignoring them due to their frequency (2002). Similarly, practitioners may confuse hazard alerts with “more advisory information” if this is not made clear by the system (Cousins and Baker, 2004). Furthermore, there is a danger that doctors may rely on computerised systems to alert them to contraindications, when in actual fact many existing computing systems have “clinically important deficiencies” which may result in them failing “warn in a situation when a warning is expected” (Fernando et al., 2004).

In addition to the promotion of computerised prescribing as a means of improving medication safety in primary care, the National Patient Safety Agency has acted to deal with some particularly hazard-prone drugs such as methotrexate (Cousins and Baker, 2004), often by securing a change in the packaging of drugs (as a means of alerting practitioners to possible problems, and potentially to prevent confusion with other similarly named or packaged drugs).

As well as problems arising entirely within the primary care context, numerous medication errors can occur at the boundaries of primary care, such as when a patient returns to primary care after a period in hospital, or when a patient is admitted into a care home, where a new GP may take over the patient's care. In these circumstances, a structured process at 'handover' has been seen as essential to prevent delays and miscommunication between health care providers (Department of Health, 2001b). Repeat prescribing has also been identified as a potentially problematic area, where this may lead to inadequate monitoring or review of drug administration (ibid., 44).

Even given the different profile of drugs administered in primary as against in acute care, it could be argued that there is still significant potential for harm in primary care as a result of prescribing errors. This is due to the fact that although drugs used in primary care may not always have as immediate effects as those used in acute settings, dispensing errors in primary care may not be picked up for the entire length of a prescription- or even beyond this, if repeat prescriptions are involved (ibid., 46).

The (dis-)continuity of care

The extent to which different health professionals coordinate their activities towards particular patients has been proved to be core to ensuring safe and high-quality care (Freeman and Hjortdahl, 1997). Dovey et al's research on error rates has suggested that up to 86% of errors can be attributable to "aspects of care delivery systems", and further that most errors were only recognised as such by doctors significantly after the event, with errors being reported as occurring across a wide variety of healthcare settings and involving a wide range of different members of staff (2002, pp.236-7). Many of the most high-profile medical errors involving primary care have involved a lack of continuity of care (as with the case of Penny Campbell, who died in 2005 after calling a GP out-of-hours medical service eight times, and each time speaking to a different doctor who lacked access to colleagues' notes) (Kmietowicz, 2007a). Telephone consultations have been seen as particularly prone to resulting in failures in diagnosis, often due to the lack of possibilities

for examination – problems which are compounded when clinicians and patients know each other well (McKinstry et al., 2009).

Relatedly, some concerns have been expressed that new forms of primary care delivery, such as walk-in centres, might exacerbate discontinuities in care, by leading to duplication and inappropriate care. However, there is little clear evidence on this given the relative youth of such centres (Salisbury et al., 2002), and it appears that users may turn to these services as an alternative rather than addition to existing services, for a variety of reasons (Jackson et al., 2005).

Another innovative method of care delivery is the NHS direct service, which operates as a form of 'triage'. Studies suggest that such methods may increase the effectiveness of use of health care resources, with little evidence that they decrease safety (Car and Sheikh, 2003), although others have suggested that such findings may rely to an extent on contextual factors such as the quality of decision-support software, and the selection and training of nurses involved (Lattimer et al., 1998).

More broadly, a significant amount of literature has considered how communication can be improved between organisations providing healthcare to individual patients over time (see, for example, Haggerty et al., 2003; Baker et al., 2007; Baker et al., 2006). In addition to inter-organisational problems, threats to continuity of care can also relate to intra- and inter-clinician issues. Hence, fragmentation of care can occur even if it is provided by one member of staff, if that member of staff does not carry out tasks associated with a consultation in a timely manner, such as referrals or updating records. More usually however, the concept of 'continuity of care' is taken as referring to communication (or a lack, or poor quality, of it) between different members of staff, either in the same organisation or across organisations (Lehmann et al. 2005, p.98), going beyond traditional definitions in primary care which emphasised the importance of patients seeing the same practitioner over time (Guthrie and Wyke, 2000). Wilson and Sheikh suggest that most breakdowns in communication within organisations occur due to overly hierarchical

structures and insufficiently formal communication methods (such as having a chat with other medical professionals in the corridor, rather than relaying key comments in writing or in a more formal setting; or leaving a “post-it note” for colleagues which could easily be lost, rather than employing a more formal method of transferring information), as well as failures in communication during tasks like dictating letters (2002).

Volume of work

Another issue which has been seen as potentially compromising safe and high-quality care is the volume and intensity of work which individual members of staff are required to undertake. Hence Lehmann et al suggested in their study of errors resulting in emergency admissions that “excessive task demands” accounted for almost half of all “work organisation factors” which had been linked with incidents (2005, p.96). They also suggest that high task demands may be more likely to be associated with judgement errors (as opposed to process errors), which may in turn be more linked to serious rather than less-serious or minor incidents (ibid., p.97).

Relational factors

Another issue which has been linked with the safety and quality of care is that of the relationships both between GPs and their patients, and between different members of staff within GP practices.

Although subject to less research interest than the other factors mentioned above, physicians’ relationships with their patients, and, linked to this, the extent to which patients’ perspectives are taken into account, have been described in some studies are crucial for understanding threats to patient safety. Indeed, Vincent and Coulter (2002) state that “the one source of experience and expertise that remains largely ignored [by the patient safety movement] is that of the patient” (p.76).

Kuzel et al. suggest that when patients (rather than professionals) are asked to identify errors, they often discuss social or psychological issues, such as lack of access to physicians, communication breakdowns, inefficiencies, and, in particular, relationship breakdowns involving disrespect or insensitivity. This contrasts with the kinds of technical, treatment- or diagnosis-related errors often identified by physicians (Kuzel et al. 2004, pp.335-7). As Kuzel et al. note, their analysis, by including "emotional distress" as a category of harm often mentioned by patients, creates an "indistinct boundary between medical errors and patient dissatisfaction" (Kuzel et al. 2004, p.338).

It is certainly the case that where patients have been mentioned in more 'medically'-oriented studies of error, this is generally in the context of patients being seen as potentially contributing to medical error, either through helping to produce a "poor doctor-patient relationship" or through overly-demanding behaviour (Sandars and Esmail 2003, p.234). Increasingly, however, it is being suggested that both patients and practitioners are liable to make inappropriate assumptions and guesses which can compromise care (Britten et al., 2000), muddying any dichotomy between 'good' patients (who, for example, take their medicines as instructed) and 'bad' patients (who may have reasons for not complying) (see for example, Clifford et al., 2008).

A separate issue concerns the relationships between different health care professionals. Problems can occur at the boundaries between organisations, as described in the section on drug errors. However it is also important to consider the impact of intra-organisational relationships on patient safety. It is notable that what research has been done on risk management in primary care, has tended to focus on the role of the GP rather than that of practice nurses, health care assistants, and receptionists. There is significant evidence from the acute sector that failures in communication between different health care professionals and inadequate or unbalanced skill mixes within teams can have a deleterious impact on patient safety (see Mackintosh and Sandall, 2008, for a review with particular reference to maternity services). Bosley and Dale (2008) have investigated the impact of unclear role definition for health care assistants in primary care, highlighting the implications of this for patient

safety. Further work needs to be undertaken to understand how health care assistants, nurses, GPs, and receptionists interpret their roles and interact with each other, in ways that can either compromise or promote patient safety.

Improving risk management in primary care

Five methods have been employed in a variety of primary care contexts to improve the management of risks to patient safety and the quality of care: adverse incident reporting; critical incident review/significant event audit; proactive service redesign; relatedly, the use of technological tools including 'triggers'; and the use of financial incentives including contracts and commissioning.

Incident reporting

A number of studies have used formal or informal systems of incident reporting as a means of identifying particularly risky areas of care (Elder et al. 2004, p.125) and instances where patient safety incidents had been 'ameliorated' (Parnes et al. 2007) or could be prevented (Bhasale 1998). Such systems ask staff (and increasingly patients) to report adverse events, which are generally defined as ''any unintended or unexpected incidents which could have or did lead to harm for one or more patients'' (the definition used by the National Patient Safety Agency, NPSA and a variant of which was used by Bhasale et al., 1998) or occasionally an event which ''was a threat to patient well-being and should not happen. I don't want it to happen again'' (Hoffmann et al. 2008, p.308).

Both anonymous and confidential incident reporting systems have been developed, with some evidence to suggest that where reporting is confidential, this correlates with a higher level of information about incidents being provided, whilst in contrast, providing anonymity appears to drive up the number of incidents reported, if not the quality of information provided about them (Fernald et al., 2004, p.331). Since at least eight years ago, it has been proposed that primary care trusts take on board systems of incident reporting

(Sheikh and Hurwitz, 2001), with some reports suggesting that purely local systems might increase reporting, despite some scepticism about such claims (Sandars and Esmail 2003, p.235). As in acute care (Dodds and Kodate, 2008), in primary care a number of barriers to incident reporting exist, particularly concerning the classification of incidents (Elder et al. 2004, p.127).

Certainly, far less reporting of patient safety incidents occurs in primary than in acute care, with only one in 200 reports in the National Reporting and Learning System (NRLS) (operated by the NPSA) coming from GPs as at last year (Hoffmann et al. 2008, p.310). The House of Commons' Public Accounts Committee has suggested that 96% of GPs have failed to report patient safety incidents to the NRLS (Day 2007).

Incident reporting systems that have operated in primary care often suggest that most incidents are administrative (Lehmann et al. 2005, p.99), i.e. that they were not the responsibility of clinicians. As Kostopolou notes, GPs appear to be particularly reluctant to report recent diagnostic errors to incident reporting systems, with administrative or 'system' errors being viewed as far less "threatening" (Kostopoulou, 2008, p.1).

A number of explanations have been put forward as to why reporting rates are so low within primary care. Shaw et al. suggested four years ago that low reporting is partly due to a lack of reporting infrastructure (particularly electronic reporting systems), and the geographically decentralised nature of the delivery of primary care (Shaw et al. 2005). Hoffman et al., in their study of incident reporting in Germany, suggested that low rates resulted at least partly from the lower salience of both medical error and professional regulation in primary as compared with acute care (2009, p.310).

In addition, some studies have highlighted significant barriers when it comes to the potential for generating 'organisational learning' from incident reports. Sandars and Esmail have noted that in many cases, either no cause or multiple causes appear to have resulted in particular patient safety incidents (Sandars and Esmail 2003, p.233). This uncertainty over causation makes it

difficult to generate interventions to prevent such incidents from happening again, even though some studies have suggested that up to 83% of all errors could have been prevented (ibid., p.234; Fischer et al., 1997; Vincent, 2004).

Furthermore, unfortunately, incident reports do not always appear to correlate with complaints and malpractice claims, nor does either data source appear to offer a full picture of the incidence and frequency of risks to patient safety (Sandars and Esmail 2003, p.234). Even amongst those practices where incidents are routinely reported, the extent of reporting can vary significantly amongst different members of staff and between different practices, to such a degree that this does not appear to be explained by some practices or individuals simply operating in a less safe manner, or undertaking more risky procedures, than others (Elder et al. 2004, p.127; Santry, 2009).

Critical incident review/ significant event audit

The importance of significant event audit as a method of risk management in primary care has increased substantially in recent years. In 2001 Wilson et al estimated that only around 20% of GP practices employed this method (p.583), but by 2004 it was included within the new general medical services contract, and being able to act on information from significant event audits is included within the new revalidation process being introduced for GPs (Mashta 2008). These processes have, in some practices, built on the operation of informal logs of errors (Wilson and Sheikh, 2002; see also Pringle, 2009) or analyses of unexpected deaths (Cox and Holden, 2007).

Significant event audit differs from many other retrospective methods used in healthcare such as root cause analysis in its focus on positive events (i.e. “rapid diagnosis of unexpected malignancy in a fit young man” (ibid.)) as well as negative occurrences (i.e. patient safety incidents) (NPSA, 2008), although certain events (e.g. suicide or death on GP practice premises) must be examined by practices within the audit process (Cox and Holden, 2007). In practice the methods used within significant event audit are similar to those used in other risk management mechanisms aimed at promoting

organisational learning (such as ‘Mortality and Morbidity’ meetings), in that the audit process involves a structured group discussion of a significant event and attempts to spread learning from this across the organisation.

Frequent use of significant event audit is now promoted by the ‘Quality and Outcomes Framework’, part of the General Medical Services contract, which rewards GP practices which have carried out six or twelve audits in a year (ibid.).

Significant event audit is often used in parallel with incident reporting. Indeed, Cox and Holden used the NPSA’s criteria for judging the type and seriousness of incidents to classify the events chosen for audit by the GP practices they studied. Overall, Cox and Holden found that the majority of practices in the district they examined were able to produce learning points from each audit, but that a small number of practices struggled with the process- all of which were small practices, with two or fewer GPs (ibid.). This echoes the Shipman Inquiry’s suggestion that not only do some single-handed GP practices struggle with significant event audit, they also potentially suffer from an “inequality of status” between participants when auditing, which might compromise full and frank discussion (Shipman Inquiry, Fifth Report, 2004). The large reduction in single-handed GP practices over the last ten years may, therefore, have increased the efficacy of methods such as significant event audits.

In addition, they noted that sometimes learning points were not passed on to other organisations (such as the local hospital) despite their potential for improving safety across the local health service (ibid.).

Service redesign to reduce or eliminate risks to patient safety and service quality

Advocates of service redesign have been very influential within the patient safety movement (e.g. Berg et al., 2005). A number of authors have suggested relatively simple actions, as opposed to total system redesign, that

could be taken by primary care trusts which would eliminate the causes of many errors. For example, Wilson and Sheikh advocate the use of formal message books rather than informal conversations as a means of communication between staff (Wilson and Sheikh, 2002), a proposal echoed by Wilson et al., who also advocate that all sharps boxes should be securely stored on shelves, and that warfarin patients who fail to attend for checks should be routinely identified and offered aspirin or other safer alternatives (2001, p.583).

More systematic approaches have suggested that existing systems need to be scrutinised carefully, and the various tasks performed within them analysed closely, in order for large-scale changes to be made to improve quality and safety. Some such approaches have advocated the use of methods such as prospective hazards analysis as a means of detecting potential problems and redesigning systems in order to eliminate these, in a variety of settings including primary care (Anderson et al., 2007).

The use of technology in proactive risk management

One particular method of alerting practitioners to potentially dangerous situations is through the use of electronic decision aids. For example, some studies have been undertaken which highlight the potential for electronic patient record systems to aid decision-making in prescribing, where they can flag up potentially dangerous conjunctions of drugs and/or the danger of combining certain drugs with existing patient conditions (Hillestad et al., 2005). In addition, electronic patient records stored securely at a national level have been seen as a means of potentially avoiding “stabbing in the dark” when assessing new patients, for example in the emergency context (Greenhalgh et al. 2008). Finally, the automated analysis of electronic sources of information, such as patient records, could eventually lead to the development of ‘triggers’ to highlight potentially unsafe care in GPs’ practices, an area which has not been significantly explored until now (Wilson and Sheikh, 2002).

It should however be noted that with many such systems, problems arise generally not at the level of conception and planning, but that of implementation, where “social, cultural, and organizational factors” can significantly impact on their viability and effectiveness (Delpierre et al., 2004; Richards 2007). Indeed, without extensive evaluation, relying simply on the ‘face validity’ of certain technologies as evidence of their effectiveness is a highly questionable approach, given that introducing new technologies and tools can sometimes increase risks to safety and quality, rather than reduce them (Tamuz and Harrison, 2006).

The use of financial incentives to increase safety and quality

Contractual arrangements

Increasingly, financial incentives are being adopted as a means of altering behaviour within the NHS- including in patient safety and service quality. This has occurred in a context where the self-employed status of GPs as contractors has, for some, suggested that fewer levers were available to promote safe practice than in the case of acute care where health care professionals are directly employed (Fulop, 2009).

Alterations to the GP contract have been used to expand GPs’ responsibilities in some areas (e.g. diabetes care) (Atkin and Walton, 2008), and to increase the opening hours within practices, with longer opening hours having been described as improving patients’ “healthcare seeking behaviour” (Jiwa and Knight, 2008).

Vigorous debate has, however, taken place over whether the new GP contract has improved patient safety (Herbert 2007) or reduced the responsibility of GPs and practices for providing continuous and safe care (Jones 2007), concerning the specific issue of out-of-hours services.

A variety of suggestions have been put forward on how contractual arrangements could further foster patient safety and quality of care. Elwyn

(reported in Richards 2007) suggests that the Quality and Outcomes Framework (QOF) within the GP contract could be reformed to promote and maintain continuity of care, by rewarding GPs who appoint personal doctors for very ill or dying patients, and for patients with complex health problems (see also Roland, 2008, for a similar argument). Similarly, the Darzi review included discussion of how the QOF could be reformed to better incentivise good quality health (in a broader sense) as well as good quality care (in the narrower sense) (O'Dowd, 2008). This followed GPs achieving 90% of all available points from QOF in its first year of operation, rather than only 75% as was expected, thus increasing the costs of the scheme (Timmins, 2005). QOF indicators are exactly that - indicators- which are aimed at accurately operationalising the safety and quality or care. There is the danger that such indicators, as with all such measures, may, despite attempts to the contrary, reflect factors which are not under the control of primary care practitioners (such as for example, specific characteristics of the patient population).

Commissioning

Commissioning is increasingly seen as a means of improving the safety and quality of health care (O'Dowd, 2008). Since the creation of PCTs in 2002, the roll-out of practice-based commissioning from 2006, and the introduction of 'World Class Commissioning' from 2007 onwards, PCTs have become potentially powerful agents in deciding the future shape of the NHS, including its approach to quality and safety. It has been estimated that 80% of NHS spending now passes through the hands of PCTs (Hawkes, 2008). Although it may have been initially envisaged that standard-setting in the area of patient safety would fall to national bodies (Smith and Mays, 2005), PCTs are increasingly both expected and required to use their 'purchasing power' as a lever to improve patient safety. Indeed, it is arguable that in this respect, practitioners in primary care and their organisations have been incentivised to campaign for improvements in the care provided by other organisations.

It has been suggested that through judicious use of data within the commissioning process, PCTs can drive up standards in everything from

surgery (Holt et al., 2008) to diabetes care (Atkin and Walton, 2008). This capacity can cut both ways however, with PCTs also being blamed in some cases for inadequate provision of services (as with the dental service, albeit in combination with a new Dental Contract (Editorial, 2008); and problems with the provision of out-of-hours services (Herbert, 2007)). It has also been suggested that primary care in some respects lags behind the acute sector when it comes to clinical governance and, within that, effective commissioning as a means of driving up quality and safety (Day 2007; Public Accounts Committee, 2007). Indeed, some have suggested that PCTs' commissioning powers should be shared with others (such as hospital specialists (Roland, 2008) or, in the case of care for people with learning disabilities, local government (Kmietowicz, 2007b)). It has also been suggested that measures of the quality of patient experience should be incorporated into commissioning, as is the case in the US (Elwyn et al., 2007) - and patient experience is now included within the 'QOF', albeit in a limited way via patient surveys (Baeza, 2009). A measure of PCTs' aptitude at commissioning for quality and safety has been included in the Healthcare Commission's (now CQC) annual health checks since 2008-9 (on top of the regulator's traditional focus on provision) (Mashta, 2008).

It is fair to say however that PCTs' focus on quality and safety when commissioning has increased greatly over recent years. From 2006 onwards, PCTs were encouraged to adopt what could be seen as a method of (albeit very informal and undeveloped) prospective hazard analysis in their commissioning, when the NPSA suggested that PCTs should pose 'what if' questions whilst deciding whether and how to redesign services (NPSA, 2006). When it comes to the commissioning of secondary, acute care, PCTs are now expected to measure providers against their performance in relation to 'Never Events' – both the reporting of these events and also their governance in terms of protocols, investigation (in particular, the use of root cause analysis) and the implementation of ameliorative and preventative actions. A list of 'Never Events' has been produced by the NPSA in consultation with PCTs, covering both mental health and acute care. Such events (including for example, in-patient suicide using non-collapsible rails or in-hospital maternal

death from post-partum haemorrhage after elective caesarean section) have been chosen due to their severity of impact on individual patients, through either causing or threatening to cause serious harm.

The expectation is that by requiring PCTs to have Never Events reported to them (and to the public), awareness of patient safety will be increased and potentially incorporated in a more meaningful manner into incentive structures via commissioning (NPSA, 2009). The extent to which Never Events provide an accurate picture of the safety of care could be questioned however, given that the NPSA itself admits that "there is evidence that Never Events are currently under-reported" (ibid.).

This focus on Never Events is part of the introduction of the CQUIN framework (Commissioning for Quality and Innovation) (Huehns, 2009). As part of CQUIN, PCTs will be able to identify their own priorities for quality and safety improvement in conjunction with Strategic Health Authorities, building on their focus on Never Events in the first year. This process comes at the same time as 'Quality Accounts' are being introduced into the NHS following the Darzi review. This process has many similarities with the situation in the US, where avoidance of 'never events' is taken into account by insurers, both socialised (Medicare/Medicaid) and private (ibid.).

The future of research into patient safety and service quality in primary care

The WHO has suggested that research into patient safety in primary care would benefit from the use of more rigorous methods and "clearer and more consistent definitions of common terms" (WHO, undated, p.3). This brief review supports this analysis, but also suggests that specific areas are worthy of particularly close examination.

Elder and Dovey suggest that research into patient safety in particular has thus far been driven by convenience rather than need, with the "research agenda aiming to identify effective error reduction strategies" appearing to be

"based more on ease of study subject or accessibility of patients than on the severity or importance of the problem" (2002, p.932). Certainly most studies have focused almost exclusively on the perspective of physicians, rather than that of patients or other (e.g. administrative) staff (Fernald et al., 2004, p.328). Those studies which have involved patients in research in community settings have generally concerned perceived harm, but not other patient safety related issues (WHO, undated, p.5). In addition, patient safety research in primary care has often been restricted to using quantitative rather than qualitative evidence (Kuzel et al., 2003). Finally, particular clinical activities with the potential to cause risks to patient safety have received relatively little research interest, such as minor surgery and the administration of vaccines (Wilson and Sheikh, 2002).

The conclusion of the WHO's World Alliance for Patient Safety that research efforts have so far concentrated "on describing the safety environment rather than intervening to improve it" appears borne out by the works consulted for this paper (WHO, undated, p.30). Under-researched areas include the relationship between incident reporting and other methods of risk management in primary care, i.e. how the activities mentioned in the section above relate to each other; how organisational learning from previous incidents is fostered (or dissuaded) within primary care; how the use of temporary staff in both clinical and administrative roles can affect risk management; how the relationship between different members of staff (GPs, nurses, health care assistants and receptionists) can promote or reduce patient safety and service quality; and how PCTs' developing roles as *de facto* regulators of quality and safety (through their ability to impose conditions when commissioning) may, or may not, play a role in improving the quality of acute services and the safety of patients using these.

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