

## Background Paper

# A research agenda on patient safety in primary care. Recommendations by the LINNEAUS collaboration on patient safety in primary care

Wim Verstappen<sup>1</sup>, Sander Gaal<sup>1</sup>, Paul Bowie<sup>2</sup>, Diane Parker<sup>3</sup>, Miriam Lainer<sup>4</sup>, Jose M. Valderas<sup>5</sup>, Michel Wensing<sup>1</sup>, Aneez Esmail<sup>6</sup>

<sup>1</sup>Radboud University Nijmegen Medical Centre, Scientific Institute for Quality in Healthcare, Nijmegen, The Netherlands, <sup>2</sup>NHS Education for Scotland, Glasgow, UK, <sup>3</sup>Safety Culture Associates, Oakwood, Leeds, UK, <sup>4</sup>Paracelsus Medical University, Institute of General Practice, Family Medicine and Preventive Medicine, Salzburg, Austria, <sup>5</sup>University of Exeter Medical School, Pen CLAHR, Institute for Health Services Research, Exeter, UK, <sup>6</sup>NIHR Patient Safety Translational Research Centre, Manchester Academic Health Sciences Centre, University of Manchester, Manchester, UK

### KEY MESSAGE:

- To establish how patient safety in primary care can be improved, further research is needed.
- Two potentially powerful strategies for improving patient safety are (a) use of prospective methods identifying safety problems, and (b) involvement of patients.
- Methods for assessing and improving patient safety should be thoroughly evaluated before they are widely implemented.

### ABSTRACT

**Background:** Healthcare can cause avoidable serious harm to patients. Primary care is not an exception, and the relative lack of research in this area lends urgency to a better understanding of patient safety, the future research agenda and the development of primary care oriented safety programmes.

**Objective:** To outline a research agenda for patient safety improvement in primary care in Europe and beyond.

**Methods:** The LINNEAUS collaboration partners analysed existing research on epidemiology and classification of errors, diagnostic and medication errors, safety culture, and learning for and improving patient safety. We discussed ideas for future research in several meetings, workshops and congresses with LINNEAUS collaboration partners, practising GPs, researchers in this field, and policy makers.

**Results:** This paper summarizes and integrates the outcomes of the LINNEAUS collaboration on patient safety in primary care. It proposes a research agenda on improvement strategies for patient safety in primary care. In addition, it provides background information to help to connect research in this field with practicing GPs and other healthcare workers in primary care.

**Conclusion:** Future research studies should target specific primary care domains, using prospective methods and innovative methods such as patient involvement.

**Keywords:** Patient safety, research agenda, primary care, methods, patient involvement, LINNEAUS collaboration

### INTRODUCTION

Most primary care workers would acknowledge that the nature of their work might cause preventable harm to some patients, for instance by missing diagnoses of

life-threatening conditions or making treatment errors (1). The occurrence of patient safety incidents in primary care has been estimated to be between five and 80 incidents per 100 000 consultations (2). Using the

UK as an example, 85% of contacts with the National Health Service take place in primary care; there are 300 million general practice appointments and over 900 million prescription items dispensed each year. The potential for adverse events is, therefore, huge but the knowledge base about patient safety in this context is still small.

However, both the increased complexity of patients' needs and these large numbers of patient contacts in primary care lend urgency to a better understanding not only of the epidemiology of patient safety in primary care, but also to the development of effective programmes to improve patient safety. Most academics and practitioners would argue that patient safety is an essential component of quality that should be the focus of targeted activities in primary care, such as incident reporting, significant event analysis and organizational learning.

We would argue that patient safety in primary care is a significantly under-researched public health and quality of care issue, which does not currently receive the funding and national priority that it warrants in all countries. Fundamentally, research and development is needed to provide evidence on the epidemiology of errors in primary care, intervention strategies on how to enhance patient safety in primary healthcare, taking into account its specific and unique characteristics, paying particular attention to key areas such as reducing errors due to missed and delayed diagnosis.

This reflective paper will first describe some important research findings, some of them being developed within the LINNEAUS collaboration and some from research carried out by members of the collaboration. We highlight key areas of deficiency in the knowledge base related to patient safety in primary care. Based on our experience, we then suggest a number of ways forward with respect to research on improving patient safety in primary care.

## KEY RESEARCH AREAS

### *What is patient safety?*

The first challenge for improvement of patient safety is the lack of consensus about what constitutes patient safety and the large range of items that it potentially covers (3). In a study in the Netherlands, GPs related about 300 different aspects of primary care to patient safety, varying from accessibility of the practice building to repeat prescription of drugs (4). In the literature many other definitions of patient safety are mentioned, which hamper the development of improvement strategies relevant to primary care (1,4). While it is important to use the widely accepted WHO definition, more work is needed to clarify and operationalize what it exactly means in primary care.

### *Epidemiology of patient safety in primary care*

There is a misperception of primary care as a low technology environment where safety is not a problem, which therefore engenders lower investment in safety research than does the secondary care sector. The data show quite a different picture. The vast majority of incidents can be categorized into four main areas covering: diagnosis, prescribing, communication between healthcare providers and patients, and healthcare organizations. Set within the context of a large number of healthcare interactions, these areas become 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 they are mostly based upon incident reporting. A large medical record review study in primary care in the Netherlands 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 (5). These figures are higher than in previous studies in primary care, which may reflect the use of a broader definition of the term 'patient safety incident' (6). 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, it can be safely concluded that the relatively low number of incidents to be expected in each 1000 patient years adds up to substantial national numbers given the high number of patients and contacts in primary care. Understanding the epidemiology of hospital errors was crucial in developing hospital-based safety programmes and public support for efforts to improve safety. This needs to be replicated in primary care (7).

### *Types of patient safety incidents in primary care*

Although the diversity of definitions of what constitutes patient safety results in many different types of incidents being reported, it is becoming apparent that many incidents 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 (8). These kind of problems appear dominant in incident reporting studies, perhaps because these may be easier to detect and report. An important limitation of the available methods for the study of this issue 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 (9). Patients with multimorbidity in primary

care are potentially at greatest risk in terms of patient safety issues (10). The LINNEAUS project has developed taxonomy of safety events in primary care and further research is being developed to focus on how to use this taxonomy for better understanding, learning from and preventing patient safety incidents (11).

#### *Diagnosis and treatment*

Diagnostic error, including preventable delays and poor follow-up on tests, is one of the most important categories of patient safety incidents in primary care. A review of medico-litigation databases suggested that a substantial number of verdicts were related to missed diagnoses and audits have identified opportunities for improving diagnostic procedures (12). Health problems in primary care can be complex and unpredictable. The challenge is to maintain the holistic and person-orientated view that characterizes much of primary care, while avoiding both defensive medicine and an unnecessary exposure to further medical care with an increased potential of harm, and at the same time reducing the number of missed or wrong diagnoses (13). Problems underlying diagnostic error include complacency regarding uncommon dangerous causes of minor symptoms, lack of specialized knowledge of rare symptoms or diseases, and not applying specific screening tests (14).

An issue may be that diagnostic procedures are regarded as normal clinical activities, which are not necessarily seen as an area for targeted interventions to enhance patient safety. Nevertheless, computerized decision support systems are interventions that have been shown to optimize the use of diagnostic tests in clinical practice (15). The challenge is to optimize these systems and their use, whilst identifying their limitations. For example, there is concern that use of information technology results in new types of incidents, such as mixing up of patients or drugs when selecting these from electronic lists. Alert fatigue and low clinical relevance of many alerts pose challenges for optimizing computerized clinical decision support (16).

Drug treatment constitutes another important area of patient safety incidents in primary care. Medication-related adverse events represent an important cause of morbidity, and more recently, attention has been placed on medication safety in ambulatory care settings, the most frequently used components of the formal healthcare system (17,18). Again, computerized decision support systems have been found to improve performance. In this area, pharmacists can contribute to medication reviews and educational pharmacotherapy groups—two methods that have proven effective (19). Challenges are to implement these safety enhancing interventions on a large scale and sustainably.

#### *Healthcare organization*

While patients are directly harmed by inadequate care or by failing to follow evidence-based clinical procedures, there is evidence that the underlying causes of many patient safety incidents in primary care are related to organizational problems. A literature review identified 23 major patient safety topics (20). Transposed to primary care, these organizational problems would include poor teamwork, suboptimal handover of patients, and inadequate use of electronic patient records.

Most of the procedures in primary care involve low-risk situations most of the time, and, therefore, may hamper the identification and pro-active management of patient safety risks by individuals. In other words, many patient safety incidents in diagnosis and treatment have underlying organizational problems, but these do not directly result in harm to patients. Consequently, a strong emphasis on the organization of healthcare delivery could inappropriately distract attention from professional performance and clinical decision making (21). Therefore, we believe that patient safety programmes should primarily focus on clinical processes, including doctor–patient communication and professional performance, and consider whether organizational problems play a role.

Nevertheless, having better patient safety management systems and processes are expected to provide better guarantees for patient safety. The ongoing development in many countries is towards larger practice organizations in primary care. This seems a good development for patient safety management systems in primary care, similar to the positive impact of practice size on providing structured chronic care (22). One of our LINNEAUS collaboration studies suggests that larger European primary care practices had more patient safety features present (23). Although no causal relationship between these patient safety features and primary health outcome can be determined based on this study, patient safety could potentially benefit if these characteristics are present. However, focusing on organizational items may hamper active participation of practising GPs in improving patient safety in primary care.

Our assessment of the relationship between healthcare organization and patient safety focussing on clinical processes suggests that it is contested and it remains an important area of future research. For instance, organizational aspects of patient safety may be used as performance indicators in practice accreditation or pay for performance schemes.

#### *Dysfunctioning healthcare professionals*

Specific activities are needed to identify and manage dysfunctioning healthcare professionals. Given the relatively high prevalence of job stress, addictive behaviours, and psychosocial problems in frontline clinicians and the low

tendency to identify suboptimal functioning colleagues, it is crucial to set up systems to identify and help underperforming health professionals at an early stage (24). Research is needed to develop and test methods to identify the relationship between dysfunctioning health professionals and patient safety.

#### *Incident reporting systems*

Significant event analysis (SEA) is probably the most studied activity in the field of patient safety (25,26). Incident reporting has been promoted as one of the best methods to improve patient safety. Most reported incidents were related to diagnosis, medication, and clinical management. A widely used taxonomy showed that incidents in the process of healthcare were more common than those relating to deficiencies in the knowledge and skills of health professionals (6). There seems a clear chasm between the high expectations for the event analysis technique and the lack of supporting evidence of its impact on the management of risk and safety in healthcare setting. The evidence for SEA as a team-based educational and problem-solving activity, which may act as a mechanism for change, is at best moderate, but appears to have greater credence where a methodical approach is adopted (26).

#### *Safety culture*

The safety culture of a primary care organization provides the underpinning for both the individual clinical practice and the processes designed to support patient safety (27). Even with good clinical processes and safety management system in place, optimum patient safety will not be achieved unless the culture of the organization is supportive. It is important to unravel the container concept 'culture' to understand and target its most relevant components. The assessment methods recommended drawing attention to a range of organizational aspects through which safety culture is manifested, including teamwork and communication. However, the link between a well-developed patient safety culture, and good patient outcomes, remains to be established.

#### *Role of patients*

Patients are, as yet, a largely untapped resource for patient safety (28). Patients observe errors in their diagnostic and treatment care in the ambulatory setting (29). Patient-centeredness 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 (30). The quality of patient–professional interactions

and relationships seems in this respect the 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 (31,32). This method, described in more detail elsewhere in this supplement, enables a multidisciplinary team to proactively evaluate a healthcare process, focus on processes, then on the possible problems and finally identify potential solutions (33). 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 (e.g. patient safety events or death). This type of research is difficult and expensive, yet can be crucial to the enhancement of patient safety in primary care (34).

### A RESEARCH AGENDA

Our involvement in the LINNEAUS collaboration has confirmed our view that patient safety programmes in primary care should focus more on the specific clinical domains or items in primary care. They should also take into account the specific characteristics of primary care, such as the high yearly numbers of patients and contacts, the low risk of harm, and the broad diversity of conditions and procedures. Although serious patient safety incidents appear to have a low prevalence in primary care, the volume of patients and contacts in primary care imply that it nevertheless is a significant issue.

The science of how to improve healthcare provides many lessons that are also relevant for optimizing patient safety. Perhaps most importantly, it warns against ungrounded high expectations of any intervention or activity. Research on patient safety improvement is still limited, so it remains to be seen which strategies are most effective. For instance, significant event analysis and assessments of safety culture, two methods that are used relatively frequently, have unknown effects on patient safety. Our proposed focus on clinical processes (such as diagnosis, treatment, and follow-up) will enhance the willingness of primary care workers to join programmes. Most serious patient safety events are seen with diagnostic delay or failure, in serious diseases such as myocardial infarction. To enhance the engagement of physicians it may be wise to start with improvement programmes that improve safety of diagnosis in severe diseases. The effects of patient safety programmes in secondary care—for example the huge emphasis placed on



Box 1. The LINNEAUS collaboration: Key research questions for patient safety in primary care.

Definition, epidemiology and types of safety incidents

- What are high-risk patients, consultations and procedures in primary care?
- When is it no longer safe to provide care that would otherwise be considered safe because of the changing harm/benefit ratio?

Diagnosis and treatment

- How can diagnostic performance of primary care physicians be improved while avoiding defensive medicine and inefficient test ordering?
- How can effective methods for improving medication safety, such as decision support systems and pharmacist involvement, be optimized and widely implemented in primary care?

Health care organization

- Which interventions to prevent infections in minor surgery and other procedures are needed in primary care?
- Which organizational, cultural, and financial factors in primary care contribute to patient safety and how can these be optimized?

Dysfunctioning health care professionals

- How are dysfunctioning healthcare professionals detected and managed?  
Patient role
- What can patients do to enhance patient safety in primary care?

Prospective methods

- How are retrospective and prospective risk analyses integrated in the safety system of a primary care practice?

incident reporting systems—should be studied to avoid wasting resources on ineffective approaches. Box 1 gives an outline of pertinent questions for research on improving patient safety in primary care.

## CONCLUSION

Through the support of the Framework 7 programme, the LINNEAUS collaboration has developed a European network of primary care physicians and researchers, which for the first time was focusing on patient safety in primary care and developing research to address some of the identified problems. Our experience in the LINNEAUS collaboration provides a clear framework for a research programme and crucially provides the collaborative network to help to connect patient safety improvement programmes with practicing GPs and other healthcare workers in primary care. Whilst focusing on specific primary care domains and items, prospective methods identifying safety problems and involving patients are two potentially powerful strategies.

## FUNDING

The research leading to these results has received funding from the European Community's Seventh Framework Programme FP7/2008–2012 under grant agreement no. 223424.

## ACKNOWLEDGEMENTS

The authors thank all members and partners of the LINNEAUS collaboration for discussions and reflections, which helped to shape this paper.

**Declaration of interest:** The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

## REFERENCES

1. Gandhi T, Lee TH. Patient safety beyond the hospital. *N Engl J Med.* 2010;363:1001–3.
2. Sandars J, Esmail A. The frequency and nature of medical error in primary care: Understanding the diversity across studies. *Fam Pract.* 2003;20:231–6.
3. Elder N, Pallerla H, Regan S. What do family physicians consider an error? A comparison of definitions and physician perception. *BMC Fam Pract.* 2006;7:73.
4. Gaal S, van Laarhoven E, Wolters R, Wetzels R, Verstappen W, Wensing M. Patient safety in primary care has many aspects: An interview study in primary care doctors and nurses. *J Eval Clin Pract.* 2010;16:639–43.
5. Gaal S, Verstappen W, Wolters R, Lankveld H, van Weel C, Wensing M. Prevalence and consequences of patient safety incidents in general practice in the Netherlands; a retrospective medical record review study. *Implement Sci.* 2011;6:37.
6. Dovey S, Meyers DS, Phillips R, Green L, Fryer G, Galliher J, et al. A preliminary taxonomy of medical errors in family practice. *Qual Saf Health Care* 2002;11:233–8.
7. Wynia MK, Classen DC. Improving ambulatory patient safety: Learning from the last decade, moving ahead in the next. *J Am Med Assoc.* 2011;306:2504–5.
8. Fernald D, Pace W, Harris D, West D, Main D, Westfall J. Event reporting to a primary care patient safety reporting system: A report from the ASIPS collaborative. *Ann Fam Med.* 2004;2:327–32.
9. Johnson KJ, Arora VM, Barach PR. What can artefact analysis tell us about patient transitions between the hospital and primary care? Lessons from the HANDOVER project. *Eur J Gen Pract.* 2013;19:185–93.
10. Valderas JM, Ricci-Cabello I, Violan C. The impact of multimorbidity on quality and safety of health care. In: Mercer S, Salisbury C, Fortin M, editors. *ABC of multimorbidity.* 1st ed. London: Blackwell; 2014. pp. 38.

11. Klemp K, Dovey S, Valderas JM, Rohe J, Godycki-Cwirko M, Elliott P, et al. Developing a patient safety incident classification system for primary care. A literature review and Delphi-survey by the LINNEAUS collaboration on patient safety in primary care. *Eur J Gen Pract.* 2015;21(S1):35–38.
12. Gaal S, Hartman C, Giesen P, van Weel C, Verstappen W, Wensing M. Complaints against family physicians submitted to disciplinary tribunals in the Netherlands: lessons for patient safety. *Ann Fam Med.* 2011;9:522–7.
13. Walley J, Lawn JE, Tinker A, de Francisco A, Chopra M, Rudan I, et al. Primary health care: Making Alma-Ata a reality. *Lancet* 2008;372:1001–7.
14. Newman-Toker DE, Pronovost PJ. Diagnostic errors—the next frontier for patient safety. *J Am Med Assoc.* 2009;301:1060–2.
15. Roshanov PS, Misra S, Gerstein HC, Garg AX, Sebaldt RJ, Mackay JA, et al. Computerized clinical decision support systems for chronic disease management: A decision-maker-researcher partnership systematic review. *Implement Sci.* 2011;6:92.
16. van der Sijs H, Aarts J, Vulto A, Berg M. Overriding of drug safety alerts in computerized physician order entry. *J Am Med Inform Assoc.* 2006;13:138–47.
17. Gandhi T, Weingart S, Borus J, Seger A. Adverse drug events in ambulatory care. *N Engl J Med.* 2003;348:1556–64.
18. Avery AJ, Sheikh A, Hurwitz B, Smeaton L, Chen YF, Howard R, et al. Safer medicines management in primary care. *Br J Gen Pract.* 2002;52:S17–S22.
19. Tache SV, Sonnichsen A, Ashcroft DM. Prevalence of adverse drug events in ambulatory care: A systematic review. *Ann Pharmacother.* 2011;47:977–89.
20. Jha AK, Prasopa-Plaizier N, Larizgoitia I, Bates DW. Patient safety research: An overview of the global evidence. *Qual Saf Health Care* 2010;19:42–7.
21. Shortell SM, Singer SJ. Improving patient safety by taking systems seriously. *J Am Med Assoc.* 2008;299:445–7.
22. Schoen C, Osborn R, Huynh PT, Doty M, Peugh J, Zapert K. On the front lines of care: Primary care doctors' office systems, experiences, and views in seven countries. *Health Affairs* 25, w555–w571.
23. Gaal S, van den Hombergh P, Verstappen W, Wensing M. Patient safety features are more present in larger primary care practices. *Health Policy* 2010; 97:87–91.
24. DesRoches C, Rao S, Fromson J, Birnbaum R, Lezzoni L, Vogeli C, et al. Physicians' perceptions, preparedness for reporting, and experiences related to impaired and incompetent colleagues. *J Am Med Assoc.* 2010;304:187–93.
25. Bowie P, Pope L, Lough M. A review of the current evidence base for significant event analysis. *J Eval Clin Pract.* 2008;14:520–36.
26. de Wet WC, Bradley N, Bowie P. Significant event analysis: A comparative study of knowledge, process and attitudes in primary care. *J Eval Clin Pract.* 2011;17:1207–15.
27. Kirk S, Parker D, Claridge T, Esmail A, Marshall M. Patient safety culture in primary care: Developing a theoretical framework for practical use. *Qual Saf Health Care* 2007;16:313–20.
28. King A, Daniels J, Lim J, Cochrane DD, Taylor A, Ansermino JM. Time to listen: A review of methods to solicit patient reports of adverse events. *Qual Saf Health Care* 2010;19:148–57.
29. Buetow S, Elwyn G. Patient safety and patient error. *Lancet* 2007;369:158–66.
30. Davis RE, Jacklin R, Sevdalis N, Vincent CA. Patient involvement in patient safety: What factors influence patient participation and engagement? *Health Expect.* 2007;10:259–67.
31. DeRosier J, Stalhandske E, Bagian JP, Nudell T. Using health care failure mode and effect analysis: The VA national center for patient safety's prospective risk analysis system. *Jt Comm J Qual Improv.* 2002;28:248–67.
32. Habraken MMP, Schaaf TW van der, Leistikow IP, Reijnders-Thijssen PMJ. Prospective risk analysis of health care processes: A systematic evaluation of the use of HFMEA in Dutch health care. *Ergonomics* 2009;52:809–19.
33. Verstappen W, Gaal S, Esmail A, Wensing M. Patient safety improvement programmes for primary care. Review of a Delphi procedure and pilot studies by the LINNEAUS collaboration for patient safety in primary care. *Eur J Gen Pract.* 2015;21(S1):50–55.
34. Wammes JJ, Verstappen W, Gaal S, Wensing M. Organisational targets of patient safety improvement programs in primary care; an international web-based survey. *Br Med C Fam Pract.* 2013;14:145.