

# **Measuring Experiences and Outcomes of Patient Safety in Primary Care.**

## **A Systematic Literature Review of available tools.**

SHORT TITLE: PATIENT REPORTED INSTRUMENTS OF PATIENT SAFETY

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## **ABSTRACT**

**Background:** Despite the enormous potential for adverse events in primary care, the knowledge base about patient safety in this context is still sparse. The lack of appropriate measurement methods is a key factor limiting the development of research in this field. The aim of this study was to identify and characterize available patient reported instruments to measure patient safety in primary care.

**Methods:** Systematic literature review. We searched in bibliographic sources for empirical studies describing the development, evaluation or use of patient reported instruments assessing patient safety in primary care. Study selection and data extraction was independently conducted by two researchers.

**Results:** We identified 28 studies reporting on 23 different instruments. Fifteen instruments were designed for paper based self-administration, six for phone interview, and two consisted in electronic reporting systems. Most instruments focused on specific aspects of patient safety, most commonly on experiences of adverse drug reactions. Face validity was assessed for ten instruments (43%), three reported construct validity (13%) and three described reliability (13%). Responsiveness was not ascertained.

**Conclusions:** Although there is evidence of good psychometric properties for a reduced number of patient reported instruments, currently available instruments do not offer a comprehensive set of resources to measure the effects of interventions to improve patient safety in primary care from a patient perspective. Future research in the field should prioritize 1) the evaluation of the performance of already available instruments and, 2) the development of new instruments that enable an comprehensive assessment of patient safety at general practices.

Keywords: Patient Safety, Patient Reported Outcomes, Patient Experiences, Primary Care, Systematic Literature Review, Health Services Research.

## Background

Since the publication of the Institute of Medicine's 2000 report 'To Err is Human' (1), patient safety has become one of the top research priorities in most of the developed countries. Concern about the safety of patients in hospital settings has driven most research in the field and the knowledge base about patient safety in primary care is still sparse. A stronger emphasis on primary care patient safety research is needed because many safety incidents identified in hospitals actually originate in primary care (2-4), an environment in which, in most of the developed countries, the majority of healthcare contacts takes place (5). Estimates of the rate of patient safety incidents in primary care ranges from 5-80 safety incidents per 100,000 consultations (6), and it has been observed that between 45% and 76% of the errors occurring in primary care can be prevented (7-9).

Measurement is critical to progress in this research field, as having available methods to obtain reliable, valid, feasible, and repeatable rates of events is necessary for internal improvement, external accountability, and research into underlying causes and mechanisms of the safety events that happen in primary care (10). Ambulatory patient safety has been measured with information from different sources, none of which is exempt of weaknesses (11). Physician reported information has been used in instruments measuring safety culture or in voluntary physician reports of errors (9, 12-19). It has been however argued that physician reports can constitute an unreliable source of information for assessing patient harm, as they might underreport errors and their consequences for patients (19, 20). The trigger tools are also a commonly used method to measure patient safety in primary care, which rely on information from electronic medical records, and can therefore suffer from incomplete documentation. Although less frequently considered until now, patient reported information can also be used to measure patient safety in primary care. Evaluations from the perspective of the individual who has suffered medical harm are obviously relevant, but even when a safety incident has no resulted in harm, patients may still provide valid and useful information. Increasing evidence suggests that patients can be involved in improving patient safety, as they are acute observers of their own care, actively and consistently collecting observations about their healthcare experience, and highly motivated to ensure that correct treatments are adequately delivered (21-25). Patients can make important contributions to the safety of health care, either as "vigilant partners" or as observers of unsafe practices (26, 27). The reliability of patient reporting of adverse events has been established

as trustworthy (25) and it has been observed that they can identify problems that currently go unreported in healthcare provider reporting systems (28-30).

In the light of the evidence supporting the use of patient reported information in patient safety research, the Agency for Healthcare Research and Quality in its report “Research in Ambulatory Patient Safety 2000–2010: A Ten-Year Review” (11) identified as one of the main goals for improving ambulatory patient safety to be accomplished over the next ten years, to identify valid and reliable methods to measure patient safety in primary care from patients’ perspective.

Previous studies have reviewed available measurement methods of patient safety in primary care (11, 13), and of patient reports of adverse events (25) in multiple healthcare settings. However, no study has specifically reviewed the available patient reported instruments to measure patient safety in primary care.

In this study we conducted a systematic literature review to identify available patient reported instruments to measure patient safety in primary care. We analyzed the characteristics of the instruments and of the domains they included. Current gaps and future research needs are also discussed.

## **Methods**

This systematic review was planned, conducted, and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (31).

### *Data sources and searches*

A comprehensive core search strategy was designed for Medline (Ovid) and subsequently adapted and implemented in Embase, CINAHL, ISI Web of Knowledge, and Health Management Information Consortium. The search strategies were designed by the research team in conjunction with an information specialist, and combined MeSH terms and keywords (available in Appendix Table 1). Searches were not restricted by language, country or publication date. Additionally, all the references available in the bibliographic repository of the LINNEAUS Euro-PC (32) on Patient Safety in Primary Care were also screened. Grey literature search in documents by the “Agency for health care research and quality”, and the “National Patient Safety Agency” was also searched. All searches were conducted in January 2012. For all the studies finally identified as relevant after the selection process, a snow balling technique using backward and forward citation searches were performed in ISI Web of Knowledge (33). Studies published up to July 2012 were eligible for inclusion. A bibliographical database was created using EndNote X6 and used to store and manage the retrieved references.

### *Study selection*

We included studies reporting the development, use or assessment of a patient reported measure of patient safety in primary care. Patient safety was broadly conceptualized as a “property of healthcare systems and services associated with the occurrence and prevention of patient safety events”. Patient safety event was defined as “i. harm or potential harm to one or more patients due to an interaction with the health care system that fails to adhere to accepted standards of care (attributable to error or systemic dysfunctions), or ii. harm to one or more patients due the intrinsic risks of health care (interventions)” (34). In order to qualify, the studies had to include an instrument that contained at least one item measuring patient safety as previously conceptualized. We restricted our review to the primary care setting. We defined primary care broadly following the approach proposed by the WHO (35), to ensure relevance to the different health systems providing primary care in different countries. No geographic, temporal or language publication limits were established. However, we only included those studies reporting an instrument to which we could have access to its full version.

Selection criteria were applied to titles and abstracts of the retrieved references. Following this initial stage, the full texts of the selected articles were obtained and read, and those meeting the selection criteria were included. Two reviewers independently applied the selection criteria, and disagreements were resolved by consensus with a third reviewer. For studies finally included that reported the use of a relevant instrument previously developed, the seminal reference and the full version of the instrument was retrieved. When the instrument was not made available with the seminal publication, we repeatedly attempted to retrieve it by contacting all the listed authors, both via email and via other resources such as Research Gate.

#### *Data extraction and synthesis*

We designed, piloted and used structured forms to extract information on setting, number of items, constructs measured, administration method, psychometric properties and number of citations. Data were independently extracted from the instruments and their seminal paper by two reviewers, and discrepancies were resolved by consensus. Authors were contacted for clarification when needed. We ranked the relevance of all the instruments, which was estimated based on the strength of their psychometric properties and number of citations of the seminal article (used as a proxy of the frequency of use of the instrument). Two researchers identified and reviewed all the domains included in each instrument and classified them according to the main domains of patient safety they measured: attitudes and behaviors towards patient safety, general perceptions of patient safety, experiences of patient safety, and harm (Figure 1).

Extracted information was transferred into an electronic database. Descriptive analyses (percentage, mean, standard deviation, minimum, maximum, median and interquartile range) were performed as appropriate.

## Results

### *Identification of instruments*

Search results are summarized in the PRISMA flowchart (Figure 2). The initial search identified a total of 20,614 citations, of which 5,504 were duplicated. Title and abstract screening of the remaining 14,866 citations resulted in the inclusion of 244 citations for further review. After examination of full text articles, 24 articles were identified as being eligible. The search of backward and forward citations of these articles retrieved 4 additional articles, resulting in 28 articles finally included, which reported the use or development of 23 different instruments (36-58).

### *Description of the instruments*

Table 1 presents aggregated characteristics of the instruments identified, whereas table 2 details the characteristics of each instrument. The first instrument was published in 1996, although almost half of them (43%) were published from 2008 onwards. Instruments were developed in eleven countries, the US and UK being the ones with the highest number of instruments (ten and four instruments, respectively).

Instruments were designed for targeting general population and tended not to be age, or condition specific. The exception were four instruments specifically designed for elderly patients (36, 38, 46, 55), and five instruments for patients with a specific condition or treatment (37, 43, 44, 49, 51). None of them was gender specific.

Thirteen instruments were designed for paper based self-administration (36-38, 41-46, 52, 55, 57, 58), six for phone interview (40, 47-49, 53, 56), and two consisted in electronic reporting systems (computer self-administered) (50, 54). The overall number of items in each instrument ranged from four to 357 (mean=67, SD=97).

### *Instrument content*

The terms most commonly used to describe patient safety events in primary care settings were: "incident", "preventable adverse events", and "medical mistake". In most occasions there was no definition for these terms was provided. More than two thirds of the instruments (70%) focused on medication problems, mostly on patient experiences of adverse drug reactions (ADR).

No questionnaire measured all four key domains of patient safety. Nine instruments (39%) measured two or more domains, and four of them measured three domains, consistently including experiences of patient safety events and some measure of harm

Five instruments measured patients' attitudes or behaviors towards patient safety (40, 43, 46, 48, 58). Three of them were focused on patients' attitudes towards medication safety (40, 43, 48). In contrast, the questionnaire developed by Witman et al (58) measured patients' attitudes toward physician mistakes, whereas the "Seniors Empowerment and Advocacy for Patient Safety (SEAPS)" (46) examined seniors' embracement of ambulatory patient safety self-advocacy behaviors, and displayed strong psychometric properties.

Two instruments measured patients' perceptions of patient safety (39, 54). The "Perception de la dangerosite des medicaments" questionnaire (39) examined how risk of adverse drug reactions is perceived by patients, whereas the instrument developed by Philips RL et al (54) measured patients' perception of the frequency of safety events.

Twelve instruments included measures of patient experiences of safety events (40-43, 47, 48, 50, 52-54, 56, 57). Experiences of diagnosis errors (misdiagnosis, delayed diagnosis, or wrong diagnosis) and of treatment related safety events (most commonly of adverse drug events but of treatment errors) were the most frequent type experiences examined. Specially worth noting is the "Out-of-Hours Patient Questionnaire" (42) which showed strong face and construct validity and reliability. Despite not being a genuine measure of patient safety, this questionnaire included different items examining relevant aspects of patient safety, such as accuracy of the diagnosis or experience with treatment received.

Sixteen instruments measured harm (36, 37, 40, 43-45, 47-56). Harm was conceptualized in terms of the impact of a specific safety event on health outcomes, quality of life or use of health services. The questionnaire developed by Jarernsiripornkul (51) was the one displaying strongest psychometric

properties. However this questionnaire exclusively examined harm produced a consequence of an adverse drug event, mainly consisting in a symptom checklist.

There was evidence for face validity for ten instruments (43%), while evidence for construct validity was available only for three instruments: Out-of-Hours Patient Questionnaire (42), The Seniors Empowerment and Advocacy for Patient Safety (SEAPS) (46), and Medication risk questionnaire (38). These instruments were also the only ones for which there was evidence of their reliability. Responsiveness was not assessed in any of them.

## **Discussion**

This review identified 23 patient reported instruments for the measurement of different aspects of patient safety in primary care. Evidence of their psychometric properties was available for a fraction, and most of the tools focused specifically on adverse drug reactions. Although some instruments included other relevant constructs (e.g., experiencing a medical error, or being harmed), none of them comprehensively included experiences and outcomes related to experiencing a safety problem.

Most instruments were developed as part of studies in which the main aim was not to develop an instrument per se but rather to determine the frequency of specific types of safety events in a specific setting and time. The overrepresentation of medication specific instruments can also be explained by the need to test the safety of pharmaceutical products before and after they are released onto the market (13).

### *Strengths and limitations*

The main strength of this systematic review lies in that it is the first time that patient reported instruments for the measurement of patient safety in primary care are systematically identified and reviewed. This is further strengthened by the comprehensiveness of the bibliographic searches. Systematic and manual searches were performed in the most relevant bibliographic databases on biomedical research, as well as in specific sites of grey literature. This was complemented by backward and forward search of citations of the articles initially included, which allowed us to identify a higher number of instruments.

Our review also has some limitations. Despite the efforts made to obtain the full version of the instruments, we did not have access to 13 potentially eligible instruments (59-71), and therefore they were not included in the analysis of our literature review. In order to ascertain whether this group of 13 instruments had similar characteristics to the 23 instruments included in our review, we examined the information available in their corresponding seminal articles. These analyses revealed that the group of potentially eligible instruments not included in the review had very similar characteristics to the instruments included. Most of them were mainly focused on patient reported of experiences of medication related problems (59-64, 66-70), and their psychometric characteristics were not reported (59-62, 64-68, 70, 71).

An additional limitation of this review is that in some cases it was debatable whether the setting of a study should be considered as primary care; we resolved such issues through discussion. Similarly, there is no widely accepted conceptual framework for patient safety in primary care settings yet (11), and some aspects of patient safety -especially factors contributing to safety events- can be considered part of the realm of quality of care instead of patient safety. Again, we used a broad framework for patient safety and resolved such issues through discussion. We are confident that our review reflects the range of patient reported measures of patient safety in the primary care context.

#### *Remaining Gaps in Knowledge*

Most of the instruments identified in this systematic review had been published recently, suggesting an increasing awareness of the importance of taking into account patients' perspectives to improve their safety. Most of them have been however developed in the UK and US, and instruments valid for other countries with different population and health systems characteristics are very much needed. Over half of the studies did not examine the feasibility of administering the instruments. However, instruments' feasibility in primary care is a highly relevant issue, which needs to be further understood. Qualitative research with healthcare professionals, for instance based on group/individual interviews and/or workload diaries, is very much needed in order to gather evidence to inform the potential routinely use of these instruments in clinical practice.

Lack of standardization also constitutes an important gap. Taxonomies for classifying errors and harm were not consistently used for developing the instruments impairing our ability to make comparisons across studies using different instruments. Most researchers created specific taxonomies for their

research, which varied in objective and scope. Further, most taxonomies were conceptually based, and had limited empirical evidence on their utility to characterize errors or harm (15). Barriers to healthcare access, extended waiting times and emotional disaffection, generally not considered serious safety problems in hospital-based research, may turn out to be important for patient safety incidents in primary care. They have the potential for long-term consequences because a reduced trust in the health system, may decrease both continuity and the use of preventive care and resultant higher need for emergency and acute care (72). In this sense, the development of future instruments needs to be informed by qualitative research involving patients.

Another issue that limits the progress in this field is the lack of gold standards for the measurement of patient safety in primary care. Independent peer review of electronic medical records has been considered in the past as the most reliable method to measure patient safety in primary care (10). However this method it is not exempt of limitations and its ability to serve as proxy for patient perceptions might be limited.

According to the AMA's ten year report, major gaps persist in our understanding of patient safety in the ambulatory setting with virtually no credible studies on how to improve safety (11). Adequate measurement methods are crucial to progress in the field. There is a lack and an urgent need for the incorporation of patient reported assessments into clinical practice for audit and safety improvement purposes. Therefore future research in this field should be prioritized towards 1) the evaluation and head to head comparison of the performance of already available instrument and, 2) the development of new instruments that enable an overall assessment of patient safety.

There is a growing interest regarding possible strategies to involve patients in promoting their own safety. One of the key strategies that have been proposed is precisely the use of patient generated information (73). However, the potential use of patient reported instruments in clinical practice to promote safer healthcare and to reduce the prevalence of harm has yet to be explored, and constitutes an important gap in knowledge.

### *Conclusions*

Despite the substantial number of instruments identified, this systematic review observed a lack of valid and reliable instruments specifically designed to provide a comprehensive measurement of the safety of care provided in Primary Care practices. There is a need to for comprehensive,

psychometrically robust, primary care specific, patient reported instruments for measuring patient safety in its breadth, and in order to be able to evaluate the effectiveness of patient safety interventions.

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**Figure 1. General domains of patient safety identified**

**Figure 2. PRISMA flowchart.**

\* ISI WOK, ISI Web of Knowledge; HMIC, Health Management Information

Table 1. Characteristics of the instruments identified for measuring Patient Safety Experiences and Outcomes in Primary Care.<sup>1</sup>

	Number of instruments (percentage)
Country in which the instrument was developed	
US	10 (43%)
UK	4 (17%)
The Netherlands	2 (9%)
Australia	1 (4%)
China	1 (4%)
Croatia	1 (4%)
France	1 (4%)
Germany	1 (4%)
Italy	1 (4%)
Spain	1 (4%)
Year of first publication	
Before 2000	2 (9%)
2000-2003	7 (30%)
2004-2007	4 (17%)
2008 onwards	10 (43%)
Language	
English	14 (61%)
Both English and Spanish	2 (9%)
Croatian	2 (9%)
Dutch	1 (4%)
French	1 (4%)
German	1 (4%)
Italian	1 (4%)
Spanish	1 (4%)
Age	
Not specific of any particular age	19 (83%)
Instrument designed for elderly patients only	4 (17%)
Health status	
Not specific of any health condition	18 (78%)
Health condition specific	5 (22%)
Administration	
Self-administered (paper based)	14 (61%)
Self-administered (electronic reporting system)	2 (9%)
Interviewer-administered (paper based)	1 (4%)
Interviewer-administered (telephone)	6 (26%)
Main focus of the instruments	
Medication problems	16 (70%)
Experience of safety incidents	3 (13%)
Reasons to change GP	1 (4%)
Out of hours care	1 (4%)
Disclosure of medical errors	1 (4%)
Attitudes and behaviors toward patient safety	1 (4%)

1. Mean number of items is 67 (sd=97, min= 4, max=357, median= 31, interquartile range= 43)

Table 2. Instruments identified for measuring Patient Safety Experiences and Outcomes in Primary Health Care.

Rank *	Instrument name/ Publication year	Language/es	Admin method	N items	Main focus of the instrument	Domains included	Response rate (%)	Psychometric properties ¶			Number of citations†	
								Face validity	Construct validity	Reliability	ISI WoK	Google Scholar
1	Out-of-Hours Patient Questionnaire, 2007 (42)	English	Interviewer + pen and paper	56	Out of hours care	<ul style="list-style-type: none"> <li>• Patient safety experiences</li> </ul>	45.6	Yes (literature reviews, experts consultation)	Yes (exploratory factor analysis)	Yes Cronbach $\alpha$ = 0.96 and 0.82/ test-retest correlation = 0.76 (p,0.001), and 0.60 (p,0.01) for the scales "consultation satisfaction" and "entry access", respectively.	11	9
2	The Seniors Empowerment and Advocacy for Patient Safety (SEAPS), 2007 (46)	English	Interviewer + pen and paper	21	Patient safety health beliefs	<ul style="list-style-type: none"> <li>• Attitudes or behaviors toward patient safety</li> </ul>	75	Yes, (8 focus groups, 24 individual semi-structured interviews)	Yes (correlation with other measures)	Yes Cronbach $\alpha$ > 0.70 for the four scales	6	1
3	Medication Risk questionnaire, 2003 (38)	English	Interviewer + pen and paper	10	To identify patients potentially at increased risk of medication related problems	<ul style="list-style-type: none"> <li>• Other</li> </ul>	Not reported	No	Yes (correlation with other measures)	Yes Cronbach $\alpha$ = 0.69, test-retest correlation = 0.6	4	Not available
4	Witman et al questionnaire, 1996 (58)	English	Self-administered+ Pen and paper	4	Patients' attitudes toward physician mistakes	<ul style="list-style-type: none"> <li>• Attitudes or behaviors toward patient safety</li> </ul>	37	Yes (semi-structured interviews)	No	No	259	130

Rank *	Instrument name/ Publication year	Language/es	Admin method	N items	Main focus of the instrument	Domains included	Response rate (%)	Psychometric properties ¶			Number of citations†	
								Face validity	Construct validity	Reliability	ISI WoK	Google Scholar
5	Jaremsiripornkul et al., 2002 (51)	English	Self-administered+ Pen and paper	35	ADR	• Harm	36.5	Yes (semi-structured interviews)	No	No	56	34
6	Use of medication questionnaire, 2003 (40)	English	Interviewer + Telephone	81	Appropriateness of prescribing	• Attitudes/behaviors towards patient safety • Patient safety experiences • Harm	86	Yes (semi-structured interviews)	No	No	44	19
7	The Diabetes Medication Survey, 2007 (43)	English	Self-administered+ Pen and paper	35	Antihyperglycemic ADR	• Attitudes/behaviors towards patient safety • Patient safety experiences • Harm	41	Yes (literature review)	No	No	34	56
8	The Adverse Drug Reaction Survey, 1999 (45)	English	Self-administered+ Pen and paper	39	ADR	• Harm	100	Yes (literature review)	No	No	14	10
9	The Medication Risk Assessment Form, 2008 (55)	English	Interviewer + pen and paper	281	ADR	• Harm	78	Yes (expert consultation)	No	No	10	1
10	Perceptions of Medical Mistakes, 2010 (52)	English and Spanish	Interviewer + pen and paper	6	Medical mistakes	• Patient Safety experiences • Harm	63.9	Yes (expert consultation)	No	No	8	5
11	Mira et al. Questionnaire, 2010 (53)	Spanish	Interviewer administered+ Telephone	12	Medication errors	• Patient Safety experiences • Harm	75	Yes (literature review)	No	No	2	1
12	Prescription safety questionnaire, 2003 (48)	English	Interviewer + Telephone	51	ADR	• Attitudes/behaviors towards patient safety • Patient safety experiences • Harm	55	No	No	No	920	453

Rank *	Instrument name/ Publication year	Language/ es	Admin method	N items	Main focus of the instrument	Domains included	Response rate (%)	Psychometric properties ¶			Number of citations†	
								Face validity	Construct validity	Reliability	ISI WoK	Google Scholar
13	Gandhi et al., 2000 (47)	English and Spanish	Interviewer administered+ Telephone	276	ADR	<ul style="list-style-type: none"> <li>• Patient Safety experiences</li> <li>• Harm</li> </ul>	69	No	No	No	333	164
14	Vragenlijst Patiëntveiligheid, 2008 (57)	Dutch	Interviewer + pen and paper	26	Adverse events	<ul style="list-style-type: none"> <li>• Patient safety experiences</li> </ul>	Not reported	No	No	No	37	16
15	Perception de la "dangerosite" des médicaments, 2002 (39)	French	Interviewer + pen and paper	35	Perception of the risk of ADR	<ul style="list-style-type: none"> <li>• Perceptions of patient safety</li> </ul>	Not reported	No	No	No	31	17
16	AAFP Patient Safety Reports Web-based error-reporting system, 2006 (54)	English	Self-administered+ Computer	20	Medical errors	<ul style="list-style-type: none"> <li>• Perceptions of patient safety</li> <li>• Patient safety experiences</li> <li>• Harm</li> </ul>	Not applicable (web-based reporting system)	No	No	No	30	Not available
17	Hoffmann et al., web-based incident reporting and learning system, 2008 (50)	German	Self-administered+ Computer	31	Medical errors	<ul style="list-style-type: none"> <li>• Patient safety experiences</li> <li>• Harm</li> </ul>	Not applicable (web-based reporting system)	No	No	No	30	19
18	The Side-effects questionnaire, 2001 (36)	English	Interviewer + pen and paper	10	Side Effects of Influenza Vaccination	<ul style="list-style-type: none"> <li>• Harm</li> </ul>	99.3	No	No	No	28	13
19	Tam et al., 2008 (56)	English	Interviewer administered+ Telephone	5	ADR	<ul style="list-style-type: none"> <li>• Patient safety experiences</li> <li>• Harm</li> </ul>	Not reported	No	No	No	11	7
20	Haas et al., 2010 (49)	English	Interviewer administered+ Telephone	357	ADR	<ul style="list-style-type: none"> <li>• Harm</li> </ul>	43.3	No	No	No	8	5
21	Arbanas et al., 2009 (37)	Croatian	Interviewer + pen and paper	69	ADR of benzodiazepines	<ul style="list-style-type: none"> <li>• Harm</li> </ul>	72.3	No	No	No	5	2

Rank *	Instrument name/ Publication year	Language/es	Admin method	N items	Main focus of the instrument	Domains included	Response rate (%)	Psychometric properties ¶			Number of citations†	
								Face validity	Construct validity	Reliability	ISI WoK	Google Scholar
22	De Smeth et al., 2011 (44)	Dutch	Interviewer + pen and paper	54	ADR	• Harm	53	No	No	No	4	1
23	Indagine conoscitiva sulle motivazioni che inducono a cambiare il medico di famiglia, 2011 (41)	Italian	Interviewer + pen and paper	20	Reasons to change GP	• Patient safety experiences	68.5	No	No	No	2	1

\* Relevance of the instruments are ranked according to psychometric robustness and citations in ISI Web of Knowledge.

¶ Potential responsiveness not examined for any of the identified instruments.

† Number of citations extracted on June 2013.

ADR, Adverse Drug Reactions

Appendix table 1. Search strategy (Ovid Medline)

Search number	Terms searched
1	exp "Outcome Assessment (Health Care)"/
2	(outcome? adj2 assessment).tw.
3	patient reported outcome?.tw.
4	outcome? measure?.tw.
5	exp Health Status/
6	health status.tw.
7	exp "Quality of Life"/
8	quality of life.tw.
9	(QL or QoL or HRQL HRQoL).tw.
10	(function* adj2 (status or psychological or mental or physical or social)).tw.
11	disabilit*.tw.
12	exp "Activities of Daily Living"/
13	activities of daily living.tw.
14	(wellbeing or well being).tw.

15	exp happiness/
16	(happi* or happy).tw.
17	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
18	("value in health" or "value health" or "quality of life research" or "qual lif res" or "health and quality of life outcomes" or "health qual lif out").jn.
19	17 or 18
20	((Patient\$2 or client\$2 or consumer\$2 or user?) adj4 (experien\$ or opinion? or feeling? or belie\$3)) or PREM).tw.
21	((Patient\$2 or client\$2 or consumer\$2 or user?) adj4 (perspective? or perception? or view? or viewpoint? or "point of view?")).tw.
22	exp Patient Satisfaction/ or exp Consumer Satisfaction/ or ((Patient\$2 or client\$2 or consumer\$2 or user?) adj4 (satisf\$ or dissatisf\$ or preference?)).tw.
23	((Patient\$2 or client\$2 or consumer\$2 or user?).tw. and (exp "Quality of Health Care"/ or exp "health care quality, access, and evaluation"/)) or ((Patient\$2 or client\$2 or consumer\$2 or user?) adj4 "quality of care").tw.
24	20 or 21 or 22 or 23
25	19 or 24
26	assessment.tw.

27	index.tw.
28	indices.tw.
29	instrument?.tw.
30	measure?.tw.
31	profile?.tw.
32	rating?.tw.
33	report*.tw.
34	scale?.tw.
35	schedule?.tw.
36	scor*.tw.
37	exp health surveys/
38	survey?.tw.
39	26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38
40	(symptom? adj2 (assessment or index or indices or instrument? or measure? or profile? or rating? or report* or scale? or schedule? or scor* or survey?)).tw.
41	25 or 40
42	exp Self-Assessment/

43	self assess*.tw.
44	exp Questionnaires/
45	questionnaire?.tw.
46	self report*.tw.
47	42 or 43 or 44 or 45 or 46
48	(Validation Studies or Comparative Study).pt. or exp psychometrics/ or psychometr*.tw. or clinimetr*.tw. or clinometr*.tw. or exp observer variation/ or observer variation.tw. or exp Health Status Indicators/ or exp reproducibility of results/ or reproducib*.tw. or exp discriminant analysis/ or reliab*.tw. or unreliab*.tw. or valid*.tw. or coefficient.tw. or homogeneity.tw. or homogeneous.tw. or internal consistency.tw. or (cronbach* and (alpha or alphas)).tw. or (item and (correlation* or selection* or reduction*)).tw. or agreement.tw. or precision.tw. or imprecision.tw. or precise values.tw. or test-retest.tw. or (test and retest).tw. or (reliab* and (test or retest)).tw. or stability.tw. or interrater.tw. or inter-rater.tw. or intrarater.tw. or intra-rater.tw. or intertester.tw. or inter-tester.tw. or intratester.tw. or intra-tester.tw. or interobserver.tw. or inter-observer.tw. or intraobserver.tw. or intraobserver.tw. or intertechnician.tw. or inter-technician.tw. or intratechnician.tw. or intra-technician.tw. or interexaminer.tw. or inter-examiner.tw. or intraexaminer.tw. or intra-examiner.tw. or interassay.tw. or inter-assay.tw. or intraassay.tw. or intra-assay.tw. or interindividual.tw. or inter-individual.tw. or intraindividual.tw. or intra-individual.tw. or interparticipant.tw. or inter-

	<p>participant.tw. or intraparticipant.tw. or intra-participant.tw. or kappa.tw. or kappa's.tw. or kappas.tw. or repeatab*.tw. or ((replicab* or repeated) and (measure or measures or findings or result or results or test or tests)).tw. or concordance.tw. or (intraclass and correlation*).tw. or discriminative.tw. or known group.tw. or factor analysis.tw. or factor analyses.tw. or dimension*.tw. or subscale*.tw. or (multitrait and scaling and (analysis or analyses)).tw. or item discriminant.tw. or interscale correlation*.tw. or error.tw. or errors.tw. or individual variability.tw. or (variability and (analysis or values)).tw. or (uncertainty and (measurement or measuring)).tw. or standard error of measurement.tw. or sensitiv*.tw. or responsive*.tw. or ((minimal or minimally or clinical or clinically) and (important or significant or detectable) and (change or difference)).tw. or (small* and (real or detectable) and (change or difference)).tw. or meaningful change.tw. or ceiling effect.tw. or floor effect.tw. or Item response model.tw. or IRT.tw. or Rasch.tw. or Differential item functioning.tw. or DIF.tw. or computer adaptive testing.tw. or item bank.tw. or cross-cultural equivalence.tw.</p>
49	39 or 47 or 48
50	41 and 49
51	PROQUALID BLOCK
52	50 or 51
53	exp General Practice/ or exp Ambulatory Care/ or exp primary health care/ or (((primary or community) adj2 (care? or health\$ or service?)) or (ambulatory adj2 (care or service))).tw.

54	exp general practitioners/ or exp physicians, family/ or exp physicians, primary care/ or GP?.tw. or ((general adj1 (practitioner? or physician? or doctor?)) or (family adj1 (practitioner? or physician? or doctor? or nurse?)) or (primary adj1 physician?) or (community adj1 (practitioner? or physician? or doctor? or nurse? or provider?)) or (ambulatory adj1 (practitioner? or physician? or doctor? or nurs\$3 or provider?))).tw.
55	exp community health centers/ or ((general or family or primary or community or ambulatory) adj1 (center? or centre? or practice?)).tw.
56	(AMERICAN FAMILY PHYSICIAN or AM FAM PHYSICIAN or "Am. Fam. Physician" or ANNALS OF FAMILY MEDICINE or ANN FAM MED or "Ann. Fam. Med" or Atencion Primaria or ATEN PRIM or "Aten. Prim." or BMC Family Practice or "BMC Fam. Pract." or BRITISH JOURNAL OF GENERAL PRACTICE or "Br. J. Gen. Pract." or BRIT J GEN PRACT or CANADIAN FAMILY PHYSICIAN or "Can. Fam. Phys." or CAN FAM PHYSICIAN or FAMILY MEDICINE or "Fam. Med" or "FAM MED." or FAMILY PRACTICE or "Fam. Pr." or "FAM PRACT." or Journal of the American Board of Family Medicine or "J. Am. Board Fam. Med." or J AM BOARD FAM MED or JOURNAL OF FAMILY PRACTICE or "J. Fam. Pract." or "J FAM PRACTICE." or "PRIMARY CARE." or SCANDINAVIAN JOURNAL OF PRIMARY HEALTH CARE or "Scand. J. Prim. Health Care" or PRIMARY CARE or Australian Family Physician or "Aust. Fam. Physician" or AUST FAM PHYSICIAN or Australian Journal of Primary Health or "Aust. J. Prim. Health" or AUST J PRIM HEALTH).jn.

57	53 or 54 or 55 or 56
58	exp Safety Management/ or exp Patient Safety/ or patient safety.tw. or safety culture.tw. or (safe\$2 adj2 (practice? or management?)).tw. or (st.fs. and (safe or safety).tw.)
59	((adverse? or preventable?) adj1 (event? or effect? or reaction? or outcome?)) or (safet\$3 adj1 (event? or effect?)).tw.
60	harm\$2.tw.
61	exp Iatrogenic Disease/ or iatrogenic.tw.
62	exp Medical Errors/ or ((medica\$ or diagnos* or therapeutic\$ or administrat* or dispensing? or prescri\$ or clinical) adj1 (error? or mistake? or fault?)).tw.
63	exp Malpractice/ or malpractice?.tw. or negligen*.tw. or misconduct*.tw.
64	(Quality & safety in health care or Qual Saf Health Care or International Journal for Quality in Health Care or IJQHC).jn. and safe\$2.mp.
65	58 or 59 or 60 or 61 or 62 or 63 or 64
66	52 and 57 and 65
67	66 not (animals not humans).sh.