

DISCUSSION

Compared to hospital-based research, qualitative *methods* for researching safety incidents in primary care are relatively common, the body of quantitative research is immature, and few robust *measures* of patient safety events in primary care have been developed.

Methods used in primary care patient safety research:

We identified research that used one of three general methodological approaches: retrospective, concurrent or prospective, and mixed-methods. Retrospective methods included systematic literature reviews^{26, 29, 33} and retrospective analyses of significant incident,^{27, 28, 31} risk management, and malpractice claims^{30, 32, 34} databases. Concurrent and prospective methods included the qualitative approaches of interviews,^{35, 38, 44, 51} focus groups,^{43, 55} and safety incident reporting^{36, 37, 39-42, 45, 48-50, 53, 54, 57-61, 63-68} and the

quantitative approach of surveys.^{46, 47, 52, 56, 62} Mixed-method studies used combinations of two,^{69-72, 74} or three⁷³ of these methods.

Although almost all of the methods employed in hospital-based research have also been used in primary care, some are missing from the primary care literature. No studies were found that were directly comparable to the retrospective record reviews used in hospital-based patient safety studies^{84, 85} and the measures that might arise from such reviews. Numerous barriers to using this method could apply in primary care settings, where a record of the breakdown in care that leads to a safety incident might be spread over several different health care providers in different locations - unlike a hospital record, where multiple providers contribute to a single set of patient notes. However, a study of this type has the potential to draw some comparisons with hospital-based studies using this

method and may warrant further exploration. We also found no primary care research comparable to the hospital-based research that uses autopsy reports,⁸⁶⁻⁸⁸ although mortality databases have been identified as a potentially important source of safety information and one that primary care researchers are prepared to use.²⁶

There is a dearth of research on the types of methods that may better engage patients in safety research in primary care, and the value of their input in addressing different aspects of patient safety is poorly understood. Patients have engaged successfully in qualitative research in community settings about perceived harm,⁵¹ but not in other types of patient safety research.⁵⁸ This should be considered in future research planning.

Measures used in primary care patient safety research:

The terms most often used to describe patient safety incidents in primary care settings were “error”,

“medical error” and “preventable adverse events”. There was no standard definition of these terms. One literature review found 25 different definitions of “medical error”.⁷⁰

Estimates of the rate of patient safety incidents occurring in primary care varied enormously, ranging from 0.004³⁰ to 240⁷¹ per 1000 primary care consultations. Estimates of preventability ranged from 45%⁷¹-76%^{36, 37} of all “errors”.

The types of participants involved in primary care patient safety incidents were primary care physicians and trainees^{29, 30, 32, 34-42, 44-46, 48, 50, 53-62, 64-66, 68-73, 89, 90} patients,^{43, 51} nurses and other practice staff,^{45, 47, 57, 58, 65, 66, 69, 73} paramedics,³⁴ pharmacists,³⁴ computer suppliers,³⁵ academics,³⁵ acupuncturists,⁵² optometrists,⁶³ and managers.^{35, 69} Many studies included measures of the relative frequency of different types of patient safety incident. Most commonly these were “errors” in: diagnosis (26%³⁰-57%⁴⁴ of all incidents),

treatment (7%⁴³-52%³⁷ of all incidents), investigating (13%⁵³-47%⁴⁵ of incidents), office administration (9%⁶⁴-56%⁵⁸), and communication (5%⁷¹-72%⁶⁵ of incidents). Two studies^{43, 51} investigated the type of safety incident patients are concerned about. These were mainly relationship (37%⁴³-77%⁵¹ of concerns) and access problems (29%⁵¹ of concerns).

Causes or contributing factors to patient safety incidents included: environmental hazards (3%⁴⁶-14%³⁰) including work organization, physician factors (5%⁴⁶-91%⁴⁴) including excessive task demands and fragmentation, patient factors (40%⁴⁶-72%⁴⁴), and hospital factors (6%⁴⁶).

Reported harm arising from patient safety incidents ranged from 1.3 significant minor incidents per 1000 treatments⁵² to 4% of incidents resulting in death,^{36, 37} 17%⁵⁰-39%⁴² of incidents resulting in harm, and 70%⁷¹-76%⁵⁰ of incidents having

potential for harm. Patients spoke of anger, frustration, belittlement, and loss of relationship with and trust in their physician as consequences of safety incidents. Consequences of patient safety incidents that were memorable to family physicians⁴⁴ included patient death (47% of memorable incidents), no adverse outcome (26%) and malpractice suits (8%).

Factors influencing clinical educators' responses to "medical errors" were trainees' prior history, clinical knowledge levels, receptivity to feedback, training level, emotional reaction, apologizing, and offering an excuse.⁵⁵ A taxonomy of factors enabling and inhibiting voluntary disclosure of "errors" was also developed.⁷² Attitudes to reporting significant patient safety incidents were measured in one study:⁵⁶ 18% favored mandatory reporting.

Other studies did not aim to produce any outcome measures other than a contribution to a larger research study.^{47, 73} They contributed to

products such as the Manchester Patient Safety Assessment Framework,⁷⁸ a tool for developing improvements in patient safety culture in primary care teams.

Limitations of this review:

The primary care patient safety research in this review generally spans little more than a decade, although there is an older and more extensive literature interpretable as relevant to patient safety in bounded areas such as medications use and diagnosis. The scope of the current research did not include an analysis of these specific safety topics, which may provide further insight into methods and measures of relevance to patient safety incidents in community settings. We included only research publications investigating a wide view of primary healthcare activity and its risks for patient safety. We excluded studies focused on a single bounded activity or cluster of activities, such as medications use or diagnosis. There are many studies in both of these

general areas, usually focusing on particular drugs or drug classes and particular diagnoses. Because of the broad scope of primary care, it was not possible to review this literature. We included patient safety research at the interface between hospital and primary care only if it involved data derived from both settings. We included only English-language papers. For these reasons it is unlikely that we have identified all relevant literature but our search methods have likely captured the essence of the literature as a whole.

This review appraised research conducted mainly in the USA, the UK, and Australia. We caution that because the overwhelming body of published research about patient safety in primary care comes from this limited set of countries, it is unlikely to address issues of importance to many other countries – especially in the developing world. More appropriate methods and measures need to be found for patient safety research in a wider range of countries.

Recommendations for further research:

It is becoming clear that patient safety research in all settings needs to develop new methods and this process is already starting. We included in this review some papers that used the approaches of hazards or Failure Modes and Effects Analysis in primary care.^{62, 66, 69}

These new methods have recently started to be reported in the literature. However, there is also a need to use older methods (such as survey research) with greater attention to designing in research elements to enhance scientific robustness. Greater use of random samples and more attention to increasing response rates are obvious early targets for improving this type of research. All measures of primary care safety incidents identified in this review require further refinement in other primary care settings to test their reliability and validity.

In the absence of a definitive and

internationally understood set of terms and definitions the need to create classification systems, descriptions, and definitions has been compelling for researchers of patient safety in primary care settings. Point estimates were calculated for many types of safety incident but the difficulty with measurement is reflected in the fact that these estimates varied by more than 1000-fold between studies. This may be due to different research data and methods, or different interpretations of the same terms (in two studies 6%⁷⁰ and 41%⁵⁶ of participants had difficulty defining a “significant patient safety event”). Several studies grouped safety incidents according to classifications derived from incident reporting systems.^{39, 53, 60} The WHO’s International Classification for Patient Safety (beta version released July 2007)⁹¹ is an international tool designed to facilitate understanding about patient safety across health sectors and between countries. Refinement and use of this

classification system may obviate the need for further development of taxonomies in primary care patient safety research.

While Australia, the US, and the UK have started to build research programs about patient safety in primary care settings, most countries have not yet engaged in primary care patient safety research. We recommend that such research should be on the agendas of all countries because of the likely opportunities for improvement of patient safety in the most widely used sector of any health system.

Conclusions:

Primary care patient safety research is at an early stage of development, with research efforts concentrating on describing the safety environment rather than intervening to improve it. As recently as five years ago, primary health care providers were more or less exempt from considerations about patient safety and they were excluded from the seminal patient safety reports from

the US⁹ and the UK.¹⁰ Since that time there has been a growing recognition of the increasingly urgent need to reduce patient safety threats in primary care settings.

The methods of primary care patient safety research are well recognized and replicable so it is likely that they will become more widely used, refined, and ultimately deliver more useful knowledge than is currently available. The methods tend to be mainly pragmatic, dominated by studies using reporting systems that have been set up specifically for research purposes. These studies have not yet resulted in national patient safety strategies appropriate for primary care. However, they provide a form of anticipatory testing and show that primary health care providers are generally receptive to the idea of identifying and rectifying risks to patient safety. An integrated information and incident management system is probably ideal for managing threats to patient safety in both primary and other health care settings.⁹² To develop

the study, measurement, and improvement of patient safety in primary care settings, there is a pressing need to address the rigor with which research is designed in order to make their results generalizable. Researchers need to consider methods that will address the internal validity of the measures produced by their research, as well as maintaining the current concern for external validity.

Only a small amount of research has investigated patient safety in primary care from the perspective of patients. To date patients' views have been heard only through small-scale qualitative studies or in the analysis of complaints and risk management systems. An early challenge to address is how to incorporate patients' perspectives on patient safety using valid methods that are devoid of medico-legal threats to clinicians. The sustainable methods of reporting that have identified threats to patient safety from providers' perspectives have been far less successful in eliciting

patients' experiences of patient safety threats. There is a need to develop methods that allow patients more voice in researching the patient safety agenda in primary care (and other) settings. Involving patients in this type of research is likely to result in measures of patient safety that are different from the current metrics, all of which are focused on the provider perspective.

Measures of primary care patient safety are still under development and there are no agreed outcome measures of "safer" care. Identifying and measuring harms related to primary care patient safety incidents is a research gap. Some harms such as death may be applicable across health care settings but others, such as wrong side surgery, are not relevant to primary care research. Barriers to healthcare access, extended waiting times and emotional disaffection, generally not considered serious harms in hospital-based research, may turn out to be important outcomes of patient safety incidents in primary

care because of their long-term consequences in terms of reducing trust in the health system, consequent low use of preventive care and resultant higher need for emergency and acute care. The debate currently is whether these outcomes relate to quality or safety. More research is needed.

Relatively few countries appear to be engaged in primary care patient safety research. This review shows the dominantly western nature of the published scientific literature.

Attempts to increase the efforts at an international level should ideally consider ways to engage a broader range of communities and health care settings, including developing countries and different cultural groups.

Much useful work has been done but the study of patient safety in primary care is still in its infancy.

