

# Measuring and monitoring safety: a primary care perspective

Aneez Esmail

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In this thought paper, Professor Aneez Esmail discusses the measurement and monitoring of safety from the perspective of primary care. He considers the differences between primary care and other settings and explains that a variety of factors mean that assessing harm and safety in primary care remains a challenge. He identifies a number of existing tools that can be used to measure and monitor safety in primary care and considers what research will be needed in order to assess if care in a primary care organisation is safe.

The Health Foundation is calling for a stepwise change in thinking about patient safety. This paper forms part of a programme of work we are undertaking to help answer the question *How do we know care is safe?* We want to build on a culture that has focused almost exclusively on measuring past harm and enhance this to incorporate approaches to measurement that also establish the presence of safety.

Health Foundation thought papers present the authors' own views. We would like to thank Professor Esmail for his work, which we hope will stimulate ideas, reflection and discussion.

## About the author

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Aneez Esmail is Professor of General Practice at the University of Manchester. He is Director of the Greater Manchester Primary Care Patient Safety Translational Research Centre, a £6.3m five-year patient safety initiative funded by the National Institute for Health Research (<http://www.population-health.manchester.ac.uk/primary-care-patient-safety>).

Aneez's main research interests are in patient safety in primary care and he has published widely in this area. He has always argued about the importance of understanding the importance of patient safety in the primary care context and has played a leading role in developing the research agenda in this area. He leads the Europe-wide Linneaus Collaboration (Learning from International Networks about Errors and Understanding Safety in Primary Care <http://www.linneaus-pc.eu/>) which is a large network of researchers and practitioners working on patient safety in the European Union. He continues to practise clinically in a large inner-city practice in Manchester.

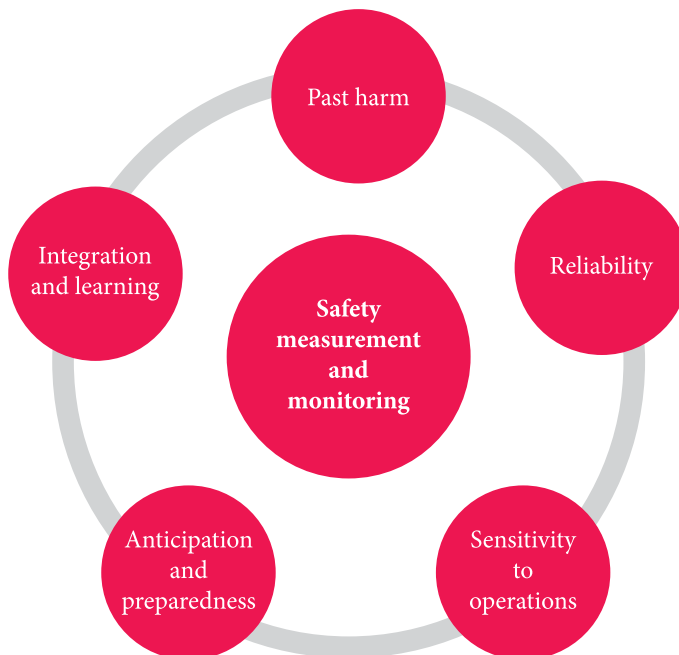
## Introduction

In *The measurement and monitoring of safety*,<sup>1</sup> Charles Vincent and colleagues have provided a framework for measuring and monitoring safety in healthcare (see below). This has a particular resonance for those of us who have been working in this field for many years. We are still grappling with understanding why some of the basic questions in improving patient safety remain unanswered. Despite the deluge of statistics and initiatives over the past 10 years we cannot answer some fundamental questions as to whether patients are safer. There are continuing examples of tragic failures where patients continue to be harmed despite the increased knowledge

base that we have developed in order to mitigate harm. TS Eliot's comment 'Where is the wisdom we have lost in knowledge? Where is the knowledge we have lost in information?' seems particularly apt.

By suggesting a framework, Vincent offers a reappraisal of where we have come from and maps out a future path for measuring and monitoring safety. Conceptualising this in the five dimensions makes sense for several reasons. It recognises the importance of measuring past harm and then focuses on strengthening systems. The emphasis on learning is also welcome as it is an area that is less frequently addressed, especially in relation to safety improvement.

**Figure 1: A framework for the measurement and monitoring of safety**



However, from the perspective of primary care, the framework is more problematic. The five dimensions are contextually focused on, and applicable to, a hospital setting. Specifically, the emphasis on reliability and sensitivity to operations requires an infrastructure of organisational capability that is absent from most areas of primary care. But, there are also aspects of the five dimensions that resonate well with primary care – for example the concept of the importance of integration and learning which, although not widely practised, does have a history of development in primary care and can be strengthened.

It is worth stating why primary care is different when considering issues related to patient safety because it will help us to understand where the framework can be best applied.

### **Why is primary care different?**

Most commentators would accept that adverse events do occur in primary care though their intuitive assessment would be that most of these adverse events are not serious and certainly too few in number to warrant any specific or system-wide action. Although there is a better understanding of the extent of harm in hospital settings, we are still grappling with developing a consensus on the harm caused by problems associated with patient safety in primary care. We therefore have less information on the harm caused in primary care. It is my view that consideration of patient safety in primary care occurs as an afterthought by policy makers and managers. This partly

reflects the long-standing resource divisions between primary and secondary care, the greater emphasis given to specialist care in our health system and the role that primary care has historically held as a ‘Cinderella’ service in the NHS.

Despite the explosion of interest in patient safety in the last 15 years, an analysis of citations shows that the vast majority of research into patient safety – whether it be on issues of epidemiology, on psychology or sociology or, much rarer, on interventions – has focused almost exclusively on hospital/specialist care.<sup>2</sup> There are several reasons for this. First, there is a perception of primary care as a low technology environment where safety is not a problem and which therefore engenders a lower profile than the acute sector. Second, primary care is much more heterogeneous in its organisational arrangements. The organisational arrangements between primary and secondary care are different and complex and there is a multiplicity of sites where primary care is carried out (the clinician’s office, on the telephone and in patients’ homes).

Third, the interfaces between primary and specialist care are hugely important yet there is very little research on exploring safety issues at this interface. The absence of research in this area compounds the perception of primary care as a discipline where safety is not an issue because one of the key areas is simply not researched. No data are mistakenly assumed to suggest no problem. Finally, consultation and interpersonal skills are critical to the

delivery of primary care and exploring issues related to patient safety in this area raises specific challenges. There is very little research to help us understand patient safety issues at this level.

All these factors make the study of patient safety in primary care difficult but it is probably the heterogeneity of the organisational arrangements that will make the implementation of patient safety initiatives so difficult. Within general practice, there is no defined leadership at a local level and most practices have organisational arrangements that are not only determined by geographical location or size of practice but by a whole host of other factors – mostly related to personnel and team dynamics. Although part of a wider system, each primary care practice and especially general practice works as an independent business with its own organisational culture and dynamic. While there is some congruence in the way the business is run, there are marked differences in systems, structure and working practices – many of which can impact on patient safety. It is this heterogeneity that has mitigated against the implementation of national initiatives, such as reporting, the implementation of guidelines and, in some respects, patient safety initiatives. It is not that primary care is inherently unsafe, but rather we need to recognise that the organisational arrangements may not be conducive to top-down initiatives. Contrast this with a hospital where a dynamic chief executive and chair can run and implement a major programme on improving patient safety, engage the board and the senior

management team, and allocate resources to improving patient safety.

Interestingly the lack of research in primary care has also been found in North America where patient safety researchers contribute a significant proportion of the research on patient safety. A recent review of research on ambulatory safety between 2000 and 2010 looked at published literature and private initiatives, government grants and regulatory and legislative initiatives in the USA.<sup>3</sup> It concluded that major gaps persist in our understanding of patient safety in the ambulatory setting and with virtually no credible studies on how to improve safety.

### **Challenges – understanding the extent of past harm**

If primary care presents problems in terms of its organisation for implementing patient safety initiatives, there are additional problems in relation to assessing how big a problem there is in primary care. Acknowledging these problems is directly pertinent to understanding past harm as a dimension in measuring and monitoring patient safety.

Research suggests that adverse events and error are not uncommon in primary care and, when considered in context, a huge number of interactions may represent a significant problem. In the UK, 85% of contacts with the NHS take place in primary care and there are 300 million general practice appointments each year. This means that nearly 750,000 patients consult their general practitioner (GP) each day. More than 70% of all prescriptions

are issued outside hospital. The simple point that I would make is that primary care (if it includes pharmacy, community nursing and dentistry) is a vast organised sector for healthcare with over a million interactions occurring every day. The potential for adverse events is therefore huge but the knowledge base about patient safety in this context is minimal. A literature review of the nature and frequency of error in primary care suggested that there are between 5 and 80 safety incidents per 100,000 consultations<sup>4</sup> which, in the UK, would translate to between 37 and 600 incidents per day. Perhaps a more realistic estimate is provided in a large retrospective review carried out in the Netherlands (where general practice is organised in a similar way as in the UK), which suggested that 2% of all general practice consultations resulted in a patient safety incident.<sup>5</sup>

Set within the context of a large number of healthcare interactions, this becomes a major problem, and one that may potentially affect the daily experience of a larger number of patients. Prevalence figures for incidents in primary care vary widely, and are mostly based upon incident reporting. The medical record review study referred to above found patient safety incidents in 2.5% of all contacts, and noticeable effects for the patients in 0.7% of the contacts in primary care.<sup>5</sup> These figures are higher than in previous studies in primary care and this may reflect the use of a broader definition of the term 'patient safety incident'.

Even though more studies in other countries with different healthcare systems

are needed to determine the epidemiology of patient safety incidents in primary care, both in terms of frequency and their characteristics, we can assert that the relatively low number of incidents to be expected in each 1,000 patient years adds up to substantial national numbers given the high number of patients and contacts in primary care.

The majority of incidents in general practice can be categorised into four main areas covering:

- diagnosis
- prescribing
- communication between healthcare providers and patients
- organisational factors (administrative problems fall within this category).

So, although the potential for error is great, our own analysis of medico-legal databases (which Professor Vincent was involved in) suggests that 50% are of no consequence, 20% result in non-clinically relevant delays in diagnosis, 10% result in upset patients but, more significantly, 20% of errors could have serious consequence.<sup>6</sup> Set within the context of a large number of healthcare interactions, this becomes a significant problem, even if we accept the limitations of transposing information from studies of medico-legal databases to the generality of care.

Without a clear understanding of the extent of the problem we will invariably be constrained in terms of describing past harm – understanding the epidemiology of hospital errors was crucial in developing hospital-based safety and public support for efforts to improve safety. This needs to be replicated in primary care.<sup>3</sup>

However, in relation to past harm there are several areas that GPs could measure even though we do not have a clear understanding of the epidemiology of error. Monitoring mortality rates is underused yet they can give useful insights into the extent of harm in primary care – at its most obvious when mortality rates are greater than expected. Because of its costs, record review is rarely used yet also has the potential to give an indicator of past harm. However, the value of measuring harm through these parameters is not the absolute measure that it gives us but the contribution they give to understanding the quality of care in the context of safety. So, although we do not have measures of past harm as described in the hospital setting, we can use such measures to give us insights and help our learning – a very different purpose to the way these measures tend to be used.

Incident reporting is perhaps the one area of measurement that has been attempted in primary care but has never become established in the same way as hospital incident reporting. There is an emerging consensus that top-down approaches to incident reporting will not work in primary care. However, local systems, usually in large practices or local networks of GPs meeting for postgraduate learning, which undertake to record incidents for short periods (usually for four weeks in a year) do provide information which can assess the reliability of systems and, more importantly, provide a means for learning.<sup>7</sup> Provided that these principles can be adopted, incident reporting can have a role to play in the measurement and monitoring of safety in primary care.

What is clear from the few studies of incident reporting that have been published is that the diversity of definitions of what constitutes patient safety results in many different types of incidents being reported. Many are related to diagnosis and treatment (delayed or inappropriate) and indirectly also to failures in the doctor–patient relationship and in communication between healthcare professionals.<sup>8</sup> These sorts of problems appear dominant in incident reporting studies, perhaps because they may be easier to detect and report.

An important limitation of the available methods for the study of these issues is that existing taxonomies for safety incidents are not well adapted to primary care. Primary care transcends professional boundaries and is part of a wider integrated health system with interfaces with other community providers and secondary care. Failures of coordination of care and medication errors are examples of problems that may occur across an interface. Patients with multimorbidity in primary care are potentially at greatest risk in terms of patient safety issues yet we are only now beginning to think about how we might start to classify harm in this area. So, the challenge of describing and monitoring areas such as delayed diagnosis, polypharmacy and the problems experienced by patients who have a range of diseases creates additional challenges when trying to measure past harm.

Finally, there is very little research on using routine databases in assessing metrics related to patient safety in the primary care context, though the potential

is significant since, in contrast to secondary care, most care in a primary setting, including clinical care, medication ordering and referral information, is recorded on electronic databases. Further research is being undertaken and, if some of the methodological problems associated with this research are overcome, the findings could make a significant contribution to the measurement of past harm.

### **Priorities for understanding safety and improving care**

However, as mentioned earlier, the framework that Vincent has developed does provide a basis for conceptualising the measurement and monitoring of safety and there is value in having a consistent approach across all parts of the health service – it allows researchers to share methodological expertise, it deals with issues around the interface and it allows the sharing of information.

Having discussed the problems of assessing past harm, there is more information that can be gathered in relation to the framework dimensions of reliability, sensitivity to operations and anticipation and preparedness. Significant event auditing has been widely used in primary care, though the processes that underpin its effective use are variable.<sup>9</sup> For example, there is a huge diversity in the way that it is carried out, variability in its recording and in the way that learning is incorporated in its use. However, if there is further research to enable consistency in its use, there is potential for significant event auditing to play an important role in assessing

reliability, sensitivity to operations and as a mechanism for integration and learning.

Safety culture analysis has been well developed at a theoretical level and has been widely field tested in primary care. Tools like Manchester Patient Safety Framework (MaPSaF)<sup>10</sup> have a resonance with practitioners when used in the primary care setting and have a role to play in anticipation and preparedness. MaPSaF has been widely used in European primary care, has been translated into many languages and its use in widely differing primary care systems suggests that the heterogeneity of primary care in the UK should not be a barrier to its much wider implementation. The adoption of MaPSaF by the National Patient Safety Agency and the development of training materials by the NHS Institute for Innovation and Improvement provide an important legacy for its future use as part of a wider framework for measuring and monitoring safety.

Research is currently being undertaken to develop a dashboard for safety for use in primary care which may provide a means for assessing how we respond to, and improve, primary care. The work will not be completed for another 18 to 24 months but, if successful, will be another tool that is available for use in primary care.

### **Future developments**

Having considered the different components of the framework and how they may be developed and used in primary care, it is worth considering future developments and how they may impact on safety measurement and monitoring.



## Role of patients

Patients are, as yet, a largely untapped resource for patient safety.<sup>11</sup> Patients observe errors in their diagnostic and treatment care in the ambulatory setting.<sup>12</sup> Patient-centredness is a key feature of primary care, but this has not been translated into an explicit involvement in patient safety programmes. Although patients cannot be held responsible for patient safety, they can make valid reports on adverse events, while playing a role in some aspects of the planning and delivery of their healthcare at the same time.<sup>13</sup> The quality of patient-professional interactions and relationships seems, in this respect, key for engaging patients in the process. Future research is particularly needed and has to focus on how to involve patients in patient safety programmes.

## Prospective methods

Education for practices in techniques such as a prospective risk analysis might prove particularly useful as a patient safety improvement programme.<sup>14</sup> This method enables a multidisciplinary team to proactively evaluate a healthcare process, focusing on processes, then on the possible problems and finally identifying potential solutions. In this way, the vulnerabilities are not only judged by the likelihood of occurrence but also by the potential severity and the ease with which they might be detected and intercepted before causing harm. Until now, no prospective research has been conducted with testing patient safety improvement programmes on end points (eg patient safety events or

death). This type of research is difficult and expensive, yet can be vital to the enhancement of patient safety in primary care and crucially provide an important contribution to assessing if care in a primary care organisation is safe.

## Conclusions

Although initially it may seem that Vincent's proposed framework will have problems when used in the primary care setting, I believe that the greatest problem is in identifying the tools that can be used. The dimensions against which we should measure and monitor healthcare are relevant to primary care and I have given examples of existing tools which can be used to inform most of the dimensions. It is clear that we can measure and monitor safety in primary healthcare and, as the outputs of current research become available, what currently constitutes a relatively sparse research base will improve. The greatest challenge is getting uniformity in the use of tools and this may require working at a local level with clinical commissioning groups, recognising that they will all be at different levels and therefore not always able to contribute to all the framework dimensions. They will have different trajectories in their implementation.

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