

Brief communication (Original)

Developing Iranian patient safety indicators: an essential approach for improving safety of healthcare

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Background: Patient safety indicators are valuable tools by which to monitor quantitatively patient safety.

Objective: We developed patient safety indicators for the Iranian health system.

Methods: Fifty-four patient safety indicators were identified in literature and 24 of them were selected as candidate indicators. In the first round of Delphi, panelists agreed upon 20 of them and suggested eight new indicators. In the second round, four uncertain and eight new indicators were evaluated. In this round, nine indicators were agreed upon and three were dropped.

Conclusion: This study suggested 29 consensus-based indicators for the Iranian health system to assess safety of care. Establishing reporting systems and pilot testing of this set of indicators are strongly recommended.

Keywords: Health care evaluation mechanisms, Iran, patient safety, patient safety indicators, patient safety management, quality indicators, quality of health care

Despite that health care provided to patients should be safe, evidence has shown that medical errors and patient safety incidents are international concerns. According to the Institute of Medicine (IOM), 44,000–98,000 Americans die from medical errors annually [1]. In this regard, several studies in different countries have shown that the rate of adverse events is from 2.9% to 16.6% of hospitalizations and many are preventable [2-4].

According to the World Health Organization (WHO), patient safety is the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum [5]. In addition, patient safety is defined as the identification, analysis, and management of patient-related risks and incidents, in order to make patient care safer and minimize harm to patients [6]. Today, establishing patient safety management programs and reducing medical errors and harm are emphasized by many organizations such as the IOM

and WHO. For example, WHO member countries were asked to paying more attention to the problem of patient safety, and develop patient safety policies and practices [1, 7].

In Iran, there is not enough information about medical errors and most of the existing information is based on case studies and reviews of the patients' complaints [8]. Additionally, some studies have shown that the rate of complaints has increased in recent years [9]. Recently, the health minister called "Clinical Governance" the priority of the Iranian Ministry of Health (MOH) to improve health care quality, demanding the implementation of the program in hospitals all around the country. Improving patient safety is one of the most important and critical issues in the Iranian clinical governance.

Improving patient safety requires an information system to enable policy makers to continuously monitor the rates of adverse events and near misses [10]. To this end, patient safety can be quantitatively assessed through patient safety indicators (PSIs), which are measures to monitor adverse events or medical errors with the main aim of establishing a quantitative patient safety surveillance system [11,12].

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Health indicators including PSIs are an important component of the health information system of a country and information gained from analyzing such indicators enable healthcare organizations to better understand patient safety risks and problems, prioritize the problems, and determine the appropriate interventions to improve patient safety [13]. Analyzing PSIs increases information and knowledge about different aspects of patient safety and enables healthcare providers and policy makers to assess and improve the safety of care provided to patients, make comparisons between hospitals and providers, and evaluate the success of patient safety programs in reducing medical errors and harm [11].

Regarding the importance of these types of health indicators, several studies were conducted worldwide to develop and/or validate PSIs [14-17]. Additionally, some researchers have applied these indicators to assess the safety of health care [16]. Most of the literature related to develop PSIs is from western countries and Australia and little is known about PSIs needed in the developing countries and/or Asia. On the other hand, developing these indicators based on a national consensus and tailoring such indicators regarding the current health information system is needed in every country [11, 18-21].

Despite the importance of analyzing patient safety incidents, it seems that Iran lags behind the international standards in the methods of recording and analyzing medical errors and patient safety incidents. Establishing clinical governance and patient safety programs in Iranian hospitals clearly requires developing national PSIs. Consequently, this study was conducted to develop national PSIs through a consensus building process for the Iranian health system.

Materials and methods

In the first phase, published and unpublished literature was reviewed and patient safety indicators developed by some countries or organizations were identified. In this regard, such indicators have been developed or applied in countries such as the USA, Australia, and England. In addition, some well-known organizations including the Organization for Economic Cooperation and Development (OCED) and European Society for Quality in Healthcare (ESQH) have developed several PSIs [11, 18-21]. These five sets of indicators were reviewed.

The Delphi study as an iterative consensus-building process is a well-known approach to develop health indicators [11, 21, 22]. Therefore, in the second phase, we used a two-round Delphi study to evaluate each candidate indicator and achieve consensus. The Delphi panel included national experts in the fields of health information management/systems, health management and policy, medicine and nursing, patient safety as well as clinical governance in different settings including medical sciences universities, medical administration offices, hospitals, and the ministry of health.

The general criteria for selecting panelists were their experience, willingness to participate, availability and at least five years of professional experience. Specific criteria for including experts in the fields of health information management/systems, and health management and policy were being a faculty member, holding a PhD degree, adequate knowledge and experience of patient safety, clinical governance, healthcare quality, and/or developing health indicators. In addition, specific criteria for including physicians and nurses in the final panel were having a managerial position in the health sector such as medical officers/directors; ward directors, hospital supervisors, quality/clinical governance directors, patient safety officers, and adequate knowledge about developing health indicators. Finally, 38 potential panelists were identified through a snowball sampling method and were invited to participate. Ultimately, 34 of them consented to freely participate in the study.

The first-round questionnaire consisted of some questions about candidate PSIs. Panelists were asked to identify those indicators that should be included in a national set of patient safety indicators according to their validity, importance, and feasibility. The possible answers were in the form of agreement (completely or somewhat), disagreement (completely or somewhat), and neutral. Besides providing opportunities for panelists to explain the reasons behind their disagreements, they also had opportunity to suggest additional indicators. We also asked questions about the method of data gathering for these indicators, and the timeframe for calculating the indicators. A draft of questionnaire was evaluated by five experts. According to their comments, only more common outcome indicators were selected as candidate PSIs and three indicators ("hospital standardized mortality rates", "in-hospital hip fracture", and "problems with childbirth") were dropped because of their ambiguity.

The reliability of the questionnaire was evaluated using a split-half method ($r = 0.81$). The first questionnaire was sent to 34 potential panelists in March 2011. After three reminder letters, finally, 26 experts participated and sent back their responses (response rate = 76.5%).

The design of the second-round questionnaire was based on additional indicators suggested in the previous round and experts' comments. "Uncertain indicators" and feedback from the previous round were also included in the second questionnaire and experts were asked to re-rate these indicators. The validity and reliability of the new questionnaire was evaluated in a similar way to the first one ($r = 0.87$). The second questionnaire was sent to the 26 panelists who participated in the first round, in June 2011. Nineteen experts finally participated in this round (response rate = 73.1 %).

We calculated the frequency of agreements/disagreements for each indicator. An indicator

was accepted if it received at least 75 percent of agreement. Furthermore, indicators with score less than 50 percent of agreement were dropped. Uncertain indicators (those did not fall in either of the above groups) were re-evaluated in the second round of the Delphi.

Results

Table 1 shows 54 PSIs were identified in five indicator sets, many of which are calculated in a population at risk for a particular event (as a denominator). The most common set of PSIs has been developed in the USA by the *Agency for Healthcare Research and Quality (AHRQ)* in 2003. Of 27 AHRQ indicators, 20 hospital-level, and seven area-level PSIs (indicators 5, 6, 7, 16, 20, 22, 23 in **Table 1**) are mainly calculated by hospital administrative data coded using the International Classification of Diseases (ICD codes) [18].

Table 1. Patient safety indicators identified through literature review

Indicators	Sources of the indicators
1. Complications of anesthesia	AHRQ, Australia, OCED, ESQH
2. Death in low-mortality diagnostic related groups (DRGs)* □	AHRQ, England, Australia, ESQH
3. Decubitus ulcer □	AHRQ, England, Australia, OCED, ESQH
4. Death among surgical inpatients with serious treatable complications	AHRQ
5. Foreign body left during procedure*	AHRQ, England, Australia, OCED, ESQH
6. Iatrogenic pneumothorax*	AHRQ, England, Australia, ESQH
7. Central venous catheter-related bloodstream infections	AHRQ
8. Infections due to medical care/health care associated infections acquired in hospital*	England, Australia, OCED, ESQH
9. Postoperative sepsis	AHRQ, England, Australia, OCED, ESQH
10. <i>Staphylococcus aureus</i> bacteremia in hospitals	Australia
11. Ventilator pneumonia	OCED, ESQH
12. Hand hygiene—measured by the alcohol consumption	ESQH
13. Hand hygiene—staff's compliance with guidelines*	ESQH
14. Wound infections)postoperative(□	OCED, ESQH
15. Postoperative hip fracture	AHRQ, England, OCED, ESQH
16. Postoperative hemorrhage or hematoma	AHRQ, Australia, ESQH
17. Postoperative physiologic/metabolic derangements □	AHRQ, Australia, ESQH
18. Postoperative respiratory failure	AHRQ, Australia, ESQH
19. Postoperative pulmonary embolism or deep vein thrombosis* □	AHRQ, Australia, OCED, ESQH
20. Postoperative wound dehiscence □	AHRQ, Australia
21. Wrong site surgery*	OCED, ESQH
22. Accidental puncture or laceration (technical difficulty with/in procedures)*	AHRQ, Australia, OCED, ESQH
23. Transfusion reaction/complications of transfusion	AHRQ, Australia, OCED, ESQH
24. Wrong blood type	OCED, ESQH
25. Birth trauma, injury to neonate	AHRQ, Australia, OCED, ESQH
26. Obstetric trauma, vaginal delivery with instrument (third and fourth degree) □ □	AHRQ, England, Australia, OCED, ESQH
27. Obstetric trauma, vaginal delivery without instrument (third and fourth degree) □ □	AHRQ, England, Australia, OCED, ESQH
28. Obstetric trauma, caesarean delivery (third and fourth degree)* □	AHRQ, England, Australia, OCED, ESQH
29. Problems with childbirth*	OCED, ESQH
30. Failure to rescue*	ESQH
31. In-hospital hip fracture or fall	OCED, ESQH
32. Adverse drug events in hospitals	Australia, ESQH
33. Medication error (resulting in death or harm)*	OCED, ESQH

Table 1. Patient safety indicators identified through literature review (Con

Indicators	Sources of the indicators
34. Intentional self-harm in hospitals	Australia
35. Malnutrition in hospitals and residential aged care facilities	Australia
36. Patient falls (falls resulting in patient harm)*	Australia, OCED, ESQH
37. Unplanned return to operating theatre	Australia
38. Unplanned readmission to an intensive care unit	Australia
39. Hospital standardized mortality rates	Australia, ESQH
40. Independent peer review of surgical deaths	Australia
41. Presence of appropriate incident monitoring arrangements	Australia
42. Medical equipment-related adverse events*	OCED, ESQH
43. Patients experiencing adverse events*	ESQH
44. Institution-wide use of cultural assessment	ESQH
45. Surveying the development of the patient safety culture	ESQH
46. Patients experiencing harmful surgical adverse events*	ESQH
47. Assessment of suicidal risk in schizophrenic patients	ESQH
48. Side effect of antipsychotic treatment	ESQH
49. Patients informed about an adverse event by the staff*	ESQH
50. Patients experiences of adverse events management*	ESQH
51. Electronic trigger tool for surveillance of adverse drug events	ESQH
52. Patient's understanding of the purpose of their medication	ESQH
53. Potentially avoidable deaths (in multiple service categories not hospitals)	Australia
54. People receiving a medication review (in residential aged care or primary care, not hospitals)	Australia

AHRQ = Agency for Healthcare Research and Quality (USA), OCED = Organization for Economic Cooperation and Development, ESQH = European Society for Quality in Healthcare, *These PSIs were not finally validated as workable or suitable indicators for Europe. □ In England, this indicator was calculated based on the low mortality diseases not DRGs. □ These indicators are considered in Victoria and are not in the national Australian indicators. □ In the OCED indicators, only “wound infections” is considered, but in ESQH, “wound infections” and “postoperative wound infections” are considered in separate indicators. □ □ In the national indicators of Australia and OCED indicators, “obstetric trauma, vaginal delivery with instrument” and “obstetric trauma, vaginal delivery without instrument” are not considered separately.

Table 2. Demographic characteristics of Iranian experts participated in two rounds of Delphi

Demographics	Round 1 (n = 26) Frequency (%)	Round 2 (n = 19) Frequency (%)
Sex		
Female	12 (46.1)	10 (52.6)
Male	14 (53.9)	9 (47.4)
Level of education		
PhD	18 (69.2)	12 (63.2)
PhD candidate	3 (11.5)	2 (10.5)
Master	3 (11.5)	3 (15.8)
Bachelors'	2 (7.7)	2 (10.5)
Field of education		
Medicine	7 (26.9)	5 (26.3)
Nursing	5 (19.2)	4 (21.1)
Health management and Policy	8 (30.8)	5 (26.3)
Health information management	6 (23.1)	5 (26.3)
Positions		
Faculty member	9 (34.6)	7 (36.8)
Medical officer	2 (7.7)	-
Director of clinical governance	5 (19.2)	4 (21.1)
Quality director/consultant	3 (11.5)	2 (10.5)

Table 2. Demographic characteristics of Iranian experts participated in two rounds of Delphi (Con

Demographics	Round 1 (n = 26) Frequency (%)	Round 2 (n = 19) Frequency (%)
Patient safety officer/consultant	3 (11.5)	2 (10.5)
Hospital supervisor	2 (7.7)	2 (10.5)
Hospital ward director	1 (3.8)	1 (5.3)
Evaluation director	1 (3.8)	1 (5.3)
Years of professional experience/work		
Less than 10	4 (15.4)	3 (15.8)
10 to 20	16 (61.5)	12 (63.2)
More than 20	6 (23.1)	4 (21.1)
Place of work		
University	11 (42.3)	8 (42.1)
Medical administration office	2 (7.7)	2 (5.3)
Hospitals	9 (34.6)	8 (42.1)
Ministry of Health	4 (15.4)	2 (10.5)

Table 3. Panelists' views regarding suggested PSIs in the first Delphi round

Indicators (the rates of)	Agreed (completely or somewhat) (%)	Neural (%)	Disagreed (completely or somewhat) (%)	Without answer (%)	Decisions
1. Complications of anesthesia	24 (92.3)	1 (3.8)	—	1 (3.8)	Accept
2. Death in low-mortality diseases*	21 (80.8)	3 (11.5)	—	2 (7.7)	Accept
3. Decubitus ulcer (3 rd or 4 th degree)	22 (84.6)	3 (11.5)	—	1 (3.8)	Accept
4. Foreign body left during procedure	24 (92.3)	1 (3.8)	—	1 (3.8)	Accept
5. Iatrogenic pneumothorax	23 (88.5)	2 (7.7)	—	1 (3.8)	Accept
6. Health care associated infections	24 (92.3)	1 (3.8)	—	1 (3.8)	Accept
7. Postoperative sepsis	23 (88.5)	2 (7.7)	—	1 (3.8)	Accept
8. Postoperative hip fracture	18 (69.2)	6 (23.1)	1 (3.8)	1 (3.8)	Round 2
9. Postoperative hemorrhage or hematoma	22 (84.6)	2 (7.7)	1 (3.8)	1 (3.8)	Accept
10. Postoperative physiologic/metabolic derangements	19 (73.1)	4 (15.4)	1 (3.8)	2 (7.7)	Round 2
11. Postoperative respiratory failure	22 (84.6)	2 (7.7)	1 (3.8)	1 (3.8)	Accept
12. Postoperative pulmonary embolism or deep vein thrombosis	23 (88.5)	1 (3.8)	—	2 (7.7)	Accept
13. Postoperative wound dehiscence	21 (80.8)	2 (7.7)	1 (3.8)	2 (7.7)	Accept
14. Accidental puncture or laceration (technical difficulty with/in procedures)	23 (88.5)	1 (3.8)	1 (3.8)	1 (3.8)	Accept
15. Transfusion reaction/complications of transfusion (blood or blood product)	24 (92.3)	1 (3.8)	—	1 (3.8)	Accept
16. Wrong blood type	19 (73.1)	4 (15.4)	2 (7.7)	1 (3.8)	Round 2
17. Birth trauma, injury to neonate	22 (84.6)	3 (11.5)	—	1 (3.8)	Accept
18. Obstetric trauma, vaginal delivery with instrument (third and fourth degree)	21 (80.8)	4 (15.4)	—	1 (3.8)	Accept
19. Obstetric trauma, vaginal delivery without instrument (third and fourth degree)	20 (76.9)	4 (15.4)	—	2 (7.7)	Accept
20. Obstetric trauma, caesarean delivery (third and fourth degree)	21 (80.8)	4 (15.4)	—	1 (3.8)	Accept
21. Adverse drug events in hospitals	23 (88.5)	2 (7.7)	—	1 (3.8)	Accept
22. Patient falls (falls resulting in patient harm)	23 (88.5)	2 (7.7)	—	1 (3.8)	Accept
23. Wrong site surgery	22 (84.6)	3 (11.5)	—	1 (3.8)	Round 2 because of comments
24. Medical equipment-related adverse events	24 (92.3)	1 (3.8)	—	1 (3.8)	Accept

In Iran, the DRG system has not been used. Therefore, we modified this indicator.

In Australia, some of the AHRQ PSIs (with modifications) have been applied to monitor adverse events [23]. Furthermore, the Australian Institute of Health and Welfare developed national PSIs in 2009. Australian PSIs are calculated using coded administrative data. Among these PSIs, “independent peer review of surgical deaths” and “presence of appropriate incident monitoring arrangements” are considered at an area-level (state/national) only [19]. In England, there is seemingly no indicator developed by a national institution; however, some experts have suggested some AHRQ indicators [17, 20]. Additionally, England is a participating country in developing the OCED indicators. Moreover, in 2004 and 2005, the OCED and ESQH separately, and in cooperation with their participating countries developed 21 and 42 PSIs, respectively. Among 42 ESQH indicators, ultimately 24 of them were considered as workable PSIs in the whole or a part of Europe [11, 21, 24-26].

To develop a set of Iranian PSIs, a Delphi study was performed. The characteristics of the panelists in two rounds of the Delphi are shown in **Table 2**. Most of the panelists had a PhD degree and more than 10 years professional experience. Most of them were educated in medicine and health management and policy.

Table 3 shows the panelists' views about candidate indicators. According to this table, 20 of 24 candidate indicators were accepted by panelists. Three indicators (“postoperative hip fracture”, “postoperative physiologic/metabolic derangements”, and “wrong blood type”) were “uncertain”. In the first round, panelists suggested that “wrong site surgery” should be changed to “wrong site/side surgery” and “wrong blood type” should be clear. In addition, they suggested eight new candidate indicators. The panelists' views regarding the 12 new or modified indicators are shown in **Table 4**. According to this Table, nine of the twelve indicators were finally accepted and “postoperative hip fracture”, “suicide or attempt to suicide”, and “patient escape in mental health services” were finally dropped.

According to panelists, these indicators should be calculated at national and organizational levels. Moreover, these indicators should be calculated by root causes (96%), severity of outcome (80.8%), the type of procedure induced the event (76.9%), patients' age groups (57.7%), and the place of occurrence/clinical wards (57.7%). Other factors suggested by experts were “medical specialties”, “patient sex”, “new/reoccurrence”, “the stage of the care process”, “work shift”, and “the source of event detection”. Ninety-two percent of experts believed the frequency

Table 4. Panelists' views regarding suggested PSIs in the second Delphi round

Indicators	Agreed (completely or somewhat) (%)	Neural (%)	Disagreed (completely or somewhat) (%)	Without answer (%)	Decisions
1. Postoperative hip fracture	11 (57.9)	1 (5.3)	7 (36.8)	–	Reject
2. Transfusion of wrong blood type	19 (100)	–	–	–	Accept
3. Postoperative physiologic/metabolic derangements	16 (84.2)	1 (5.3)	1 (5.3)	1 (5.3)	Accept
4. Intentional self-harm (patient suicide or attempt to suicide) in hospitals	9 (47.4)	2 (10.5)	8 (42.1)	–	Reject
5. Unplanned return to operating room	16 (84.2)	2 (10.5)	1 (5.3)	–	Accept
6. Unplanned readmission to an intensive care unit (ICU)	16 (84.2)	2 (10.5)	–	1 (5.3)	Accept
7. Patients/families' complaints related to safety issues/medical errors	16 (84.2)	2 (10.5)	1 (5.3)	–	Accept
8. Patient misidentification	17 (89.5)	2 (10.5)	–	–	Accept
9. Patient escape in mental health services	8 (42.1)	3 (18.5)	8 (42.1)	–	Reject
10. Infant discharge to a wrong family	18 (94.7)	1 (5.3)	–	–	Accept
11. Patients harm resulted from intentional violations	16 (84.2)	2 (10.5)	1 (5.3)	–	Accept
12. Wrong site/side surgery	19 (100)	–	–	–	Accept

of other events (other than PSIs) should be monitored. Additionally, most experts believed that these indicators should be calculated quarterly (73.1%) or monthly (57.7%). Panelists believed that a variety of methods should be run to collect needed data for these PSIs including “reviewing deceased patients’ charts in mortality committee” (96.2%), “reviewing patients’ charts screened by ICD codes” (84.6%), “reporting systems” (84.6%), and “reviewing patients’ complaints” (84.6%).

Discussion

There is increasing agreement that promoting patient safety requires continuous monitoring of incidents and adverse events. In this regard, PSIs are considered valuable tools to monitor adverse events and support quality improvements [10, 11]. Consequently, as this study indicates, several PSIs have been developed and applied in western countries and Australia [11, 17-21, 23-26]. However, there are some controversies over the types of PSIs included and even their definitions in different countries. Clearly, health indicators should be tailored to a country’s needs, infrastructure, and health information systems.

In Iran, the patient safety program is in its early stages and any indicators except those related to nosocomial infections (urinary tract infections, surgery site [wound operation] infection, pneumonia, and bloodstream infection) are not widely used to monitor patient safety [27]. In this study, 24 PSIs were initially suggested and also panelists suggested eight candidate indicators. Finally, 29 PSIs indicators were accepted as Iranian PSIs; however, “postoperative hip fracture”, “suicide or attempt to suicide”, and “patient escape in mental health services” were finally dropped.

Comparing the final set of accepted PSIs with those identified in literature shows that 25 Iranian PSIs are similar to those of other countries. Additionally, four indicators (“patient harm resulted from intentional violations”, “infant discharge to a wrong family”, “patient misidentification”, and “patients/families’ complaints related to safety issues/medical errors”) are new. These incidents/errors are not considered in the reviewed PSIs (for example, wrong site surgery, discharge of infant to a wrong family, and patient suicide in the USA, as well as wrong site surgery in England); however, such incidents are reportable in these countries and their frequency can be monitored accordingly [28, 29].

Scientific evidence about the accepted indicators has been adequately mentioned in literature [18, 19, 23, 25, 26]. In consequence, the final set of Iranian PSIs can be assumed as a suitable tool for monitoring patient safety in the Iranian health system. Data quality, PSI definitions (inclusion and exclusion criteria), and data comparability are some main issues for implementing PSIs [11, 21]. Therefore, Iranian ministry of health should be held responsible to precisely define these indicators and conduct pilot studies in some hospitals to solve such potential issues.

Some researchers believe that PSIs are limited to some specific clinical outcomes and do not include other incidents and near misses [21, 25]. In this regard, many patient safety researchers have considered the rates of adverse events and have not restricted their analysis to PSIs [2-4, 10, 30, 31]. Consistent with these researchers, most Iranian panelists believed that the frequency of other events should be monitored.

Gathering data needed for these PSIs is another issue. Many of these indicators are measured using ICD secondary codes (diagnostic and/or procedural codes) in administrative databases [11, 32]. Therefore, their validity is dependent upon accurate and complete coding of events and related procedures [16]. However, the validity of these databases (and codes) may not be adequately audited [21, 25]. Some researchers showed that the validity of some PSIs are influenced by coding errors [33, 34], and the rates of diagnostic and procedure coding errors may not be similar in different countries [35, 36]. Therefore, it is believed that PSIs (and their related codes) should be mainly used as triggers to identify potential events for more reviewing patients’ charts [37]. In Iran, there is no routine quality audit for ICD codes, and their accuracy is questionable [35, 36]. Therefore, many panelists believed that more comprehensive methods should be run and ICD codes can be used as screening tools. Additionally, establishing reporting systems, reviewing charts of the deceased patients in the mortality committees, and reviewing the patients’ complaints were supported by panelists to gather needed data to monitor these indicators. Among these methods, Iranian hospitals lack formal reporting systems for medical errors and adverse events. Consequently, developing patient safety databases and reporting systems is strongly recommended.

In this study, some limitations should be considered. First, we mostly focused on outcome PSIs identified in the literature. Other sets of PSIs similarly focus on

outcomes. Among the reviewed PSIs, only a few input or process indicators were supported by the ESQH. We think that developing others such as input and process indicators requires more studies. Additionally, the sensitivity and specificity of these indicators are other issue that has been mentioned by some researchers in the western countries [33, 34]. To our knowledge, there is no evidence regarding the sensitivity and specificity of these indicators in developing countries including Iran. This issue requires further research.

Conclusion

Although several PSIs have been developed worldwide, there is a need for every country to develop national consensus-based PSIs. This study suggested 29 consensus-based PSIs for the Iranian health system to assess the safety of care provided to patients. These PSIs enable healthcare managers and policy makers to monitor and prioritize patient safety problems, identify and conduct potential effective interventions, and improve safety of health care provided. To support these actions, developing patient safety database, establishing reporting systems, and pilot testing of this set of indicators are strongly recommended. More studies to develop input and process indicators are also suggested.

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