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<tr>
<th><strong>Title</strong></th>
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<tr>
<td><strong>Author(s)</strong></td>
<td>Lydon, Sinéad; Cupples, Margaret; Murphy, Andrew W.; Hart, Nigel; O'Connor, Paul</td>
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A systematic review of measurement tools for the proactive assessment of patient safety in general practice


ABSTRACT

Background. Primary care physicians have reported a difficulty in understanding how best to measure and improve patient safety in their practices.

Objectives. To identify measures of patient safety suitable for use in primary care and provide guidance on proactively monitoring and measuring safety.

Methods. Searches were conducted using Medline, Embase, CINAHL and PsycInfo in February 2016. Studies that utilised a measure assessing levels of, or attitudes towards, patient safety in primary care were considered for inclusion. Only studies describing tools focused on the proactive assessment of safety were reviewed. Two independent reviewers extracted data from articles and applied the Quality Assessment Tool for Studies with Diverse Designs.

Results. 2,800 studies were screened, of which 56 were included. The majority of studies had utilised healthcare staff survey or interviews to assess patient safety (N=34), followed by patient chart audit (N=14), or use of a practice assessment checklist (N=7). Survey or interview of patients, active monitoring systems, and simulated patients were used with less frequency.

Conclusions and relevance. A lack of appropriate measurement tools has been suggested to limit the ability to monitor patient safety in primary care and to improve patient care. There is no evident “best” method of measuring patient safety in primary care. However, many of the measures are readily available, quick to administer, do not require external involvement, and
are inexpensive. This synthesis of the literature suggests that it is possible for primary care physicians to take a proactive approach to measuring and improving safety.
INTRODUCTION

There has been an increasing focus on patient safety in healthcare in recent decades. However, the target has tended to be secondary care, with studies concerned with measuring and improving safety in primary care settings less commonplace. This lower interest in safety in primary care settings may result from a widespread perception of primary healthcare delivery as being a lower risk endeavour than hospital care. It is certainly the case that in terms of adverse events, rates have been found to be higher in secondary care (approximately 10% of admissions) as compared to primary care (approximately 2-3% of consultations).

Given these low rates of adverse events in primary care, these data are of limited utility as a metric for practitioners, researchers, or policy makers in measuring and/or improving safety. It is likely, however, that minor adverse events occurring in primary care are sometimes unrecognised. Another issue is that there is considerable variation in how incidents have been classified in primary care settings. Indeed, British primary care physicians have reported a difficulty in understanding how best to measure and improve patient safety in their practices. Therefore, there is a need to move from a focus on ‘lagging’ indicators of safety such as adverse events, and shift the interest to identifying valid and reliable precursors, conditions, events or measures before an incident or event has occurred (known as ‘leading’ indicators of safety). This shift will support a more proactive approach to safety measurement and monitoring.

Previous reviews on measuring patient safety in primary care have identified a variety of measurement systems. However, these reviews were broad in nature, describing measures applicable to a variety of primary care professions (e.g., dentistry, nursing home care) and it can often be difficult to ascertain or estimate the utility of specific measures within individual general practice settings. Further, many of these measures offer a very specific focus (e.g., management of a specific medication) and general practitioners seeking
to improve the safety of their practices or patients may struggle to select one specific safety focus and/or implement more than one measurement system concurrently. Finally, many of these measures (e.g., event reporting systems) are focused on lagging indicators of safety, and require an adverse event to occur in order for data to be collected to inform improvement efforts.

Thus, the aim of the current systematic review was to identify and review articles that presented, or described the use of, measures of patient safety suitable for use in general practice settings. The objective of the paper was not to look at the outcomes of such measurements of patient safety, as this data has been reviewed elsewhere,5,6 but instead to focus on the tools being used to gauge patient safety and estimate levels of harm. The purpose was to provide a synthesis of existing measures in order to provide guidance on suitable means of proactively monitoring and measuring patient safety.

METHODS

Search strategy

Systematic searches were carried out in February 2016 using the following electronic databases: OVID Medline, Embase, CINAHL, and PsycINFO. Our search protocol (see Online Supplementary Material 1) included Medical Subject Headings (MeSH) search terms and keywords and was altered as appropriate for databases other than Medline. No time inclusion was specified. In order to ensure the accuracy of study screening and inclusion/exclusion, two of the authors conducted the Medline searches independently and their resulting lists of studies for inclusion were compared. Agreement between the reviewers during this process was found to be almost perfect ($\kappa=.87$).11 The reference lists of all articles identified for inclusion were reviewed in order to identify other potentially suitable papers.
Further, the reference lists of two reviews of tools for assessing safety in primary care were also screened.\textsuperscript{1,10}

\textbf{Study selection}

\textit{Inclusion criteria}

In order to be included within the current review, studies had to: a) be written in English; b) be published in a peer-reviewed journal; c) report original research; d) evaluate a tool or measure for assessing levels of, or attitudes towards, patient safety in a specific general practice setting, and; e) employ a tool or measure that was focused on the proactive measurement of patient safety and aligned with the definition of a leading indicator of safety (i.e., “focus on identifying precursors, conditions, events or measures before an incident or event has occurred and which purportedly predict whether an event will occur”; e.g., safety management system audits, safety climate surveys).\textsuperscript{8}

\textit{Exclusion criteria}

Studies that were focused solely on tools or measures consistent with definitions of lagging indicators of safety (i.e., “measures that are made after an incident or event has occurred and which assess different types of outcome… reactive measures of an organisation’s or system’s safety performance”; e.g., incident reporting)\textsuperscript{8} were not eligible for inclusion in this review. Other studies were excluded due to a focus on: quality of patient care; patient safety among those with a specific medical condition or those prescribed a specific medication, the assessment of participants’ perceptions of, or attitudes towards, particular types of patient safety measures; one particular primary care process or function alone (e.g., prescribing only); being conducted in a hospital setting only; a primary care setting other than general practice; being conducted in an ambulatory care setting that did not provide primary care services.
Data extraction

Data extraction was independently conducted by two of the authors. Any disagreements were resolved through discussion until consensus was reached. A structured tool was used to extract information on the tool(s) name, type, and descriptions from each study along with information concerning the country in which the study had been conducted and the clinical applications of the tool.

Quality assessment

Included studies were also critically appraised by the two reviewers using the Quality Assessment Tool for Studies with Diverse Designs (QATSDD). This instrument allows for a standardised approach to the assessment of studies utilising qualitative, quantitative, and mixed methods research designs. Scores on this measure can range from 0-48. The two reviewers completed the quality assessment in tandem and disagreements were resolved through discussion.

RESULTS

Over 2,800 articles were screened, of which 56 studies met the inclusion criteria (see Figure 1) and described 64 assessments of patient safety in general practice settings. Studies were published between 2003 and 2015 and had been conducted in Europe, North America, South America, Australia, Asia, and Africa. Of the included studies, 50 were quantitative (80.6%), seven were qualitative (11.3%), and five employed a mixed-methods research design (8.1%). Across all studies, the mean score on the QATSDD was 21.8 (SD=6.5; range= 10-37).
Study categorisation

Studies were categorised according to the nature of the patient safety measurement tool that they included. Six categories were developed inductively throughout the data extraction process. These categories were:

1) healthcare staff survey or interview- assess staff members’ attitudes to safety through surveys and/or interviews;

2) patient chart audit- review of patient charts in order to identify instances of undetected harm or potential harm;
3) *practice assessment checklist*- use of a checklist to evaluate specific safety-related indicators (e.g. sharps disposal);

4) *patient survey or interview*- surveys and/or interviews with patients on their perceptions of the safety of care;

5) *active monitoring system*- physicians’ assessment immediately following a consultation in order to identify any potential harm, and;

6) *simulated patient*- utilised actors as patients who presented specific cases to assess the care provided by the physician.

A summary of studies included within each category is presented in Table 1.

**Table 1.** Summary data across the six categories of patient safety measurement tools identified

<table>
<thead>
<tr>
<th>Category</th>
<th>Number of Studies*</th>
<th>Quantitative</th>
<th>Qualitative</th>
<th>Mixed Methods</th>
<th>QATSDD Score (Mean; SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare staff survey or interview</td>
<td>34</td>
<td>27</td>
<td>5</td>
<td>2</td>
<td>23.7; 6.2</td>
</tr>
<tr>
<td>Patient chart audit</td>
<td>14</td>
<td>13</td>
<td>1</td>
<td>-</td>
<td>19.3; 5</td>
</tr>
<tr>
<td>Practice assessment checklists</td>
<td>7</td>
<td>4</td>
<td>-</td>
<td>3</td>
<td>19; 8.5</td>
</tr>
<tr>
<td>Patient survey or interview</td>
<td>3</td>
<td>3</td>
<td>-</td>
<td>-</td>
<td>18; 4</td>
</tr>
<tr>
<td>Active monitoring system</td>
<td>2</td>
<td>1</td>
<td>-</td>
<td>1</td>
<td>21; 0</td>
</tr>
<tr>
<td>Simulated Patients</td>
<td>2</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>19.5; 10.6</td>
</tr>
</tbody>
</table>

*Note.* These figures do not total to 56 as six of the studies included in the review employed two different types of patient safety assessment tools.
Studies utilising healthcare staff survey or interview.

A total of 34 studies (see Tables 1 and 2; for detailed study descriptions, see Online Supplementary Material 2) employed a measure of patient safety that was reliant on input from healthcare professionals (e.g., doctors, nurses, practice managers). Of these, staff surveys alone were employed in 25 studies, seven studies employed staff interviews, focus groups, or workshops, and two studies utilised a combination of staff interview and staff survey.

Table 2. Overview of healthcare staff survey or interview tools used in included studies

<table>
<thead>
<tr>
<th>Tool</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety Attitudes Questionnaire</td>
<td>Used in five studies</td>
</tr>
<tr>
<td>Manchester Patient Safety Framework</td>
<td>Used in four studies</td>
</tr>
<tr>
<td>PC SafeQuest</td>
<td>Used in three studies</td>
</tr>
<tr>
<td>SCOPE questionnaire</td>
<td>Used in three studies</td>
</tr>
<tr>
<td>Medical Office Survey on Patient Safety Culture</td>
<td>Used in three studies</td>
</tr>
<tr>
<td>Frankfurt Patient Safety Climate Questionnaire</td>
<td>Used in three studies</td>
</tr>
<tr>
<td>Hospital Survey on Patient Safety Culture</td>
<td>Used in two studies</td>
</tr>
<tr>
<td>Perceived hazard questionnaire</td>
<td>Used in two studies</td>
</tr>
<tr>
<td>Survey tool/interview protocol used in only one study</td>
<td>Used in 11 studies</td>
</tr>
</tbody>
</table>

Studies utilising patient chart audit methodologies

In total, 14 studies (see Tables 1 and 3; for detailed study descriptions, see Table 2 in Online Supplementary Material 2) used existing patients’ charts in order to identify previously undetected patient safety incidents.
Table 3. Overview of studies utilising patient chart audit methodologies

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trigger tool/criteria</td>
<td>Used in five studies</td>
</tr>
<tr>
<td>Physicians’ clinical judgement only</td>
<td>Used in four studies</td>
</tr>
<tr>
<td>Clear definition of what constituted an error along with clinical judgement</td>
<td>Used in three studies</td>
</tr>
<tr>
<td>Chart review using clinical judgement following patient report of perceived harm</td>
<td>Used in two studies</td>
</tr>
</tbody>
</table>

Studies utilising practice assessment checklists

Seven studies utilised some form of practice assessment checklist to assess patient safety in a primary care setting (see Table 1; for detailed descriptions, see: Table 3 in Online Supplementary Material 2). None of the practice assessment checklists were employed in more than one research study. One study\(^60\) describes a tool suitable for use in correctional health care facilities while the tools described in the other studies were more general in nature. Schauberger and Larson\(^61\) present a patient safety toolkit that is comprised of 11 tools that assess patient safety in a range of domains.

Studies utilising patient survey or interview

Three studies utilised patient-centric measures of patient safety (see Table 1; for detailed descriptions, see: Table 4 in Online Supplementary Material 2). Each of these studies\(^15,17,18\) asked patients about the care they had been receiving in order to identify any potential errors or adverse events that the patient perceived had occurred in their care. In two of these studies,\(^15,17\) any potential errors or adverse events reported by patients were further explored via patient chart audit.

Studies utilising active monitoring systems
Two studies (for detailed descriptions, see: Table 5 in Online Supplementary Material 2) described the use of active monitoring systems in primary care. Both studies\textsuperscript{13,62} required physicians to complete a structured form following all patient consultations that allowed them to reflect on the consultation and care provided and to identify any errors made or potential harm.

**Studies utilising simulated patients**

Two studies (for detailed descriptions, see: Table 6 in Online Supplementary Material 2) used simulated patients as a means of assessing patient safety. Moriarty et al\textsuperscript{63} used simulated patient phone calls to assess 85 primary care nurses’ patient triaging. Weiner et al\textsuperscript{64} used simulated patients to assess primary care doctors’ abilities to recognise hints of complicating factors that needed to be considered in order to develop an appropriate care plan.

**DISCUSSION**

Over 300 million visits to a general practitioner are made in the UK annually.\textsuperscript{65} This volume of patients creates a large potential for medical error that must be considered and addressed. The aim of the current review was to provide a synthesis of existing measures of patient safety suitable for use in primary care settings in order to provide guidance to general practitioners, policy makers, and researchers on identifying suitable means of proactively monitoring and measuring patient safety. The review of 56 studies describing 64 assessments of patient safety revealed six distinct categories of measurement tools that have been employed to proactively measure patient safety in primary care settings.

There is no evident “best” method of measuring patient safety in primary care. However, the greatest amount of research described the use of staff survey or interview techniques in order to elicit perceptions of patient safety in a setting. Safety surveys can offer
a relevant and valid measure\textsuperscript{66} of safety and are easily implemented. There is no apparent consensus on the most suitable survey or interview measure. However, the most frequently employed tools which include the Safety Attitudes Questionnaire, the Manchester Patient Safety Framework, PC SafeQuest, SCOPE, or the Medical Office Survey of Patient Safety Culture. Researchers or medical practitioners looking for a measure that provides more immediately actionable knowledge may wish to opt for patient chart audit methodologies or the use of practice assessment checklists, the next two most frequently used categories of tools. Such tools have been well-described and evaluated in the research literature, many are accompanied by explicit and structured guidelines for use that will increase the ease of employment, and these processes can be implemented at a relatively low cost.

The other three categories of tools identified in the literature review (patient-report measures, active monitoring, and simulated patients) were used with less frequency in the research literature. This is potentially due to the resource intensive nature of these tools. Further, the recruitment of patients to complete patient-report measures may add another layer of difficulty that may reduce the use of such measures. However, it is recognised that the triangulation of patient safety assessment methods is desirable as the use of differing data sources may provide a more comprehensive or insightful overview of safety in a setting.\textsuperscript{5,9,67} Research investigating the potential for the various categories of measurement tools to contribute to quality improvement efforts within general practice is needed in order to best inform measurement tool selection in general practice settings.

Some key findings emerging from our review are noted here for those interested in measuring patient safety in primary care. First, the assessment of patient safety within individual practices is feasible. Previously, physicians have highlighted the lack of external support, guidance and data that they receive as a barrier to improving patient safety in their practices.\textsuperscript{7} The current review focused on studies describing measures that provided practice-
level feedback or data. Many of the instruments which were used are freely available online, are quick to complete, do not require external involvement and are inexpensive to conduct. Therefore, the resource constraints that often preclude patient safety monitoring\textsuperscript{7} may be avoided. It may be that specific categories of measurement tools may be more appropriate for the particular types of primary care practices (e.g., practices with/without electronic health records, hospital/non-hospital associated practices). For example, the use of a healthcare staff survey is likely to be more informative in practices with a larger team of staff members than in smaller practices. Future research that specifically examines the appropriateness of the various measurement tools for differing types of primary care practices would be of great interest.

Next, the importance of using an established tool to measure patient safety in order to produce reliable estimates of patient safety incidents that are comparable across studies, across settings, and over time, is evident. Different understandings and definitions of medical error exist among medical practitioners and in the research literature.\textsuperscript{68} Similarly, inter-observer variability between physicians has been demonstrated to be high during patient chart audits.\textsuperscript{69}

Finally, there is a need for systematic, rather than opportunistic, measurement of patient safety incidents in primary care. A shift in focus towards the proactive measurement of patient safety and identifying precursors, conditions, or indicators of a patient safety incident should lead to an improved quality of patient care and safety in practices. Further, a focus on identifying patient safety incidents before harm has occurred may be more palatable to physicians than utilising lagging measurement systems that typically identify, or are focused on, cases of severe harm that can have negative repercussions for the physicians involved.\textsuperscript{7}
Strengths and Limitations

The current review has a number of strengths. Key among these is the rigour afforded by two PhD level researchers conducting both the searches and the data extraction independently in order to ensure the accuracy of outputs. Further, a rigorous search process was conducted as indicated by the comprehensive nature of the search terms utilised and the lack of specification of a publication year range. The inclusion of studies utilising qualitative, quantitative, and mixed method research studies, and the assessment of the methodological rigour of all studies, may also be considered strengths of this review.

The scope of the review is intentionally quite narrow, and this may be considered both a strength and a limitation. It is a strength given that previous reviews of patient safety measurement in primary care have been broad in nature and arguably of limited utility for medical practitioners and researchers as a result. However, the inclusion criteria in the current review may be faulted for providing a limited overview of the true range of measures that exist. For instance, readers may question the exclusion of measurement tools focused on assessing specific safety issues (e.g., prescribing errors). However, our inclusion criteria were centred on improving the safety of organisations more broadly rather than targeting specific areas. The more general measures described in this review may allow for the identification of specific weaknesses within an organisation and guide more targeted assessments within these areas.

Our focus on proactive, or leading, assessments of safety might also be challenged. Previous reviews indicate a predominant focus on lagging indicators of safety such as incident reporting systems in primary care. However, given the low levels of adverse events in primary care, along with the lack of practice-specific data that result from incident reporting systems, and the confusion that exists among general practitioners on how to best
measure and improve safety in their practice, such lagging measures of safety are unlikely to effectively guide improvement efforts. The leading, or proactive, measures of patient safety described in the current review all offer practice specific, relevant, actionable data that can be used to improve day-to-day patient safety within individual practices. The consideration of patient chart reviews as a proactive means of assessing patient safety may also be challenged. However, this form of patient safety assessment often allows for the identification of errors that have been made and for a practitioner to take action to avert potential harm and to make changes to reduce the likelihood of such errors occurring again. In this way, it is not only adverse events that have already occurred which are identified, as in the case of lagging measures of safety. Thus, patient chart reviews conducted for living patients were considered to be proactive assessments of safety and included for review.

Finally, categorisations of the various forms of measurement tools may also be disputed. There is a lack of a useful definition of what constitutes a tool or a set of criteria for categorising tools. As a result, a pragmatic approach to inductively developing categorisations for tools was adopted and the resulting categorisations were assessed for face validity by the authors.

Future research

Based upon this systematic review, it is possible to make a number of recommendations for improving the rigour and utility of leading measures of patient safety in primary care.

1. Patients’ inputs were largely missing from the studies included in this review. Only three of the included studies described a means of measuring patient safety through direct patient engagement. This is perhaps unexpected given the increasing awareness of the benefits of patient participation in healthcare, including improved patient outcomes and reductions in medical error and malpractice claims. There is a need for greater
consideration of how patients are included in patient safety research. For instance, Solberg et al.\textsuperscript{17} found that of the 247 patient safety incidents reported by patients, only five of these constituted real clinician errors. Therefore, patients may require educational programs in order to equip them with the skills necessary to participate in healthcare research such as this. An educational program in this area could focus on teaching around medical error and what constitutes harm.\textsuperscript{72}

2. \textit{There is a need to focus on improving the psychometric properties of existing tools as opposed to developing new tools.} This issue is not confined to primary care, but is a common issue with safety climate measures in other industries.\textsuperscript{73,74} The need to assess the psychometric properties of existing tools, especially when employed outside of the context in which they were developed, is clear: “the lack of reliable data on safety, and indeed quality, over time hinders improvement efforts at every level”.\textsuperscript{75} Methodological differences often contribute to discrepancies in estimates of patient safety incidents.\textsuperscript{67} Thus, in order to assess the effectiveness of patient safety interventions, to examine changes over time, and to make (inter)national comparisons, there is a requirement for valid and reliable measurement tools.

3. \textit{Need to take a multi-methods approach to assessing patient safety.} Only six of the studies included more than one type of patient safety measure in their assessment. A ‘single measure of safety is a fantasy’\textsuperscript{9} and the triangulation of multiple methodologies in order to obtain a comprehensive overview of patient safety within a specific setting has been recommended by a number of researchers.\textsuperscript{5,9,67} Future researchers should evaluate multi-method assessments and determine the utility, necessity, or sufficiency of particular measures within such a multi-method toolkit. Data from such studies may also aid with the understanding of the reliability of estimates of patient safety incidents or patient harm occurring in primary care. There were substantial variations in the methodologies used,
even within the specific measurement tool categories that may contribute to differing estimates of the prevalence of patient harm. Studies employing multiple methods of patient safety measurement would provide insight into the comparability of estimates of harm arising from the use of various measures and may allow for the identification of measures that over- or under-estimate patient safety in primary care.

CONCLUSIONS

A lack of tools available to measure patient safety in primary care settings has been suggested to limit the ability to avert patient safety incidents and to improve patient care and outcomes. This review has provided a useful overview of existing measurement tools that can be employed in primary healthcare settings that may help researchers and practitioners to identify how to best measure patient safety and evaluate interventional strategies or tactics intended to prevent or ameliorate patient harm. Key recommendations that can be made from the extant literature are limited by the continual use of novel or modified tools and a distinct lack of focus on the use of multi-method assessments of patient safety, but future research must focus on involving patients in patient safety measurement and improvement processes, further establishing the psychometric properties of existing tools, and evaluating the optimal strategy of conducting multi method assessments of patient safety.
Conflict of Interest

The authors declare that they have no conflicting interests.

Funding

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References


## Appendix 1: Summary of Medline OVID Search Strategy

1: Primary care.ti,ab.  
2: Primary Health Care.ti,ab.  
3: General Practice.ti,ab.  
4: Family Practice.ti,ab.  
5: Ambulatory care.ti,ab.  
6: Community care.ti,ab.  
7: 1 or 2 or 3 or 4 or 5 or 6  
8: exp Organizational Culture/  
9: exp Medical Error/  
10: (safe* adj2 manag*).ti,ab.  
11: (safe* adj2 culture*).ti,ab.  
12: (safe* adj2 climate*).ti,ab.  
13: (patient* adj2 safe*).ti,ab.  
14: (patient* adj2 harm).ti,ab  
15: (safe* adj2 attitude*).ti,ab.  
16: (safe* adj2 behav*).ti,ab.  
17: (diagnos* adj2 error*).ti,ab.  
18: (iatrogenic adj2 disease).ti,ab.  
19: (adverse adj2 event*).ti,ab.  
20: 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19  
21: 7 and 20  
22: limit 19 to (english language and humans and (addresses or autobiography or bibliography or biography or comment or congresses or dictionary or directory or duplicate publication or editorial or festschrift or in vitro or interactive tutorial or interview or lectures or legal cases or legislation or letter or news or newspaper article or overall or patient education handout or periodical index or portraits or twin study or video-audio media or webcasts)).

*Note:* Exp= explode, ti=title, ab=abstract,
### Appendix 2

Table 1. Summary of studies utilising staff-centric measurement tools.

<table>
<thead>
<tr>
<th>Study</th>
<th>Tool Format</th>
<th>Detailed Tool Description</th>
<th>Country</th>
<th>Clinical Setting and Number of Applications</th>
<th>Study Quality Score</th>
</tr>
</thead>
</table>
| Astier-Pena et al.32    | Staff survey: Spanish version of Agency for Healthcare Research and Quality (AHRQ) Medical Office Survey on Patient Safety Culture | 67 items assess 15 dimensions of patient safety:  
- Patient safety and quality issues  
- Information exchange with other settings  
- Teamwork  
- Work pressure and pace  
- Non-healthcare staff training  
- Healthcare staff training  
- Office processes and standardization for non-healthcare staff  
- Office processes and standardization for healthcare staff  
- Communication openness  
- Patient care tracking/follow-up  
- Communication about error (non-healthcare staff)  
- Communication about error (healthcare staff)  
- Leadership support for patient safety  
- Organizational learning  
- Overall perceptions of patient safety and quality                                                                                          | Spain                        | 4,344 primary care professionals (GPs, nurse, non-healthcare professionals, allied healthcare professionals) at 215 public health centres | 24                 |
| Bell et al.27           | Staff Survey: PC-SafeQuest   | 30-item questionnaire that measures staff perceptions of safety in primary care practices. Consists of five dimensions:  
- Workload  
- Communication  
- Leadership  
- Teamwork  
- Safety Systems                                                                                 | England                      | 335 staff members from 31 primary care practices in one Primary Care Research Network                  | 21                 |
| Bodur & Feliz37         | Staff Survey: Turkish version of modified Hospital Survey on Patient Safety Culture | 42 items that assess patient safety culture. Includes 12 subscales:  
- Manager expectations and actions promoting safety  
- Organizational learning  
- Teamwork within units  
- Communication openness  
- Feedback and communication about errors  
- Non-punitive response to errors  
- Staffing  
- Management support for patient safety  
- Teamwork within units  
- Communication openness  
- Feedback and communication about errors  
- Non-punitive response to errors  
- Staffing  
- Management support for patient safety  
- Teamwork within units  
- Communication openness  
- Feedback and communication about errors  
- Non-punitive response to errors  
- Staffing  
- Management support for patient safety  
- Teamwork within units  
- Communication openness  
- Feedback and communication about errors  
- Non-punitive response to errors  
- Staffing  
- Management support for patient safety                                                                                  | Turkey                       | 180 healthcare staff (54 GPs, 48 nurses, 51 midwives, and 27 health officers) at 12 primary healthcare services within metropolitan city | 22                 |
<table>
<thead>
<tr>
<th>Study</th>
<th>Method</th>
<th>Description</th>
<th>Country</th>
<th>Participant Details</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bondevik et al. (20)</td>
<td>Staff Survey: Norwegian version of Safety Attitudes Questionnaire-Ambulatory Version</td>
<td>Measures safety attitudes among healthcare professionals. Subscales include: - Teamwork climate - Safety climate - Job satisfaction - Perceptions of management - Working conditions</td>
<td>Norway</td>
<td>266 health providers (including 139 nurses and 124 doctors) at seven out-of-hours clinics and 17 general practices</td>
<td>26</td>
</tr>
<tr>
<td>Bondevik et al. (19)</td>
<td>Staff Survey: Norwegian version of Safety Attitudes Questionnaire-Ambulatory Version</td>
<td>62-item instrument that measures safety attitudes among healthcare professionals. Subscales include: - Teamwork climate - Safety climate - Job satisfaction - Perceptions of management - Working conditions - Stress recognition</td>
<td>Norway</td>
<td>266 health providers (including 139 nurses and 124 doctors) at seven out-of-hours clinics and 17 general practices</td>
<td>28</td>
</tr>
<tr>
<td>DeWet et al. (28)</td>
<td>Staff Survey: PC SafeQuest</td>
<td>48-item questionnaire that measures perceptions of safety climate among the primary care workforce.</td>
<td>Scotland</td>
<td>49 group general practices with 563 staff members (165 GPs, 43 practice managers, and 343 other employees)</td>
<td>37</td>
</tr>
<tr>
<td>DeWet et al. (29)</td>
<td>Staff Survey: PC SafeQuest</td>
<td>30-item questionnaire that measures perceptions of safety climate among the primary care workforce. Measures five dimensions: - Leadership - Teamwork - Communication - Workload - Safety systems</td>
<td>Scotland</td>
<td>49 group general practices with 563 staff members (165 GPs, 43 practice managers, and 343 other employees)</td>
<td>29</td>
</tr>
<tr>
<td>Elder et al. (13*)</td>
<td>Staff Interview</td>
<td>During the first phase of this study, physicians implemented an active monitoring system in order to identify errors made in patient care. For each error indicated, a research assistant interviewed the physician and asked them to describe what had happened and to make a judgement about whether any harm came to the patient or whether potential harm was possible.</td>
<td>USA</td>
<td>15 family physicians in seven offices</td>
<td>21</td>
</tr>
<tr>
<td>Study</td>
<td>Study Type</td>
<td>Methodology</td>
<td>Context</td>
<td>Participants</td>
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<tr>
<td>Gaal et al.</td>
<td>Staff Interview</td>
<td>Semi-structured interview explored perceptions of patient safety in primary care and solicited views on aspects of care that are associated with patient safety.</td>
<td>Holland</td>
<td>22 doctors and seven practice nurses across 29 practices</td>
<td>17</td>
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<tr>
<td>Gehring et al.</td>
<td>Staff Survey</td>
<td>Consisted of a list of 23 safety incidents derived from empirical studies. Incidents related to: - Diagnostic process - Medication - Other therapeutic and preventive measures Respondents asked to rate the frequency and severity of such incidents occurring in their office.</td>
<td>Switzerland</td>
<td>316 primary care physicians and 314 nurses working in outpatient offices</td>
<td>21</td>
</tr>
<tr>
<td>Gehring et al.</td>
<td>Staff Survey</td>
<td>Survey adapted from Safety Attitudes Questionnaire (Ambulatory version), PC SafeQuest, and the Frankfurt Patient Safety Climate Questionnaire. Survey consisted of 31 items relating to: - Teamwork - Stress recognition - Job satisfaction - Working conditions - Perception of management - Safety systems and climate</td>
<td>Switzerland</td>
<td>316 primary care physicians and 314 nurses working in outpatient offices</td>
<td>28</td>
</tr>
<tr>
<td>Gorman et al.</td>
<td>Staff Survey: Perceptions of safety and quality factors from the Medical Office Survey of Patient Safety Culture</td>
<td>Participants completed the overall ratings of quality (5 items) and overall ratings of safety (1 items). Participants were asked to rate the items from 1 (poor) to 5 (excellent).</td>
<td>USA</td>
<td>6,534 clinicians and staff in 306 ambulatory primary care practices from 11 practice based research networks in 16 states</td>
<td>26</td>
</tr>
<tr>
<td>Study</td>
<td>Survey Details</td>
<td>Country</td>
<td>Sample Size Description</td>
<td>Summary</td>
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<tr>
<td>Hedskold et al.38</td>
<td>Staff Survey: Swedish version of the Hospital Survey on Patient Safety Culture</td>
<td>Sweden</td>
<td>84,215 questionnaires from healthcare staff working in primary care centres (11%) and hospital departments</td>
<td>48-item survey that measures staff perceptions of patient safety culture in healthcare settings. Measures 14 dimensions of patient safety culture: Communication openness, Feedback and communication about error, Frequency of error reporting, Handoffs and transitions between units and shifts, Executive management support for patient safety, Nonpunitive response to error, Organizational learning-continuous improvement, Overall perceptions of safety, Staffing, Supervisor/manager expectations and actions promoting safety, Teamwork across units, Teamwork within the unit, Information and support to patients and family who have suffered an adverse event, Information and support to staff who have been involved in an adverse event. Three single item outcome questions were also included: Patient safety grade, Number of events reported, Number of risks reported.</td>
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<tr>
<td>Hoffmann et al.35</td>
<td>Staff Survey: Frankfurt Patient Safety Climate Questionnaire for General Practices</td>
<td>Germany</td>
<td>332 healthcare professionals (89 doctors, 220 healthcare assistants, 21 other, and 2 unknown) working in 60 general practices in the Rhine-Main region of Hesse.</td>
<td>72-item German-language questionnaire that assesses safety climate in general practice settings adapted from the Safety Attitudes Questionnaire-Ambulatory Version. Factor analysis revealed that the items grouped into nine factors: Teamwork climate, Error management, Safety of clinical processes, Perception of causes of errors, Job satisfaction, Safety of practice structure, Receptiveness to healthcare assistants and patients.</td>
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</tr>
</tbody>
</table>
| Hoffmann et al. | Staff Survey: Frankfurt Patient Safety Climate Questionnaire | 44-item German-language measure that assesses patient safety climate in primary care settings. It consists of nine dimensions:  
- Teamwork climate  
- Error management  
- Perception of causes of errors  
- Safety of clinical processes  
- Job satisfaction  
- Safety of practice structure  
- Receptiveness to health care assistants and patients  
- Staff perception of management (employees only)  
- Quality and safety of medical care (doctors only) | Germany | 2,111 health care professionals (1,480 health care assistants, 599 doctors, and 32 participants with unspecified professional group) from 618 practices | 27 |
| Hoffmann et al. | Staff interview: The Frankfurt Patient Safety Matrix | Structured team meetings were guided by an external facilitator using the Frankfurt Patient Safety Matrix which is an assessment of a practice’s patient safety grade. Patient safety grade is derived from practice performance across nine separate dimensions:  
- Overall commitment to quality  
- Priority given to patient safety  
- Perception of critical incidents and their causes  
- Analysis of critical incidents  
- Learning from critical incidents  
- Communication as it relates to patient safety  
- Personnel management as it relates to patient safety  
- Staff education and training as they relate to patient safety  
- Team work as it relates to patient safety | Germany | 28 practices in the intervention group were involved in three structured team meetings conducted using the Frankfurt Patient Safety Matrix | 30 |
A later stage in this study involved the administration of patient safety culture checklist within practices.

<table>
<thead>
<tr>
<th>Study</th>
<th>Methodology</th>
<th>Measurement Tool</th>
<th>Description</th>
<th>Country</th>
<th>Participants</th>
</tr>
</thead>
</table>
| Holden et al. | Staff Survey: Safety Attitudes Questionnaire-Ambulatory Version | 77-item measure that assesses both communication and collaboration between professional groups and safety attitudes. Staff perceptions of safety attitudes are measured across six dimensions:  
- Teamwork climate  
- Job satisfaction  
- Perceptions of management  
- Safety climate  
- Working conditions  
- Stress recognition | USA | 213 primary care staff from 4 U.S. Air Force ambulatory care facilities (38 physicians, 46 registered nurses, 103 technicians, 4 physician assistants, 12 nurse practitioners, and 10 pharmacists) |
| Hutchinson et al. | Staff Survey: Teamwork and Safety Climate Survey | 27-item measure consisting of two sections: Teamwork and Safety Climate. Analysis indicated that the teamwork section consisted of two factors:  
- Input into decisions and collaboration with other staff  
- Information handover  
The Safety Climate section was found to consist of three factors:  
- Attitudes to safety within own team; capacity to learn from errors  
- Overall confidence in safety of organization  
- Perceptions of management’s attitudes to safety | UK | 1,307 healthcare professionals from four acute hospital trusts and nine primary care trusts |
| Kirk et al. | Staff interviews and focus groups: Manchester Patient Safety Framework | Semi-structured interviews and focus groups to elicit participants’ insights and experiences of patient safety in primary care using a framework comprising nine dimensions of patient safety:  
- Overall commitment to quality  
- Priority given to patient safety  
- Perceptions of the causes of patient safety incidents and their identification  
- Investigating patient safety incidents  
- Organizational learning following a patient safety incident  
- Communication about safety issues  
- Personnel management and safety issues  
- Staff education and training about safety issues  
- Teamworking around safety incidents | UK | 63 or interviews and 14 focus groups were conducted with a variety of staff members (e.g., clinical governance managers, primary care trust chief executives, primary care trust managers, community nurses, general practitioners etc) from six primary care trusts |
<table>
<thead>
<tr>
<th>Study</th>
<th>Methodology</th>
<th>Findings/Comment</th>
</tr>
</thead>
</table>
| Manwell et al. 45 | Staff Focus Groups | As part of a larger study, three questions related to safety and quality were asked during focus groups:  
- How does the way that work is organized in your office influence the quality of care that you are able to provide to your patients?  
- Have you been involved in situations where medical errors, “oops,” and near misses, or adverse patient outcomes have occurred?  
- How could changes in the practice office environment prevent such situations from happening in the future?  
USA | 32 physicians (18 family physicians and 14 general internists) participated in nine focus were conducted across 5 regions | 16 |
| Martijn et al. 16* | Staff Survey: Questions from the Safety Attitudes Questionnaire-Ambulatory version | Retrospective chart audit conducted using clinical judgement and the World Health Organization’s definition of a patient safety incident “an unintended event during the care process that resulted, could have resulted or still might result in harm to the patient” to identify previously undetected mistakes or adverse events.  
Another phase in this study involved the completion of a retrospective patient chart audit.  
The Netherlands | 4000 patient records from 20 primary care practice (general practice, general dental practices, midwifery practices, and allied health care practices) | 17 |
| McGuire et al. 22 | Staff Survey: Modified Safety Attitudes Questionnaire | 29-item version of the Safety Attitudes Questionnaire that assessed employees’ perceptions of safety in their practice. Included five dimensions:  
- Job satisfaction  
- Perceptions of executive management  
- Perceptions of local management  
- Safety Climate  
- Stress Recognition  
- Teamwork climate  
- Working conditions  
A practice-specific needs assessment survey was also completed by staff. This survey assessed actionable issues specific to each practice at a level more detailed than the questionnaire. Participants were asked to describe the most important safety issue(s) affecting their practice.  
USA | 17-18 primary care practices from one large medical group practice. Staff members participated across three assessment timepoints (103, 123, and 143 participants) | 17 |
| Schutz et al. 46 | Staff Survey: Survey on Patient Safety in | 21-item measure for assessing patient safety in ambulatory care settings. Areas assessed were:  
- Teamwork  
- Leadership  
USA | An expert panel comprised of six medical practice managers with | 21 |
<table>
<thead>
<tr>
<th>Ambulatory Care Organizations</th>
<th>Communication - Tendency to report errors</th>
<th>expertise in patient safety reviewed the instrument</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schwappach et al.(^47)</td>
<td>Staff survey</td>
<td>Switzerland 219 physicians and 172 nurses working at primary care offices in Switzerland</td>
</tr>
<tr>
<td>Singer et al.(^48)</td>
<td>Staff Survey</td>
<td>USA 482 members of staff (doctors, physician assistants, nurse practitioners, nurses, other clinicians, managers and administrators) from 25 small to medium sized primary care practices</td>
</tr>
<tr>
<td>Singh et al.(^39)</td>
<td>Staff Survey: Perceived Hazard Questionnaire</td>
<td>USA Staff from one academic rural primary care practice with 32 staff members took part in this study</td>
</tr>
<tr>
<td>Singh et al.(^40)</td>
<td>Staff survey</td>
<td>USA 45 staff members including</td>
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<tr>
<td>Study</td>
<td>Methodology</td>
<td>Description</td>
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<tr>
<td>Failure Modes and Effects Analysis (FMEA) Survey based on a perceived hazard questionnaire</td>
<td>The purpose of the survey was to help individual practices identify the greatest threat, or hazard, to the safety of their patients.</td>
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<tr>
<td>Skalkidis et al.24</td>
<td>Staff interview: Manchester Patient Safety Framework</td>
<td>The Manchester Patient Safety Framework was used to identify key patient safety issues within individual practices.</td>
</tr>
<tr>
<td>Travaglia et al.49</td>
<td>Staff Interviews</td>
<td>Interviews sought demographic information from participants along with information on participants’ perspectives of the quality and safety of the practices that they worked in. The current study focused on participants’ responses to the standard of care within their practice. While responding to the questionnaire, participants were asked to consider the approach taken to quality and safety and how responsibility for standards and quality enacted.</td>
</tr>
<tr>
<td>Verbakel et al.30</td>
<td>Staff Survey: SCOPE-PC Questionnaire</td>
<td>The SCOPE-PC is a modified form of the Dutch Hospital Survey on Patient Safety. The final form of the questionnaire in this study consisted of 41 items that measure patient safety in primary care settings. Items relate to: - Open communication and learning from error - Handover and teamwork - Adequate procedures and working conditions - Patient safety management - Support and fellowship - Intention to report events - Organisational learning - The discussion of errors that occurred with other disciplines.</td>
</tr>
<tr>
<td>Verbakel et al.25</td>
<td>Staff survey: SCOPE Questionnaire</td>
<td>The SCOPE questionnaire measures patient safety culture in primary care settings.</td>
</tr>
</tbody>
</table>
### Staff workshop: Dutch translation of the Manchester Patient Safety Framework

In-practice workshops are facilitated by an external GP and the discussion on patient safety is guided by the Manchester Patient Safety Framework.

### Wallis & Dovey<sup>26</sup>

**Staff workshop:** Modified version of The Manchester Patient Safety Framework

The Manchester Patient Safety Framework assesses nine dimensions of patient safety:
- Overall commitment to quality
- Priority given to patient safety
- Perceptions of the causes of patient safety incidents and their identification
- Investigating patient safety incidents
- Team learning following a patient safety incident
- Communication about safety issues
- Staff management and safety issues
- Staff education and training about safety issues
- Team working around safety issues

**New Zealand**

All practice personnel present on the day of the workshop at 12 general practices took part

### Zwart et al.<sup>31</sup>

**Staff Survey:** SCOPE

Questions for the instrument were derived from the Dutch translation of the Hospital Survey on Patient Safety Culture in order to develop a safety culture instrument suitable for use in general practice settings. The resulting instrument consisted of 46 questions about patient safety culture. Two additional items related to the frequency of adverse event reports in the past year and patient safety grade.

**The Netherlands**

294 staff members (GPs, medical-administrative assistant, or practice nurse) from 72 practices completed the questionnaire

**Note.** * studies accompanied by an asterisk used more than one means of measuring patient safety and are included in more than one category for this reason. GP = general practitioner.
<table>
<thead>
<tr>
<th>Study</th>
<th>Tool Name (if any)</th>
<th>Detailed Tool Description (inc safety elements addressed and tool outcomes)</th>
<th>Country</th>
<th>Clinical Setting and number of Applications</th>
<th>Study Quality Score</th>
</tr>
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<tbody>
<tr>
<td>Bowie et al.</td>
<td>Trigger Review</td>
<td>Trigger tool allows for a structured review of electronic patient records in</td>
<td>Scotland</td>
<td>Nine exemplar undetected patient safety incidents from chart audits conducted at “around” 40 Scottish</td>
<td>10</td>
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<td>order to identify any undetected patient safety incidents.</td>
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<td>general practices</td>
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<td>DeWet &amp;</td>
<td>Trigger Review</td>
<td>Trigger tool allows for a structured review of electronic patient records in</td>
<td>Scotland</td>
<td>500 clinical records identified by five GPs and two practice nurses at five urban general practices</td>
<td>24</td>
</tr>
<tr>
<td>Bowie</td>
<td></td>
<td>order to identify any undetected patient safety incidents.</td>
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<tr>
<td>Eggleton &amp;</td>
<td></td>
<td>Trigger tool consisting of 36 triggers intended to facilitate the review of</td>
<td>New Zealand</td>
<td>170 patient records from one large general practice (~12,000 patients) with a catchment that included rural</td>
<td>22</td>
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<tr>
<td>Dovey</td>
<td></td>
<td>patient records in order to identify any instances of undetected patient harm.</td>
<td></td>
<td>and urban areas</td>
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<td>Gaal et al.</td>
<td></td>
<td>Retrospective medical record review. Records reviewed by 2-3 physicians</td>
<td>Netherlands</td>
<td>1,000 patient records from 20 general practices</td>
<td>19</td>
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<td>and clinical judgement used to identify patient safety incidents.</td>
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<td>Khoo et al.</td>
<td></td>
<td>Reviewers used operational definitions of errors to assess patient records for</td>
<td>Malaysia</td>
<td>1,753 medical records from 12 primary care clinics</td>
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<td>the presence of diagnostic errors, management errors, and documentation</td>
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<td>errors. The potential for harm from, and preventability of, errors identified</td>
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<td>were also rated.</td>
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<tr>
<td>Khoo et al.</td>
<td></td>
<td>Reviewers used operational definitions of errors to assess patient records for</td>
<td>Malaysia</td>
<td>3,546 medical records from 12 primary care clinics</td>
<td>19</td>
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<td></td>
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<td>the presence of diagnostic errors, management errors, and documentation</td>
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<td>errors. The potential for harm from, and preventability of, errors identified</td>
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<td>were also rated.</td>
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<tr>
<td>Martijn et</td>
<td></td>
<td>Retrospective chart audit conducted using clinical judgement and the World</td>
<td>Netherlands</td>
<td>4,000 patient records from 20 primary care practice (general practice, general dental practices, midwifery</td>
<td>17</td>
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<td>al.</td>
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<td>Health Organization’s definition of a patient safety incident, “an unintended</td>
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<td>practices, and allied health care practices)</td>
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<td>event during the care process that resulted, could have resulted or still</td>
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<td>might result in harm to the patient”, to identify previously undetected</td>
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<td>mistakes or adverse events.</td>
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<tr>
<td>McKay et al.</td>
<td>Trigger Review</td>
<td>Trigger tool allows for a structured review of electronic patient records in</td>
<td>Scotland</td>
<td>21 GP trainees each applied the TRM. A total of 520 records were reviewed</td>
<td>22</td>
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<tr>
<td></td>
<td>Method</td>
<td>order to identify any undetected patient safety incidents.</td>
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<tr>
<td>Montserrat-Capella</td>
<td>-</td>
<td>During the initial phase of this study, patients were asked to report any health issues they had experienced within the past 6 months in order to identify potential adverse events. Data from patient interviews were used to guide patient chart audits that were conducted to identify whether adverse events had occurred.</td>
<td>4 South American Countries (Mexico, Peru, Brazil, and Colombia)</td>
<td>180 safety incidents were reported and investigated within 116 adverse events affecting 108 patients identified</td>
<td>22</td>
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<tr>
<td>Sears et al.</td>
<td>-</td>
<td>Trained nurse reviewers completed retrospective audits of patient charts using 23 specific screening criteria in order to identify undetected adverse events. Physician reviewers then reviewed charts where one or more of the screening criteria had been identified as presented by the nurse reviewer. Physicians then determined using specific criteria whether or not an adverse event had occurred. Physicians provided information on the source of the adverse event and its preventability.</td>
<td>Canada</td>
<td>430 patient charts from three publicly-funded home care programs</td>
<td>30</td>
</tr>
<tr>
<td>Smits et al.</td>
<td>-</td>
<td>Patient records reviewed using a form developed for this study specifically. Reviewers recorded information on basic patient variables (i.e., age, gender, risk factors), variables concerning contact with the GP cooperative (e.g., time, degree of urgency, diagnosis), and follow-up contacts (with all possible healthcare settings). Reviewer was required to use a variety of sources (e.g., medical records, diagnostic test results, letters from specialists) to determine if the record showed a potential for unsafe care to have occurred. Where this was deemed to be possible, the record was reviewed by a panel to determine if a patient safety incident had occurred and to categorise the type, cause, and consequences of the incident.</td>
<td>Netherlands</td>
<td>1,145 patient medical records from four general practice cooperatives</td>
<td>21</td>
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<tr>
<td>Solberg et al.</td>
<td>-</td>
<td>During the initial phase of this study, patients were asked to report an errors that had occurred in their care. Patient-reported errors were reviewed by the practice nurse who determined the category of the complaint (e.g., medical error, nonmedical error, behavior/communication, misunderstanding, inadequate information, unable to determine) and whether it constituted a medical error that warranted review of the patient’s charts. The patient’s submission and the nurse’s review were sent to two doctors who reviewed the materials and consulted the patients’ records to determine if an error had been made in their care. In cases in which a patient had reported harm, a doctor estimated the likelihood and severity of harm. Possible or probable medical error cases identified by doctors were reviewed by the department’s chair who decided whether or not the case should undergo formal committee peer review.</td>
<td>USA</td>
<td>247 error reports were received and the corresponding patient charts were reviewed</td>
<td>18</td>
</tr>
</tbody>
</table>
Two independent researchers reviewed randomly selected medical records and used clinical judgement to determine whether they contained an adverse event. Any adverse events identified were categorized by type (e.g., errors in office administration, errors in diagnosis, errors in treatment, errors in communication).

Another independent stage in this study involved asking patients to report on any errors that had occurred in their care.

Two independent researchers reviewed the medical records and used clinical judgement to determine whether they contained an adverse event. Any adverse events identified were categorized by type (e.g., errors in office administration, errors in diagnosis, errors in treatment, errors in communication) and researchers determined the actual consequence of the error for that patient. Potential harm likeliness was also indicated.

Note: * studies accompanied by an asterisk used more than one means of measuring patient safety and are included in more than one category for this reason. GP=general practitioners.
Table 3. Summary of studies utilising practice assessment checklists to measure levels of patient safety.

<table>
<thead>
<tr>
<th>Study</th>
<th>Tool Name (if any)</th>
<th>Detailed Tool Description (inc safety elements addressed and tool outcomes)</th>
<th>Country</th>
<th>Clinical Setting and number of Applications</th>
<th>Study Quality Score</th>
</tr>
</thead>
</table>
| Alhassan et al. | SafeCare Essentials | Assesses patient safety and risk status. 41 items across five risk areas:  
- Leadership and accountability  
- Competent and Capable workforce  
- Safe environment for staff and patients  
- Clinical care of patients  
- Improvement of quality and safety | Ghana | 64 accredited primary healthcare clinics and health centres | 26 |
| Bowie et al. | Preliminary Safety Checklist for General Practice | 78-item prototype checklist based on human factors principles that assesses system-wide safety hazards and risks in general practice. Safety domains assessed include:  
- Medication management  
- Housekeeping  
- Information systems  
- Practice team  
- Patient access and identification  
- Health and safety | Scotland | 18 general practice clinicians and managers implemented the checklist within their general practice (10 managers, 5 nurses, and 3 GPs) | 27 |
| Hoffmann et al. | - | This study employed staff interviews and staff surveys during an initial phase  
A 12-item patient safety culture indicator checklist was administered via an interview and assessed:  
- Quality measures  
- Basic life support training  
- Emergency medication  
- Critical incidents  
- Error management  
- Complaints management  
- Documentation of allergies  
- Monitoring repeated prescriptions  
- Repeat prescribing  
- Oral anticoagulants  
- Laboratory tests  
- Flu vaccinations | Germany | 60 general practices took part in this research study | 30 |
| Marsteller et al. | - | A three-hour site visit included the review of practice operations and clinical records, and 21 | USA | 34 small internal | 14 |
measures of safety were assessed by two researchers:
- Good hand-washing techniques
- Two identifiers used routinely in patient care documentation
- Staff are trained and assessed on equipment and procedures
- Quality control processes performed
- Sample medications managed appropriately
- Sharps are secured
- Sharp boxes are mounted, locked with safety covers
- Hazardous waste receptacles are clearly labelled
- Hazardous waste materials stored appropriately
- Medications and vaccines stored properly
- A temperature log is maintained for refrigerators
- Refrigerators appropriately labelled
- Clean supplies are stored appropriately
- Cleaning and sterilization processes are appropriate
- Fire extinguishers are present
- Had a record of fire extinguisher inspection
- Vaccine information documented
- Vaccine information sheets provided
- Sample medication log used
- Labels for sample medication used
- Storage of medication appropriate

This tool acquires information on the practice and level of information technology adoption. It also contains items that assess:
- Medications management
- Handoffs and transitions
- Personnel/qualifications/competency
- Practice management/culture
- Patient Education/Communication

A sixth domain (surgery/anaesthesia and sedation/invasive procedures) is included in the tool but not relevant to primary care so was not administered in the current study. The practice assessment tool is designed for clinical use and independent completion collectively by providers, key managerial, and other staff. In the current study, the process was facilitated by an external interviewer.
This best practice for patient safety toolkit included 11 tools intended to aid practices in improving patient safety. These tools were:
- Maintaining accurate and complete medication list
- Ensuring medication allergy documentation
- Standardising prescription writing
- Removing all IV potassium chloride from all locations
- Emphasizing non-punitive error reporting
- Educating about look-alike, sound-alike drugs
- Improving verbal orders
- Ensuring safety and security of sample drugs
- Following protocols for hazardous drug use
- Partnering with patients
- Notifying patients of laboratory results.

Each tool was accompanied by an explanation of its rationale and importance in patient safety, a description of how progress in the area could be assessed and improved, criteria indicative of accomplishment in this area, and suggestions for re-assessment of performance in this area.

<table>
<thead>
<tr>
<th>Study</th>
<th>Ambulatory Patient Safety Toolkit</th>
<th>Tools and Specific Conditions</th>
<th>Country</th>
<th>Setting/Number</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schauberg &amp; Larson61</td>
<td></td>
<td></td>
<td>USA</td>
<td>Seven regional primary care clinics, comprising more than 500 physicians, participated</td>
<td>10</td>
</tr>
<tr>
<td>Stern et al.60</td>
<td></td>
<td></td>
<td>USA</td>
<td>30 experts in correctional health care</td>
<td>16</td>
</tr>
</tbody>
</table>

Note. * studies accompanied by an asterisk used more than one means of measuring patient safety and are included in more than one category for this reason. GP = general practitioner.
Table 4. Summary of studies utilising patient-centric measures of patient safety.

<table>
<thead>
<tr>
<th>Study</th>
<th>Tool Format</th>
<th>Detailed Tool Description (inc safety elements addressed and tool outcomes)</th>
<th>Country</th>
<th>Clinical Setting and number of Applications</th>
<th>Study Quality Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Montserrat-Capella(^*)</td>
<td>Patient Interview -</td>
<td>During the initial phase of this study, patients were asked to report any health issues they had experienced within the past 6 months in order to identify potential adverse events. During the following phase, data from patient interviews were used to guide patient chart audits that were conducted to identify whether adverse events had occurred.</td>
<td>4 South American Countries (Mexico, Peru, Brazil, and Colombia)</td>
<td>2,080 patients (1,071 in ambulatory care and 1,009 in primary care centres) from 22 sites</td>
<td>22</td>
</tr>
<tr>
<td>Solberg et al.(^*)</td>
<td>Patient Survey -</td>
<td>Patients completed a two-page questionnaire with eight questions concerned with whether they had received a wrong diagnosis, a wrong treatment, a wrong prescription, a wrong procedure, or had experienced any other form of error. Patients who reported errors were asked to provide specific feedback on what had happened, when this it happened, and if the error had caused them harm. Patient-reported errors were then further investigated using retrospective patient chart audits.</td>
<td>USA</td>
<td>1,998 patients completed the survey.</td>
<td>18</td>
</tr>
<tr>
<td>Wetzels et al.(^*)</td>
<td>Patient Survey -</td>
<td>Patients were invited to complete a survey that asked for information on any experienced problems with safety of their health care in the previous six months. In another independent phase of this study, doctors conducted patient chart audits using randomly selected medical records.s</td>
<td>The Netherlands</td>
<td>91 patients attending five different GPs at two different practices participated.</td>
<td>14</td>
</tr>
</tbody>
</table>

* studies accompanied by an asterisk used more than one means of measuring patient safety and are included in more than one category for this reason. GPs=general practitioner.
Table 5. Summary of studies employing active monitoring systems as a means of assessing patient safety.

<table>
<thead>
<tr>
<th>Study</th>
<th>Tool Name (if any)</th>
<th>Detailed Tool Description (inc safety elements addressed and tool outcomes)</th>
<th>Country</th>
<th>Clinical Setting and number of Applications</th>
<th>Study Quality Score</th>
</tr>
</thead>
</table>
| Aranaz-Andrés et al.\(^{62}\) | Adapted University of Washington Safety Questionnaire | Spanish adaptation of the University of Washington Safety Questionnaire. Primary care professional completed form immediately after each consultation and reported:  
- Condition that may indicate adverse event  
- Incidents which did no harm  
- Disease complications or problems related to the patient themselves  
- Causality  
- Preventability  
- Impact  | Spain   | 1,932 patient consultations in 48 primary care health centres conducted by 452 primary care professionals (249 GPs, 152 nurses, and 40 paediatricians)                                      | 21      |
| Elder et al.\(^{13}\) | - | A one-page form was attached to each patient chart and the physician completed the form immediately after leaving the examination room. The form required the physician to reflect upon diagnosis, management and treatment, physicians and staff, charting, administration, investigations and flow, and to determine whether any problems or errors had been made during the patient consultation.  
A later stage in this study involved the physician being interviewed about the errors identified. | USA     | 15 family physicians in seven offices completed forms for 351 patient visits                                                                                                                         | 21      |

* studies accompanied by an asterisk used more than one means of measuring patient safety and are included in more than one category for this reason. GP= general practitioner.
Table 6. Summary of studies utilising simulated patients to assess patient safety.

<table>
<thead>
<tr>
<th>Study</th>
<th>Detailed Tool Description (inc safety elements addressed and tool outcomes)</th>
<th>Country</th>
<th>Clinical Setting and number of Applications</th>
<th>Study Quality Score</th>
</tr>
</thead>
</table>
| Moriarty et al.\textsuperscript{63} | Simulated patient phonecalls were used to evaluate the clinical safety of a telephone triage service. Four cases were used:  
- A male patient with a past history of rheumatic fever calling about a sore throat  
- A female patient with venous thromboembolism risk factors calling about chest pain  
- A young woman with sexually transmitted disease risk calling about genitourinary symptoms  
- A female caregiver calling about a systemically unwell child  

Performance was evaluated based on the nature of the greeting received, the overall impression of the consultation, and some case-specific details of triage questioning.                                                                                                      | New Zealand              | 85 simulated calls made to primary care nurses                                                            | 12                  |
| Weiner et al.\textsuperscript{64} | Simulated patients were used to present four scenarios that were designed to assess physicians’ abilities to detect hints of contextual and biomedical complicating factors that needed to be considered or discussed in order to form an appropriate, error-free treatment plan.                                                                                                           | USA                      | 96 physicians from 14 primary care internal medicine practices                                            | 27                  |