

## Patient safety in primary health care: a systematic review

Segurança do paciente na atenção primária à  
saúde: revisão sistemática

La seguridad del paciente en la atención primaria:  
una revisión sistemática

Simone Grativol Marchon <sup>1</sup>  
Walter Vieira Mendes Junior <sup>1</sup>

<sup>1</sup> Escola Nacional de Saúde  
Pública Sergio Arouca,  
Fundação Oswaldo Cruz,  
Rio de Janeiro, Brasil.

**Correspondence**  
S. G. Marchon  
Departamento de  
Administração e  
Planejamento em Saúde,  
Escola Nacional de Saúde  
Pública Sergio Arouca,  
Fundação Oswaldo Cruz,  
Rua Senador Pompeu 208,  
Araruama, RJ 28970-000,  
Brasil.  
simonemarchon@gmail.com

### Abstract

*The aim of this study was to identify methodologies to evaluate incidents in primary health care, types of incidents, contributing factors, and solutions to make primary care safer. A systematic literature review was performed in the following databases: PubMed, Scopus, LILACS, SciELO, and Capes, from 2007 to 2012, in Portuguese, English, and Spanish. Thirty-three articles were selected: 26% on retrospective studies, 44% on prospective studies, including focus groups, questionnaires, and interviews, and 30% on cross-sectional studies. The most frequently used method was incident analysis from incident reporting systems (45%). The most frequent types of incidents in primary care were related to medication and diagnosis. The most relevant contributing factors were communication failures among member of the healthcare team. Research methods on patient safety in primary care are adequate and replicable, and they will likely be used more widely, thereby providing better knowledge on safety in this setting.*

*Patient Safety; Primary Health Care; Quality of Health Care*

### Resumo

*O objetivo deste artigo foi identificar metodologias utilizadas para avaliação de incidentes na atenção primária à saúde, os tipos, seus fatores contribuintes e as soluções para tornar a atenção primária à saúde mais segura. Foi realizada uma revisão sistemática da literatura nas bases de dados bibliográficas: PubMed, Scopus, LILACS, SciELO e Capes, de 2007 até 2012, nos idiomas português, inglês e espanhol. Foram selecionados 33 artigos: 26% relativos a estudos retrospectivos; 44% a estudos prospectivos, incluindo grupo focal, questionários e entrevistas; 30% a estudos transversais. O método mais utilizado nos estudos foi análise dos incidentes em sistemas de notificações de incidentes (45%). Os tipos de incidentes mais encontrados na atenção primária à saúde estavam associados à medicação e diagnóstico. Os fatores contribuintes mais relevante foram falhas de comunicação entre os membros da equipe de saúde. Métodos de investigação empregados nas pesquisas de segurança do paciente na atenção primária à saúde são adequados e replicáveis, é provável que estes se tornem mais amplamente utilizados, propiciando mais conhecimento sobre a segurança na atenção primária à saúde.*

*Segurança do Paciente; Atenção Primária à Saúde; Qualidade do Cuidado*

## Introduction

The report by the U.S. Institute of Medicine entitled *To Err is Human: Building a Safer Health System*<sup>1</sup> defined patient safety as a central issue on the agendas of many countries. The publication was a milestone for patient safety and issued an alert against errors in health care and harm to patients.

Concern with patient safety led the World Health Organization (WHO) to create the program called The World Alliance for Patient Safety in 2004<sup>2</sup>, aimed at developing global policies to improve patient care in health services. The program's initiatives featured the attempt to define issues involved in patient safety. The International Classification for Patient Safety was developed, in which incident is defined as any event or circumstance that could have resulted or did result in unnecessary harm to the patient<sup>2</sup>.

The current study defines adverse event as an incident that results in harm to the patient<sup>3</sup>, while contributing factors are circumstances, actions, or influences that are believed to have played a role in the origin or development of an incident, or that increase the risk of an incident occurring<sup>3</sup>. As defined in this study, incident types involve the origin: due to medication; lack, delay, or error in diagnosis; or treatment or procedure not related to medication<sup>4</sup>. In 2006, the European Committee on Patient Safety acknowledged the need to consider patient safety as a dimension of health quality at all levels of care, from health promotion to treatment of the disease<sup>5</sup>.

Although most care is provided at the primary level, research on patient safety has focused on hospitals. Hospital care is more complex, and the hospital setting thus naturally provides the main focus of such research.

In 2012, the WHO established a group to study the issues involved in safety in primary care<sup>5</sup>, the aim of which is to expand knowledge on risks to patients in primary care and the magnitude and nature of adverse events due to unsafe practices.

Various methods have been adopted to evaluate errors and adverse events. Each method's weaknesses and strengths are discussed in order to choose the most appropriate one for intended measurement. However, such methods are used for research in hospitals. A systematic review from 1966 to 2007 showed that the study of patient safety in primary care was just beginning<sup>6</sup>. Most adverse events in hospitals are associated with surgery and medication, while the most frequent adverse events in primary care are associated with medication and diagnosis<sup>7</sup>. Most hospital studies use retrospective review of pa-

tient files<sup>7</sup>, while the most widely used method in studies on primary care is the analysis of incident reporting by health professionals or patients<sup>6</sup>. In studies conducted in hospitals, the mean number of adverse events per 100 inpatients was 9.2, and the mean proportion of avoidable adverse events was 43.5%<sup>7</sup>. Estimates of incidents in primary care vary greatly, from 0.004 to 240.0 per 1,000 consultations, and estimates of avoidable errors vary from 45% to 76%, depending on the method used in the study<sup>6</sup>.

The objectives of this study were to identify the methodologies used to evaluate incidents in primary care, types, severity, contributing factors, and solutions to make primary care safer.

## Methodology

A literature review was conducted to achieve the objectives. The following databases were consulted: MEDLINE (via PubMed), Embase, Scopus, LILACS, SciELO, and the thesis database of the Federal Agency for Support and Evaluation of Graduate Education (Capes), from 2007 to November 2012. The search strategy was the same for all the databases (MEDLINE, Embase, Scopus, LILACS, SciELO, and Capes). The key words for searches were in Portuguese, English, and Spanish, as shown in Table 1.

The starting point for the review was set at 2007 due to the existence of another systematic review<sup>6</sup> that had used a similar search strategy in the MEDLINE, CINAHL, and Embase databases from 1966 to 2007.

Article selection followed the following inclusion criteria: (i) articles related to patient safety in primary care and (ii) articles in Portuguese, English, and Spanish. The following studies were excluded: (i) in the format of letters, editorials, news, professional commentaries, case studies, and reviews; (ii) without available abstracts; (iii) focusing on a specific process of care at the primary level; (iv) on hospital incidents; (v) on a specific type of disease or incident; or (vi) published in languages other than Portuguese, English, or Spanish.

The two authors independently performed an initial search for article titles; articles not excluded in the first stage proceeded to independent evaluation of the abstracts, after excluding duplicate articles and those without available abstracts; and the articles not excluded were read by independent reviewers. After independent reading of the full texts, the articles were finally selected. Data were extracted based on information about the author, title, and year of publication and the study characteristics, such as objectives,

Table 1

Search strategy in electronic databases.

Strategy	Key words
#1	Family practice OR primary care OR primary health care OR general practice [English] Cuidados primários OR cuidados primários de saúde OR atenção primária OR médico de família OR clínico geral [Portuguese] La atención primaria OR de atención primaria OR médico de familia OR médico general [Spanish]
#2	Medical error OR medication error OR diagnostic error OR iatrogenic disease OR malpractice OR safety culture OR near failure OR near miss OR patient safety method OR patient safety indicator OR patient safety measure OR patient safety report OR safety event report [English] Erro médico OR erro de medicamentos OR erro de diagnóstico OR doença iatrogênica OR imperícia OR cultura de segurança OR método segurança do paciente OR indicador segurança do paciente OR medida de segurança do paciente OR relatório de segurança do paciente OR relatório de eventos de segurança [Portuguese] El error médico OR error de medicamento OR error de diagnóstico OR de enfermedad iatrogénica OR negligencia OR de la cultura de seguridad OR cerca de fracaso OR método de seguridad del paciente OR el indicador de la seguridad del paciente OR medida de seguridad de los pacientes OR el informe de seguridad del paciente OR el informe de eventos de seguridad [Spanish]
#3	#1 AND #2

methods, findings, limitations as described, and relevant observations.

The quality of the selected studies was evaluated using the tool Strengthening the Reporting of Observational Studies in Epidemiology (STROBE), adapted to Portuguese, which has a 22-item checklist called the *STROBE Statement*<sup>8</sup>.

## Results

The initial database search took place from May to November 2012 and identified 1,956 relevant article titles for the review. Figure 1 shows the flowchart for the study selection.

The selected studies were all from developed countries, including 14 in the United States (41%), five in the United Kingdom (16%), five in New Zealand (16%), three in the Netherlands (9%), two in Spain (6%), and one each in Scotland (3%), Australia (3%), Canada (3%), and Europe (3%) (Table 2).

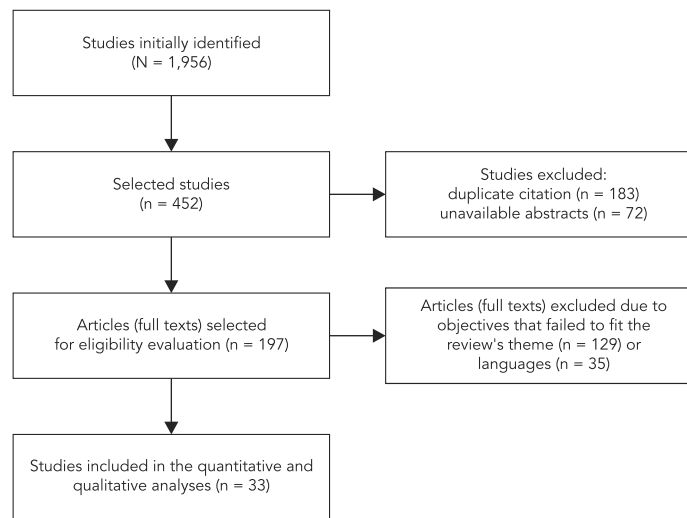
There was a balance in the yearly distribution of the articles' publication: four in 2007<sup>9,10,11,12</sup>, six in 2008<sup>13,14,15,16,17,18</sup>, three in 2009<sup>19,20,21</sup>, ten in 2010<sup>22,23,24,25,26,27,28,29,30,31</sup>, six in 2011<sup>32,33,34,35,36,37</sup> and four in 2012<sup>38,39,40,41</sup> (Table 2).

As for design, 32 studies were observational and only one experimental<sup>25</sup>. All the studies were descriptive. Nine studies were retrospective<sup>9,13,14,15,18,19,32,37,38</sup>, 14 prospective<sup>10,16,20,22,23,24,25,26,27,28,33,34,39,40</sup>, and ten cross-sectional<sup>11,12,17,21,29,30,31,35,36,41</sup>.

Various data sources were used. Some studies used administrative data from incident reporting systems fed by health professionals<sup>9,13,14,15,18,19,37,38</sup> or by health professionals and patients and family members<sup>32</sup>. Data were also obtained from focus groups with physicians and other health professionals<sup>23</sup>, or with health professionals and patients and family members<sup>20</sup>. Some studies used interviews to obtain data, either with physicians<sup>25,33,39</sup> or with physicians and other health professionals<sup>24</sup>. Questionnaires were also used by some authors to extract data, and were answered by physicians<sup>22,40</sup>, physicians and other health professionals<sup>10,16,28,34</sup>, or patients and family members<sup>26,27</sup>. Other studies used a combination of methods for data sources: incident reporting systems, direct observation, and focus groups<sup>35</sup>; incident reporting systems, direct observation, and interviews<sup>11</sup>; direct observation with audio recording<sup>29</sup>; direct observation and expert consensus<sup>36</sup>; incident reporting systems, patient file review, and interviews<sup>41</sup>; incident reporting systems and patient file review<sup>21</sup>; incident reporting systems, interviews, and questionnaires<sup>30</sup>; expert consensus, questionnaires for patients, and focus groups<sup>31</sup>; incident reporting systems, patient file review, and questionnaires<sup>41</sup> (Table 2). Six studies<sup>12,17,21,30,31,41</sup> used a combination of data sources. Reporting system were the most frequent data source: 15 studies (45%)<sup>9,11,12,13,14,15,18,19,21,30,32,35,37,38,41</sup>.

Figura 1

Study selection flowchart.



The definition of adverse events differed, while the great majority of studies did not present a definition for these events. Four studies <sup>26,31,38,39</sup> defined adverse event related to the existence of harm to the patient caused by care. In four other studies <sup>15,17,21,37</sup> adverse event did not necessarily express harm to the patient as a result of care. In two studies <sup>16,33</sup>, patient safety culture was defined similarly as individual and/or group values, attitudes, perceptions, and behavioral patterns that led to a safety management team or organizational commitment (Table 2).

The study population consisted of physicians and other health professionals <sup>9,10,13,14,15,16,19,20,22,24,25,28,30,32,33,34,35,36,39,40</sup>, patients and families <sup>26</sup>, and health professionals and patients and families <sup>11,21,23,27,29,31,41</sup>, while in some studies the study population was not described in complete detail <sup>17,22,38</sup> (Table 2).

Contributing factors for incidents reported in the various studies included: failures in communication between professionals and with the patient; administrative failures: lack of medical and surgical supplies and medicines, professionals pressured to be more productive in less time, flaws in patient files, flaws in patient reception, inadequate floor plan or infrastructure in the health service, inadequate waste disposal by the health service, overworked staff, and failures in care. There were various forms of failures in care:

failures in drug treatment (mainly prescription errors); diagnostic failure; delay in performing diagnosis; delay in obtaining information and interpreting laboratory findings; failure to recognize the urgency of the disease or its complications; deficient professional knowledge.

To better present the findings, the studies were organized in three groups according to the objective. Eight studies <sup>13,14,15,17,21,27,32,34</sup> aimed to identify the types and severity of incidents in primary care and their contributing factors; 19 studies <sup>9,11,16,18,19,20,22,23,24,25,26,29,30,33,35,37,39,40</sup> aimed to indicate solutions to make primary care safer for the patient; and six studies <sup>12,28,31,36,38,41</sup> aimed to evaluate the tools for improving patient safety in primary care.

#### **Studies with the objective of identifying the types and severity of adverse events in primary care and their contributing factors**

Eight studies <sup>13,14,15,17,21,27,32,34</sup> evaluated the types and severity of adverse events in primary care and their contributing factors (Table 3). Only two <sup>27,32</sup> defined the adverse event by relating it to the harm caused by the patient's care. Four studies <sup>14,15,21,34</sup> did not relate the adverse event to the harm, but presented the incident's impact and/or severity in the patient. These four studies did not distinguish between incidents that did not

Table 2

Characteristics of the selected studies.

Reference (year)	Local	Study design/ Data source/ Study population	Relevant definitions	Study results and relevant conclusions by authors	Items not fully covered by the STROBE instrument
Wallis & Dovey <sup>32</sup> (2011)	New Zealand	Retrospective, descriptive observational study; analysis of data systems for incident reporting by physicians, family members, and patients	There were no relevant definitions for the study	83% of reports showed less serious harms and 12% showed more serious harms. Medication was the type of care with greatest risk to the patient	Study limitations; interpretation of findings
McKay et al. <sup>19</sup> (2009)	United Kingdom	Retrospective, descriptive observational study; analysis of data from systems for incident reporting by GPs	The study used the term error resulting from care with or without harm to the patient	32.5% of reports involved diagnostic errors (most frequent), 25.1% with harm to the patient. 80.1% of the AE reports suggested measures to improve clinical practice, e.g.: dissemination of protocols for safe practices; training health teams; programs to improve physician/patient communication	None
Gaal et al. <sup>22</sup> (2010)	Europe	Retrospective, descriptive observational study; questionnaire applied in 10 European countries	There were no relevant definitions for the study	Analyzed 10 dimensions of patient safety, where medication and safety in physical infrastructure showed the strongest association with patient safety	Financing
Parnes et al. <sup>9</sup> (2007)	United States	Retrospective, descriptive observational study; analysis of data from systems for incident reporting by physicians and staff	The study used the term medication error with or without harm to the patient	Of the 754 reported events, in 60 there was an interruption in the error cascade before reaching patients in primary care. In one participant it was possible to interrupt progression of the event before reaching or affecting the patient. Despite many individual and systematic methods to avoid errors, a system to avoid all potential errors is not feasible	Study limitations; interpretation of findings

(continues)

Table 2 (continued)

Reference (year)	Local	Study design/ Data source/ Study population	Relevant definitions	Study results and relevant conclusions by authors	Items not fully covered by the STROBE instrument
Kuo et al. <sup>13</sup> (2008)	United States	Retrospective, descriptive observational study; analysis of data from systems for reporting medication errors recorded by family physicians and other health professionals	The study used the term error resulting from care with or without harm to the patient	70% of medication errors involved prescription, 10% errors in administration of medication, 10% errors in patient documentation, 10% errors in distribution and control of the medicine. 24% of errors reached patients. The study concluded that involvement by physicians, multidisciplinary teams, and patients combined with technology improve the process of managing medicines, reducing medication errors	Outcome
Graham et al. <sup>14</sup> (2008)	United States	Retrospective, descriptive observational study; analysis of data from incident reporting systems; 8 AAFP clinics	There were no relevant definitions for the study	25% of errors showed evidence of mitigation; these mitigated errors resulted in less frequent and less serious harm to patients. Training physicians and other health professionals and developing protocols are the best measures for reducing AEs	None
Hickner et al. <sup>15</sup> (2008)	United States	Retrospective, descriptive observational study; analysis of data from incident reporting systems; 243 physicians and administrative staff from eight AAFP services	The study did not specify whether the AE harmed the patient	In 18% there was some harm. Losses were financial and lost time (22%), delays in care (24%), pain/suffering (11%), and adverse clinical consequences (2%). AE reports should be integrated into electronic patient files	None
Bowie et al. <sup>38</sup> (2012)	United Kingdom	Retrospective, descriptive observational study; analysis of data from systems for reporting errors	The study used the term AE to mean an injury resulting from care	The method used in the study was unable to identify risks of errors in care, highly relevant for GPs. Important to conduct new studies in this area	Participants

(continues)

Table 2 (continued)

Reference (year)	Local	Study design/ Data source/ Study population	Relevant definitions	Study results and relevant conclusions by authors	Items not fully covered by the STROBE instrument
Buetow et al. <sup>23</sup> (2010)	New Zealand	Prospective, descriptive observational study; focus group; 11 homogeneous groups of 5-9 persons, including 8 groups of patients and 3 groups of health professionals in the North of New Zealand	The study used the term error resulting from care with or without harm to the patient	Four patient safety issues were identified: improve inter-professional relations, allow patients and health professionals to recognize and manage AEs, shared capacity for team changes, and motivation to act in defense of patient safety. This methodology can help reduce tension between health professionals and the patient in the work process and reduce errors in health care	None
Manwellel et al. <sup>20</sup> (2009)	United States	Prospective, descriptive observational study; focus group; 9 focus groups with 32 family physicians and GPs from 5 areas in the Midwest United States and New York City	There were no relevant definitions for the study	Physicians described factors that affect patient safety in primary care: patients are clinically and psychosocially complex; pressure from health plans; communication is complicated due to different languages; time pressure in patient care; inadequate information systems; lack of supplies; lack of medicines; slow diagnostic tests; principal administrative decisions made without participation	Context/Justification for method
Wallis et al. <sup>33</sup> (2011)	New Zealand	Prospective, descriptive observational study; interviews with 12 family physicians	Safety culture was defined as shared values, attitudes, perceptions, skills, and individual or collective behaviors	The adapted <i>Manchester Patient Safety Framework</i> was tested and can be used to evaluate safety culture in primary care in New Zealand	None

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Table 2 (continued)

Reference (year)	Local	Study design/ Data source/ Study population	Relevant definitions	Study results and relevant conclusions by authors	Items not fully covered by the STROBE instrument
Balla et al. <sup>39</sup> (2012)	United Kingdom	Prospective, descriptive observational study; interviews with 21 GPs	The study used the term AE to mean an injury resulting from care	GPs described risk factors for patient safety: uncertainty in patient diagnosis and time pressure at work. Improvements in primary care could be achieved with feedback between GPs and specialists. The authors recommend regular meetings for clinical case discussions	Context/Justification for method
Gaal et al. <sup>24</sup> (2010)	Netherlands	Prospective, descriptive observational study; semi-structured interviews with 29 physicians and nurses	The definitions were given by the interviewed health professionals	Primary care physicians and nurses cited problems with medication as the most important safety issue. Some professionals quoted " <i>not harming the patient</i> " as a brief definition for patient safety	None
Gaalet al. <sup>25</sup> (2010)	Netherlands	Prospective, descriptive observational study; semi-structured interviews with 68 GPs	There were no relevant definitions for the study	GPs listed the following risk factors for patient safety: medical records and prescriptions. Of the 10 clinical cases presented to the GP, 5 were considered unsafe (50%)	None
Ely et al. <sup>40</sup> (2012)	United States	Prospective, descriptive observational study; questionnaire sent to a random sample of 600 family physicians, GPs, and pediatricians	The study used the term diagnostic error with or without harm to the patient	Physicians described 254 lessons learned from diagnostic errors. The three patient complaints most frequently associated with diagnostic errors were abdominal pain (13%), fever (9%), and fatigue (7%). Patient diagnosis is a lonely task, more prone to error. The authors recommend reinforcing teamwork	None

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Table 2 (continued)

Reference (year)	Local	Study design/ Data source/ Study population	Relevant definitions	Study results and relevant conclusions by authors	Items not fully covered by the STROBE instrument
De Wet et al. <sup>16</sup> (2008)	Scotland	Prospective, descriptive observational study; questionnaire sent to 49 primary health teams	Safety culture was defined as shared values, attitudes, perceptions, skills, and individual or collective behaviors that determine a team or organizational commitment to safety management	Safety culture measure by primary care teams identified the following contributing factors for incidents: professional training, professional experience, communication. The data only provided a superficial and partial description of conditions at a given moment. Capturing the complexity and more in-depth aspects of safety culture requires more studies	None
Kistler et al. <sup>26</sup> (2010)	United States	Prospective, descriptive observational study; questionnaire in a sample of 1,697 patients	There were no relevant definitions for the study	Patients reported having perceived a medical error (15.6%); erroneous diagnosis (13.4%); incorrect treatment (12.4%); having changed physicians because of an error (14.1%). 8% reported "one or more" serious perceived harms, for diagnostic and treatment errors	Context/Justification for method
Mira et al. <sup>27</sup> (2010)	Spain	Prospective, descriptive observational study; questionnaire for 15,282 patients treated at 21 primary health care centers in Spain	The study used the term AE to mean an injury resulting from care	For most participants, the increase in frequency of AEs is related to communication between physicians and patients. Factors like duration of the consultation and work style of GPs influence the result. Protocols for information provided to patients should be reviewed	Limitations

(continues)

Table 2 (continued)

Reference (year)	Local	Study design/ Data source/ Study population	Relevant definitions	Study results and relevant conclusions by authors	Items not fully covered by the STROBE instrument
Singh et al. <sup>10</sup> (2007)	United States	Prospective, descriptive observational study; questionnaire to 45 rural primary health care professionals	There were no relevant definitions for the study	Type of errors and contributing factors, according to interviewees: emergency cases not identified in triage; incorrect medication / wrong dose; wrong patient; incorrect reading of test results; delay in test results; incorrect communication of results; malfunctioning equipment; nurse tired, stressed, ill, and/or rushed	Context/Justification for method
Hickner et al. <sup>28</sup> (2010)	United States	Prospective, descriptive observational study; questionnaire to 220 physicians and other health professionals	The study used the term medication error with or without harm to the patient	Seventy per cent included medication errors, 27% involved AEs, and 2.4% both. Most frequent contributing factors for drug-related AEs were communication problems (41%) and insufficient knowledge (22%). 1.6% of the reported events led to hospitalization. Time pressure and punitive culture were the main barriers to reporting medication errors. The authors suggested an online system to facilitate reporting medication errors	None
O'Beirne et al. <sup>34</sup> (2011)	Canada	Prospective, descriptive observational study; questionnaire for 958 health professionals in Calgary	The study used the term incident to mean with or without harm resulting from care	Physicians and nurses were more likely than administrative personnel to report incidents. 50% of incidents were associated with harm. Most reported incidents were avoidable and with limited severity. Only 1% of the incidents had a serious impact. The main types of reported incidents involved: documentation (41.4%), medication (29.7%), management (18.7%), and clinical process (17.5%)	None

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Table 2 (continued)

Reference (year)	Local	Study design/ Data source/ Study population	Relevant definitions	Study results and relevant conclusions by authors	Items not fully covered by the STROBE instrument
Cañada et al. <sup>35</sup> (2011)	Spain	Descriptive observational study; analysis of data from incident reporting systems; analysis based on direct observation of safe practices; focus groups; 21 health centers in Madrid	There were no definitions	42 safe practices were identified and recommended for application in primary care. The main barriers to implementation of safe practices in primary care services related to training of health teams, culture, leadership and management, and limited awareness-raising about safe practices	Context/ Justification for method
Kostopoulou et al. <sup>11</sup> (2007)	United Kingdom	Mixed descriptive observational study; analysis of data from incident reporting systems; analysis based on direct observation of patient safety events and interviews with 5 GPs	The study used the term error resulting from care with or without harm to the patient	78 reports pertained to patient safety, of which 27% with AEs and 64% with "near misses". 16.7% had serious consequences for the patient, including one death. Only 60% of reports contained sufficient information for cognitive analysis. Most reports of AEs were related to work organization, which included overwork (47%) and fragmentation of the service (28%). The authors recommend more studies to improve information in electronic records on AEs	None
Weiner et al. <sup>29</sup> (2010)	United States	Experimental study with audio taping of simulated medical consultations; 8 actor-patients approached 152 physicians from 14 health services	The study used the term error resulting from care with or without harm to the patient	81% of physicians believed they were seeing a real patient during the visit. Physicians investigated less contextual information (51%) than biomedical information (63%). Lack of attention to contextual information, such as patient's transportation needs, economic status, or caregiver's responsibilities can lead to error, which is not measured in physician performance assessment	Study limitations and financing

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Table 2 (continued)

Reference (year)	Local	Study design/ Data source/ Study population	Relevant definitions	Study results and relevant conclusions by authors	Items not fully covered by the STROBE instrument
Avery et al. <sup>36</sup> (2011)	United Kingdom	Descriptive observational study; analysis based on direct observation; expert consensus method (12 GPs) to identify quality assessment indicators for medical prescriptions	There were no relevant definitions for the study	34 safety indicators were considered appropriate for evaluating prescription safety	Context/Justification for method
Singh et al. <sup>41</sup> (2012)	United States	Descriptive observational study; analysis of data from incident reporting systems; review of patient charts; interviews with patients in Houston, Texas	The study used the term error resulting from care with or without harm to the patient	The authors identified diagnostic errors in 141 records out of 674 detected as potentially positive for diagnostic errors. None of the evaluation methods for diagnostic errors was considered reliable	Participants
Wetzels et al. <sup>21</sup> (2009)	New Zealand	Mixed descriptive observational study; analysis of data from incident reporting systems with primary care physicians; review of patient charts; total of 8,000 patients from 5 family physicians in Nijmegen	The study used the term AEs as potentially causing harm to the patient	Some 50% of the events had no health consequences, but 33% led to worsening of symptoms resulting in unplanned hospitalization, 75% of the incidents with potential harm to health. The authors recommended that patient safety programs not concentrate only on harms	Participants
Wetzels et al. <sup>17</sup> (2008)	New Zealand	Descriptive observational study that used 5 different data sources to evaluate primary care (Nijmegen)	The study used the term AEs as potentially causing harm to the patient	Studies with reports by patients showed more AEs than those with reports by pharmacists, with the lowest number. In the evaluation of patient charts, analysis of errors featured treatment and communication. There were 1.5 events per 10 deaths. None of the methods proved better for identifying de AEs	Participants

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Table 2 (continued)

Reference (year)	Local	Study design/ Data source/ Study population	Relevant definitions	Study results and relevant conclusions by authors	Items not fully covered by the STROBE instrument
Harmsen et al. <sup>30</sup> (2010)	Netherlands	Retrospective, descriptive observational study; analysis of data from incident reporting systems; prospective study of incidents using interviews; questionnaire on management	The study used the term incident to mean with or without injury resulting from care	Difficulties in estimating frequency of incidents in primary care, which depends on accuracy of patient files; lack of professional consensus on recognition of incidents. The study showed that in primary care there is virtually no system for recording or reporting incidents. There is a need to implement an electronic AE recording system in primary care	Other analyses of the results and financing
Wessell et al. <sup>31</sup> (2010)	United States	Descriptive observational study; consensus method with 94 experts to select indicators for medication errors; questionnaires sent to patients; focus group; study in 14 States of the USA	The study used the term AEs as harm due to the use of medicines	Thirty indicators were selected for medication safety: inadequate treatment, drug-drug interactions, and drug-illness interactions were adequate in 84%, 98%, and 86% of the eligible prescriptions in the databank, respectively. Identifying errors is a difficult task, but crucial for improving medication safety	None
Singh et al. <sup>12</sup> (2007)	United States	Descriptive observational study; analysis of data from reporting systems on diagnostic errors; blinded patient chart review by 2 independent reviewers, determining presence or absence of diagnostic error; questionnaires for patients	The study used the term diagnostic error with or without harm to the patient	The system's error rate was 4%. Most common errors in the diagnostic process were: insufficiency or delay in obtaining and interpreting information in the visit. Most common secondary errors were failure to recognize the urgency of the disease or its complications	Participants

(continues)

Table 2 (continued)

Reference (year)	Local	Study design/ Data source/ Study population	Relevant definitions	Study results and relevant conclusions by authors	Items not fully covered by the STROBE instrument
Makeham et al. 18 (2008)	Australia	Retrospective, descriptive observational study; analysis of data from incident reporting systems with 84 GPs	The study used the term error resulting from care with or without harm to the patient	Seventy percent of reported errors were due to problems in care without evidence of deficiencies in knowledge or professional skills. The study indicated that patients with chronic diseases are more susceptible to AEs	Context/Justification for method
Gordon & Dunham 37 (2011)	United States	Retrospective, descriptive observational study; analysis of data from incident reporting systems with physicians and primary care professionals	The study used the term AE to mean with or without harm resulting from care	326 AE reports in the system by GPs were related to the environment (63), laboratory (49), and patient flow and scheduling (38). Patients with chronic health problems may be more vulnerable to AEs. Self-reporting was rare, suggesting that individuals could be reluctant to admit errors	None

AAFP: American Academy of Family Physicians; AEs: adverse events; GPs: general practitioners.

did not cause harm. One study<sup>13</sup> distinguished between incidents that did or did not affect the patient and whether some intervention was necessary (monitoring, clinical follow-up, including hospitalization). Only one study<sup>17</sup>, which evaluated contributing factors, did not define adverse event or present the incident's impact and/or severity.

The studies that presented the impact and/or severity of harm caused to the patient by care failed to specify how the impact and/or severity were assessed, and no scale was used. The way the impact and/or severity were presented varied from study to study. Various terms were used, such as harm (minor, moderate, or severe), complication, impact (none, slight, moderate, or severe). Some studies classified incidents based on how they reached the patient (did not reach, reached but without harm, reached and required some intervention), ranging as far as death. One study<sup>14</sup> distinguished between emotional and physical harm. One study<sup>15</sup> approached the consequences of the harm, whether temporary or permanent. Most

of the incidents evaluated in the studies did not reach the patient, and when they did, the severity was limited (frequency of incidents varied from 50 to 83%).

Some studies chose to present the types of adverse events. Medication was the most frequent type of adverse event in primary care according to the selected studies. One study<sup>13</sup> specifically investigated the types of medication errors. Diagnostic incidents were also frequent (Table 3).

Other studies<sup>14,15,17,21,27,34</sup> presented the contributing factors to adverse events. Administrative procedures, communication between professionals and with patients, and documentation were the principal contributing factors. As in the majority of studies on hospital care, the most frequent contributing factor in primary care was also communication.

#### **Studies that suggested solutions to make primary care safer for patients**

Nineteen studies<sup>9,10,11,16,18,19,20,22,23,24,25,26,29,30,33,35,37,39,40</sup> suggested solutions to improve patient

Table 3

Studies with the objective of identifying types and/or contributing factors and severity of adverse events (AEs) in primary health care.

Reference (year)	Impact/Severity of AEs	Types/Contributing factors for AEs
AE defined in studies as incident with harm due to care		
Wallis & Dovey <sup>32</sup> (2011)	Minor harm (83%); moderate harm (12%); severe harm (4%), half of which were deaths	Types of AEs were related to delay in diagnosis (16%), medication (38%), dental treatment (16%), injections and vaccines (10%), and others (20%)
Mira et al. <sup>27</sup> (2010)	Without treatment complications (80.4%); with complications (19.6%)	The most frequent contributing factors for errors related to physician-patient communication (17.3%)
AE defined in studies as an incident with or without harm due to care		
Kuo et al. <sup>13</sup> (2008)	Did not reach patient (41%); reached patient, but did not require follow-up (35%); reached patients and follow-up was necessary (8%); reached patients and intervention was necessary (13%); resulted in hospitalization (3%); no deaths	Medication errors related to: prescription (70%), administration (10%), recording (10%), dispensing (7%), and others (3%)
Graham et al. <sup>14</sup> (2008)	Did not reach patient – without harm (40.3%); reached patient – without harm (20.7%); reached patient – without harm, but action was necessary (11.6%); reached patient with emotional harm (8.0%); reached patient with physical harm (19.4%)	The most frequent contributing factors for errors were related to communication and administrative procedures
Hickner et al. <sup>15</sup> (2008)	Did not cause harm (54%); unknown (28%); caused harm (18%); emotional harm (6%); physical harm (70%); temporary physical harm (90%); temporary physical harm requiring hospitalization (3%); permanent harm (7%)	The most frequent contributing factors for errors were related to communication of test results to the physician (24.6%), administrative procedures (17.6%), ordering tests (12.9%), and others (44.9%)
O’Beirne et al. <sup>34</sup> (2011)	Without impact on patient (57%); slight impact (24%); moderate or severe impact (9%); incidents with permanent duration (1%); no deaths	The types and/or contributing factors for AEs were related to documentation (41.4%), medication (29.7%), and administrative procedures (29.3%)
Wetzels et al. <sup>21</sup> (2009)	Did not cause harm (50%); aggravation of symptoms (40%); led to unplanned hospitalization (4%); irreversible disability (6%); no deaths	The types and/or contributing factors for AEs were related to administrative procedures (31%), diagnosis (20%), treatment (23%), and communication (26%)
Wetzels et al. <sup>17</sup> (2008)	Severity not mentioned	The types and/or contributing factors for AEs were related to administrative procedures (24%), diagnosis (19%), treatment (30%), and communication (27%)

safety. Communication among health staff members or between health professionals and patients were considered the main contributing factor to tackle in order to improve safety, according to five studies <sup>23,24,33,39,40</sup>. Information exchange between family physicians and specialists, reinforcement of team work, regular clinical case discussion meetings, and dissemination of safe practices were recommend-

ed as solutions to improve inter-professional communication.

In studies <sup>10,18,20,24,25,37,39,40</sup> that exclusively heard the opinions of health professionals, factors contributing to incidents were: pressure to decrease time in individual patient care; lack of supplies, including medicines; incorrect communication of test results; delays in test results; problems with medication, mainly in prescription,

incorrect medication or dosage, wrong patient; malfunctioning equipment; tired, stressed, or ill nurses; failure to identify emergency cases in triage; uncertainty in patient diagnosis; communication problems; inadequate information systems; administrative decisions made without participation by the healthcare team; inadequate medical records.

These contributing factors were related to various solutions, such as: disseminating safe practice; adjusting infrastructure; training health team professionals; improving inter-professional communication; improving health services management, allowing patients and professionals to recognize and manage adverse events; training health professionals to share team changes to identify and act on risk situations; motivating health professionals to act for patient safety; health professionals' participating in management decisions; creating physician performance evaluation systems. The studies classified in this section as suggesting solutions to make patient care safer did not always precisely define this objective. The solution was often implicit in the evaluation of contributing factors.

In one study<sup>35</sup>, the main barriers to the implementation of safe practices in primary care services were related to cultural barriers due to the heterogeneity of local practices; management barriers, with problems in the infrastructure and for a safer environment; and limited awareness-raising on safe practices, due to communication difficulties in the health team. Health professionals' difficulty with teamwork was attributed to various factors, but especially to their type of academic training.

The study<sup>9</sup> that analyzed data from incident reporting systems showed that 80.1% of reports also suggested solutions to improve clinical practice. According to another study<sup>19</sup>, reporting incidents can be a useful practice for improving health service performance. This same study showed how cascades of errors can be interrupted before reaching patients.

Both patients and physicians are capable of identifying physician errors. In one study<sup>26</sup>, some 15% of patients reported some type of physician error. In another<sup>40</sup>, physicians described lessons learned from diagnostic errors and reported that few studies have documented personal lessons learned from errors, such as: always listening to the patient; attempting to explain all the diagnostic findings to the patient more than once; always performing a complete examination of the patient; expanding differential diagnosis; and reassessing and repeating the clinical evaluation if the patient fails to respond to the treatment as expected.

Two studies<sup>16,33</sup> that measured safety culture showed that health professionals were willing to learn, based on the detected failures, adapting their work practices to make them safer. Group meetings were suggested to facilitate inter-professional communication, consisting of health professionals, managers, and administrative staff, in order to capture their perceptions through a multidisciplinary approach<sup>33</sup>.

#### **Studies that evaluated tools to improve patient safety in primary care**

Six studies<sup>12,28,31,36,38,41</sup> aimed to evaluate tools for improving patient safety in primary care. The objective of these studies focused on application in health services. None of the selected studies evaluated research instruments on patient safety culture.

Three selected studies tracked events or circumstances involving risks that could lead to an incident. Bowie et al.<sup>38</sup> aimed to demonstrate the convenience of trackers in electronic patient files to identify risks that could lead to adverse events in primary care. Avery et al.<sup>36</sup> presented a set of safety trackers to detect potential incidents in medical prescription in electronic patient files, for physicians to select those most capable of evaluating safety in medical prescription in primary care. Wessell et al.<sup>31</sup> aimed to select patient safety trackers for medical prescription in primary care in electronic patient files.

Hickner et al.<sup>28</sup> used the *Medication Error and Adverse Drug Event Reporting System* (MEADERS) to identify specific medication errors in primary care through reporting. The authors concluded that the system allows evaluating medication errors, but that time pressure and punitive culture were the main barriers to reporting medication errors.

Singh et al.<sup>12</sup> showed that communicating abnormal imaging test results can be improved by using a system for recording the result in the electronic patient file, in the specific context of primary care. The same author published another article in 2012<sup>41</sup> on the same issue of communicating test results, but this time consulting health professionals in an attempt to understand their difficulties in reporting results to patients, even with the existing resources in the electronic patient file. The author concluded that despite the electronic patient file with resources, there are social and technical challenges for guaranteeing the recording of results for professionals and patients.



## Discussion

The theme of patient safety in primary care has grown in importance in the main international health organizations<sup>16,22</sup>. Primary care is a key area for studies on patient safety, since most health care takes place at the primary level. The current review used search terms that were similar to those in the review study by Makeham et al.<sup>6</sup>. Unlike the latter, in which 65% of studies aimed to identify the frequency and types of adverse events, the studies in our review aimed mainly to understand causes and identify solutions to make primary care safer for patients (58%).

The most common types of incidents in primary care involved medication errors and diagnostic errors, both in the review by Makeham et al.<sup>6</sup> and in the current review. Frequency of incidents associated with drug therapy in the studies varied from 12.4% to 83%<sup>13,26,32,34</sup>, while in the review by Makeham et al.<sup>6</sup>, incidents ranged from 7% to 52%. According to Ely et al.<sup>40</sup>, diagnostic errors are also common, since clinical practice in the elaboration of patient diagnosis is a lonely task and thus more prone to errors.

The harm caused by care can be emotional or physical and incapacitating, with permanent sequelae, increasing the cost of care, extending the length of hospital stay, and even leading to premature death<sup>2</sup>. In the review by Makeham et al.<sup>6</sup>, the actual harm caused by incidents varied from 17% to 39%, with potential harm ranging from 70% to 76%. In the current review, some studies<sup>34,37</sup> estimated the proportion of avoidable incidents among all incidents assessed (42% to 60%). In Makeham et al.<sup>6</sup>, 45% to 76% of all incidents were avoidable.

Some studies evaluated not only the types and severity of adverse events in primary care, but their contributing factors. The factors that most contributed to incidents were failures in communication, either among professionals or between professionals and patients (5% to 41%)<sup>14,15,17,21,27</sup>. Another relevant group of contributing factors involved management (41.4% to 47%)<sup>14,34</sup>. In relation to communication failures, Makeham et al.<sup>6</sup> found rates ranging from 9% to 56%, compared to 5% to 72% involving management. Risks in the physical environment, professional training, and geographic barriers were mentioned as other contributing factors.

The majority of studies indicated solutions to make care safer for patients in primary care (58%). Improvement in communication was the most common solution for mitigating incidents<sup>16,19,23,33,39</sup>. Other solutions were presented, such as: allowing patients and professionals to recognize and manage adverse events, shared capacity

in team changes, and motivation to act for patient safety through working groups<sup>23</sup>.

Kuo et al.<sup>13</sup> suggested solutions to reduce medication errors, including the implementation of electronic patient files in primary care services, analysis of incidents from the error reporting system, and collaborative practices between pharmacists and physicians.

A group of studies (19%) evaluated the tools for improving patient safety in primary care. As technology advances, especially information technology, the tools have evolved and improved, adapted to the reality of primary care, replicable, contributing to the improvement of risk management for incidents in primary care and to harm reduction.

Reporting systems for adverse events were the most common data source in the studies in our review (45%), exceeding the rate found in the systematic review by Makeham et al.<sup>6</sup> (23%). Focus groups were the method that contributed the least data to studies (9%). Data capture by reporting systems for adverse events has the practical advantage of data availability, speed in obtaining information, and low study cost. However, the disadvantages include lack of incident reporting culture among health professionals, especially if the system does not guarantee anonymity for person reporting the incident<sup>12,37</sup>. Wetsels et al.<sup>17</sup> showed that general practitioners (GPs) were the professionals that were most averse to reporting incidents. The GPs that were interviewed claimed lack of time to interrupt their clinical work and record the incident, while denying any feeling of mistrust towards the reporting system.

Given the concern over learning more about the causes of incidents, the qualitative methodologies that evaluated the opinions of health professionals and patients (questionnaires, interviews, and focus groups) were the most widely used.

Studies<sup>26,27,28,40</sup> with questionnaires had the advantages of reaching a wide range of health professionals and/or patients, guaranteed anonymity, and low study cost. When they used open questions, one limitation was that in some cases the answers were rather superficial. Kistler et al.<sup>26</sup> described the method's acceptability when applied to patients to explore their perceptions of errors occurring in health care.

Studies<sup>24,33,39</sup> that used interview methods highlighted the interviewee's proximity as a positive point (whether it was a health professional or patient), allowing impact analysis of a direct or indirect event or experience. Several limitations were cited in this method, including geographic barriers, reliability<sup>27</sup>, and sampling<sup>39</sup>. Balla et al.<sup>39</sup> described the method's importance in environmental risk analysis for patient safety.

Some studies <sup>16,19,27,32,33</sup> aimed to assess safety culture in primary care using questionnaires, interviews, and/or focus groups, since the approach to health professionals was more direct and simple, valuing the informant's subjectivity and allowing the study to explore sensitive issues for professionals in the psychological and affective dimensions, such as: anxiety <sup>11,20,25,39</sup>, blame for incidents <sup>11</sup>, uncertainty in clinical diagnosis <sup>25,29,39</sup>, pressure related to work organization <sup>11,16,20,23,35,39</sup>, professional competence <sup>22,35</sup>, and team motivation <sup>23</sup>. Wallis et al. <sup>33</sup> reported that the discussion on safety culture in primary care has expanded to facilitate communication, the most frequent factor contributing to errors.

Of the 33 selected studies, 14 were conducted in the United States, followed by the United Kingdom. The predominance of studies in these two countries was due to the existence of established institutional programs in the field of patient safety in primary care. As in the review by Makeham et al. <sup>6</sup>, the studies took place mainly in the USA and UK. Neither review identified any articles on patient safety in primary care in developing countries.

A limitation to the study by Makeham et al. <sup>6</sup> was that the review only searched for studies published in English, which could partially explain the lack of publications in developing countries. The current review included Spanish and Portuguese in the searches, but even so, no articles were found on this subject in developing countries, even in Brazil, where the government model for primary care is based on the Family Health Strategy. Primary care has made quantitative progress in Brazil but is still considered a faulty model, with great room for quality improvement <sup>42</sup>. According to the preliminary results of the Brazilian Program for the Evaluation of Improvement in Access and Quality in Primary Care <sup>43</sup>, 62% of health professionals fail to use the recommended protocols for performing initial clinical evaluation in patients, thus suggesting room for improvement in safe practices. The National Program for Patient Safety <sup>44</sup> launched by the Brazilian Ministry of Health in 2013 included primary care as a prime area for developing improved patient safety measures.

Important potential limitations to the current review include: (i) difficulty in generalizing results, considering the conceptual variation in the theme of patient safety in primary care, due to the multiple countries involved and differences in clinical practice and primary care; (ii) the fact that the review was conducted in English, Portuguese, and Spanish, which led to the exclusion of 35 articles; (iii) the use of a similar search strategy, limited to the MEDLINE, CINAHL, and Embase databases, excluding other databases such as Web of Science and the "gray literature"; (iv) non-inclusion in the search strategy of such terms as "safety management", "risk management", and "adverse drug reaction"; (v) lack of a meta-analysis in the review; and (vi) use of the STROBE Statement methodology <sup>8</sup> to evaluate the quality of the studies.

## Conclusion

There are gaps in knowledge on patient safety in primary care especially in developing countries and countries in transition, thus leaving room for expanding research in this area. Better understanding and knowledge are needed on the epidemiology of incidents and contributing factors, as well as the impact on health and the effectiveness of preventive methods <sup>45</sup>.

The research methods analyzed and tested in studies on patient safety in primary care are known and replicable, and it is thus likely that they be used more widely, providing greater knowledge on this type of safety.

The current study highlighted the need for expanding safety culture in primary care in order to prepare patients and health professionals to identify and manage adverse events, while raising awareness concerning their shared capacity for change, thereby reducing errors in primary care and tensions between health professionals and the population.

More in-depth studies can assist health care managers in conducting the planning and development of organizational strategies with the aim of improving quality of primary care.

## Resumen

*El objetivo fue identificar las metodologías para revisar incidentes en la atención primaria de salud, los tipos, los factores que contribuyen y soluciones para una atención primaria de salud más segura. Se realizó una revisión sistemática de la literatura sobre bases de datos bibliográficas como: PubMed, Scopus, LILACS, SciELO y Capes, desde 2007 hasta 2012, en portugués, inglés y español. Treinta y tres artículos fueron seleccionados: un 26% en relación a estudios retrospectivos; un 44% de estudios prospectivos, incluyendo grupos de discusión, cuestionarios y entrevistas y un 30% de estudios transversales. El método más común utilizado en los estudios fue el análisis de los incidentes en los informes de incidencias (45%) de los sistemas. Los tipos de incidentes se encuentran más comúnmente en la atención primaria de salud y están asociados a la medicación y diagnóstico. El factor de contribución más significativo fue la falta de comunicación entre los miembros del equipo de atención médica. Los métodos de investigación empleados en la investigación sobre la seguridad del paciente en la atención primaria de salud son adecuadas y replicables.*

*Seguridad del Paciente; Atención Primaria de Salud; Calidad de la Atención de Salud*

## Contributors

Both authors participated in all stages of the article.

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