

# Developing a Framework for Assessing the Safety of the Recipients of Primary Health Care Services

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## Abstract

**Background:** Safety has been neglected in primary health care (PHC). A review of the literature shows that a comprehensive and specific framework to assess the safety of service recipients (SRs) in PHC has not yet been developed.

**Objectives:** Therefore, this study aimed to design and validate a framework for assessing the safety of SRs in PHC.

**Methods:** This study was a qualitative research based on a grounded theory approach, designed and conducted by the Vice-Chancellor for Health of Tabriz University of Medical Sciences in 2020. The present study was conducted at three stages: conducting a comprehensive literature review, consulting 15 experts and officials of the country and the province, and conducting two stages of the Delphi technique with the participation of 23 experts. Content analysis was used to analyze the data.

**Results:** In the literature review phase, 114 criteria were identified from 16 references. Finally, 71 criteria (six main areas and 20 sub-areas) were identified for assessing the safety of SRs in PHC. The main areas included management and leadership (26 criteria), process management (eight criteria), SRs' safety audit (15 criteria), human resources (five criteria), SRs and community participation (five criteria), and occupational safety (12 criteria).

**Conclusions:** In this study, a comprehensive and systematic framework was designed, and criteria for measuring the safety of SRs in PHC were validated, which can be used by policymakers and officials of PHC.

**Keywords:** Primary Health Care; Safety; Service Recipient; Framework; Criteri

## 1. Background

Primary health care (PHC) is defined as the basic health care provided by the health system to individuals and families. Primary health care services should be practical and acceptable (in terms of methods and technology) and affordable (for the community and people), and

warrant the full participation of people with the spirit of self-reliance (1). According to the World Health Organization (WHO), PHC is the primary care that should be accessible to all individuals and families in the community (2). Primary health care services constitute a significant



portion of all the health care provided by the countries' health systems worldwide. In Australia, for example, in 2014 - 2015, 335 million people used the services provided by the PHC system (3). With the spread of this type of care in recent years, the safety of service recipients (SRs) in the PHC sector has become one of the main concerns of officials (4). Serious emphasis on studying SRs' safety in PHC is essential because many safety adverse effects in hospitals root in primary care (5-7). Since the publication of the American Medical Association's report, "To err is human: building a safer health system", patient safety has become a top priority of countries (8). Concerns about patient safety in hospitals have led to the conduct of vast research in the field, but a gap is felt about the importance and role of SRs' safety in PHC, more than ever (9).

According to the American Institute for Health Research and Quality, every year in the PHC sector, one in 20 outpatients experiences a diagnostic error by the service provider, and 55% of outpatients cite diagnostic errors as their main concerns in outpatient services. Moreover, 160 million drug errors have been recorded, and 80% of the information exchanged between the provider and SRs are immediately forgotten (10). The rate of safety adverse events for SRs in PHC is estimated 5 to 80 per 100,000 services provided, of which 45% to 76% can be prevented (11-13). In the United States, annual outpatient services by far exceed the number of hospital admissions per year, and more than half (54%) of all outpatient services occur in PHC (14). It is estimated that for every 100 outpatient services in PHC, two to three safety adverse events occur, 4% of which may result in severe and irreparable injuries to SRs (15).

Despite the larger share of the services provided in PHC from total provided care, safety assessment in PHC systems is significantly less under attention compared to inpatient services (16). An appropriate safety assessment method can improve the performance of the PHC system by identifying potential weaknesses and improving preparedness. Achieving this goal, however, requires conducting research on the causes and mechanisms of safety adverse events in PHC systems. Having a reliable and practical tool to measure progress in this field is essential (17). The US Agency for Health and Quality Research, in its report entitled "Research in ambulatory patient safety 2000 - 2010: a 10-year review" has stated that one of the most important goals of improving patient safety in health care systems over the next 10 years is identifying valid and reliable assessment methods and screening SRs' safety during receiving PHC from their own viewpoints (18).

## 2. Objectives

However, reviewing evidence shows that a comprehensive and specific framework to assess SRs' safety in PHC has not yet been developed. Therefore, this study aims to

design and validate the standards of SRs' safety for providing PHC in Iran.

## 3. Methods

This study was a qualitative research based on the grounded theory approach to design and validate SRs' safety standards in PHC. The present study was conducted at three stages, including a comprehensive literature review, designing an initial framework for the standards using experts' opinions, and validating the framework based on two rounds of Delphi technique.

### 3.1. Step 1: Reviewing Relevant Studies Worldwide

First, existing and relevant studies and evidence were searched for in invaluable scientific sources and journals to collect the standards of SR safety in PHC.

Search Strategy: Required information were collected from different databases, including EMBASE, PubMed, Scopus, and Google scholar, as well as Persian databases such as IranDoc, IranMedex, SID, and MagIran. The websites of international organizations, ministries of health, associations, and other related organizations, search engines (Google and Yahoo), libraries, organizational reports, and some reputable journals were also reviewed. The period selected for searching was from January 1, 2000, to May 30, 2020. After excluding the articles remotely related to study objectives, related articles were screened, and their references were reviewed again to ensure a comprehensive review of all available articles in the field. Experts in the field were also consulted. Databases of the European Association for Gray Literature Exploitation (EAGLE) and the Health Care Management Information Consortium (HMIC) were also searched to identify Gray literature.

#### 3.1.1. Inclusion and Exclusion Criteria

Inclusion criteria comprised: (1) Being related to the field of PHC, not clinical care; (2) being published between 2000 and 2020; (3) being written in English or Persian; and (4) referring to at least one aspect of SR safety in PHC.

#### 3.1.2. Data Extraction

To extract the data, first, a data extraction form was designed using Word 2010. First, the data of five articles were extracted as a pilot using this form, and the shortcomings and problems in the initial form were eliminated. The extracted information included the names of author/authors, year of publication, study location (country), the study' purpose, the method and source of data collection, general/key results, and conclusions.

### 3.1.3. Data Analysis

Content analysis was used to analyze the data, which is a method for identifying, analyzing, and reporting patterns (themes) within texts and is widely used for qualitative data analysis (19, 20). The steps of data analyzing and coding were familiarity with the texts of articles (immersion in the article's results), identifying and extracting primary themes from studies, placing articles in the identified themes, reviewing and completing the results of each theme using the articles' results, and assessing the reliability of the themes and their extracted results. The data were coded by two researchers separately. In the case of disagreement between the two coders, the dispute was resolved through discussion, and if an agreement was not obtained, the disagreement was resolved by including a third researcher.

### 3.2. Step 2: Developing the Main Areas, Sub-areas, and Criteria of SRs' Safety in PHC

At this stage, experts were interviewed to develop the main areas, sub-areas, and criteria of SRs' safety in PHC. After a literature review, a total of 114 criteria were identified from 16 studies (Appendix 1 in Supplementary File). After the initial and independent screening of criteria according to the study's objectives by two members of the research team, 94 criteria were finally selected. Then the two researchers discussed the selected criteria, as a result of which 13 duplicated and similar criteria were removed. Finally, 81 criteria were sent to 15 experts in PHC for secondary screening to improve the criteria based on their opinions. After several rounds of opinion polls and analysis of their comments, 75 criteria were finally selected and entered the Delphi phase. The criteria entered the Delphi phase were divided by two members of the research team into 20 sub-areas. Finally, six main areas of management and leadership, process management, auditing of SR safety, human resources, SRs and community participation, and occupational safety.

Inclusion criteria for the experts were as follows:

- 1) Being current or former managers of the vice chancellor for health and having 5-10 years of management experience.
- 2) Working in different groups of the vice chancellor for health.
- 3) Being faculty members in the fields of health services management and health economics and having research experience (books, articles, or dissertations) in PHC and safety.

### 3.3. Step 3: Delphi Technique

After finalizing the criteria based on the experts' viewpoints, the criteria were sent to 45 experts in the form of the Delphi questionnaire. In the first round of Delphi technique, 23 safety experts in PHC completed and returned the Delphi forms. In this study, the Delphi form used in a previous study by the researchers (21) was used with minor changes. Each of the experts rated each criterion based on the two dimensions of importance (whether this criterion is important and should be considered or not) and feasibility (how much information required for this criterion is extractable in terms of access to the information, time, and required human resources). The experts first chose their general opinion about the importance of the criterion from the three options of "I disagree", "I have no idea", and "I agree", and then based on their previous choices, they gave a score of one to nine to each criterion (1 to 4 = I disagree, 5 = I have no idea, 6 to 9 = I agree). The criteria that were rated as seven or higher were finally accepted. Criteria with an average score of four to seven went to the second round of Delphi, and criteria with an average score of less than four were excluded from the study. The Delphi questionnaire consisted of three sections: a brief introduction about the objectives and necessity of the study, a guide for completing the form, and a list of criteria. Delphi forms were sent to the experts via email, and one week was given to complete them, after which a reminder email was sent again.

By analyzing the results of the first round, two criteria were excluded from the study (a score less than 4), and 69 criteria were accepted (a score higher than 7). Finally, four criteria entered the second round (a score from 4 to 7). In the second round, Delphi forms were sent to 10 people, six of whom responded. At this round, people were also given one week to complete the forms. At this stage, due to agreement between the first and second rounds, the Delphi technique was stopped, and the criteria were finalized. Afterward, out of four criteria, two were excluded from the study, and two were accepted. At the end of two Delphi rounds, out of 75 included criteria, four criteria were excluded, and 71 ones were finalized for measuring SR safety in PHC.

## 4. Results

The demographic characteristics of the experts participating in the criteria screening section have been provided in Appendix 2 in Supplementary File, and that of participants in the Delphi phase have been presented in Appendix 3 in Supplementary File.

Overall, 71 final criteria were identified for assessing SR safety in PHC, which were categorized into six main areas and 20 sub-areas (Table 1).

**Table 1. The Final Framework of Standards for Assessing the Safety of Service Recipients in Primary Health Care**

Main Areas	Subareas	Criteria
<b>1) Management and leadership</b>	1) Senior management commitment to the safety of SRs	1) Serious attention to SRs' safety in organizational strategic plans of the vice chancellor for health
		2) Serious attention to the safety of SRs in the operational/executive plan of the organization/vice chancellor for health
		3) Serious attention to the safety of SRs during performance appraisal
		4) Serious attention to the safety of SRs regarding SRs' complaints
		5) Serious attention to the safety of SRs in the allocation and provision of resources
		6) Paying attention to the safety of SRs in the structure/formation of the safety committee
		7) Paying attention to the safety of SRs in service compensation programs (recorded in employees' and organizations' evaluation checklists and the attention and practical sensitivity to safety monitoring)
		8) Support for the managers and units providing safe services to SRs
		9) Paying attention to the safety of SRs in designing and providing service packages
	2) The safety culture of service providers and receivers	10) Routine measurement of safety culture status in service provider units
		11) Existence of programs and measures to improve the safety culture of service providers and recipients
		12) Constructing culture and promoting the literacy of service recipients for safety promotion
	3) Continuous quality improvement	13) Existence of routine quality improvement programs to improve the safety of SRs
		14) Use of practical methods (RCA or FMEA) to improve the safety of service providers and SRs
		15) Quality-based payment to improve the safety of service providers and SRs
	4) Evidence-based performance	16) Development of guidelines and protocols for SRs' safety based on the best global safety practices
		17) Access of service providers to SRs' safety guidelines and protocols
		18) Using the best evidence for making decisions about the safety of SRs
	5) Communication	19) Designing a transparent and effective interpersonal communication system (between service providers) to improve the safety of SRs
		20) Designing a transparent and effective inter-sectoral communication system (between different sections of PHC) to improve the safety of SRs
		21) Designing a transparent and effective intra-sectoral communication system (with other parts of the health system) to improve the safety of SRs
		22) Appointment of one of the employees of each unit (health center) as the supervisor and responsible for the safety of the center and the unit's external communications
		23) Establishing virtual networks for communications between SRs and service providers
		24) Forming teams focusing on improving SR safety protocols
	6) Teamwork	25) Monitoring and evaluating the performance of the SR safety team as a group
		26) Assigning SR safety missions to safety teams

<b>2) Process management</b>	7) Review and modification of processes to increase safety	27) Identifying problematic (problem-causing) processes in SR safety
		28) Existence of a coherent and efficient problem-solving system
		29) Electronicization of processes and the use of information technology in issues related to SR safety
	8) Complaint handling process	30) Utilizing the power of the private sector to increase safety
		31) Existence of a transparent and simple process for handling complaints of SRs
	9) Waste collection and disposal	32) Appropriately notifying SRs on the process of handling complaints
		33) Evaluation of compliance with the principles of waste management in PHC centers (management and training, segregation and collection, temporary transportation and storage, and treatment and disposal)
	10) Continuous assessment of SR safety	34) Existence of a regular monitoring program for promoting waste management in PHC
		35) Existence of specific and routine programs to assess the safety status
		36) Existence of trained manpower to assess the safety status
37) Existence of valid and reliable tools for the continuous assessment of safety status		
<b>3) Service recipients' safety audit</b>	11) Systems for recording and reporting SR safety	38) Recording, reporting, and providing feedback on safety assessment
		39) Existence of a registration system for error/safety issues
		40) Collecting, analyzing, interpreting, and reporting SR safety information
	12) Design and implementation of interventions to improve SR safety	41) Transparency in the process of handling errors and reports
		42) Training staff on how to report issues
		43) Not punishing employees to encourage them to report errors
		44) Designing interventions to improve SR safety
	13) Monitoring the results of interventions to improve SR safety	45) Prioritizing and implementing interventions to improve SR safety
		46) Running pilot evaluations and reviewing programs
		47) Monitoring the results of the implementation of the interventions aiming to promote SR safety
<b>4) Human resources</b>	14) Quantity of human resources	48) Deciding on the efficiency of interventions based on the results of monitoring
		49) Using the results of monitoring processes to enhance SR safety
	15) Quality of human resources	50) Existence of adequate human resources and following standards to reduce errors
		51) Existence of specially trained manpower in the field of safety (with a description of safety duties)
		52) Determining the percentage of the personnel who are trained in the field of SR safety
		53) Planning initial and in-service training to maintain and improve the skills and awareness of employees in the field SR safety
54) Providing sufficient incentives to manpower to improve SR safety		

<b>5) Service recipients and community participation</b>	16) SRs empowerment	55) Teaching SR safety principles to the community
	17) SRs and community participation	56) Providing adequate health care information to SRs and the community
		57) Assessing the awareness, beliefs, and practices (KAP) of SRs and the community about safety
		58) Planning to engage SRs and the community in safety
<b>6) Occupational safety</b>	18) Service providers' safety	59) Receiving informed consent when delivering special cares
		60) Providing a safe workplace for primary health care providers
	19) Building/structural safety	61) Familiarizing of health providers with the principles of ergonomics and safety in the workplace
		62) Providing personal safety equipment to health care providers
		63) Routine assessment of the safety of physical spaces
		64) Planning and implementation of workplace improvement interventions
		65) Improving the safety of the workplace by promoting structural safety
		66) Improving the safety of the workplace by promoting non-structural safety
		67) Cooperating with partner organizations to improve safety programs
		68) Engaging donors to support the PHC activities and programs
		69) Preparing a list of the equipment related to safety
20) Equipment safety	70) Assessing the safety status of safety-related equipment	
	71) Having a routine program to fix the problems of safety-related equipment (preventive maintenance)	

#### 4.1. Management and Leadership

This area consisted of six sub-areas, including senior management commitment to SR safety (nine criteria), the safety culture of service providers and receivers (three criteria), continuous quality improvement (three criteria), evidence-based performance (three criteria), communication (five criteria), and teamwork (three criteria), with a total of 26 criteria.

#### 4.2. Process Management

This area consisted of three sub-areas, including the review and modification of safety augmenting processes (four criteria), handling complaints (two criteria), and waste collection and disposal (two criteria), with a total of eight criteria.

#### 4.3. SR Safety Audit

This area consisted of five sub-areas, including the continuous assessment of SR safety status (four criteria), a system for recording and reporting SR safety (five criteria), designing and implementation of interventions to improve SR safety (three criteria), and monitoring the results of SR safety improving interventions (three criteria), with a total of 15 criteria.

#### 4.4. Human Resources

This area consisted of two sub-areas, including the number of human resources (two criteria) and the qual-

ity of human resources (three criteria), with a total of five criteria.

#### 4.5. Service Recipients and Community Participation

This area consisted of two sub-areas of SR empowerment (two criteria) and SR and community participation (three criteria) with a total of five criteria.

#### 4.6. Occupational Safety

This area consisted of three sub-areas, including service providers' safety (three criteria), building/structural safety (six criteria), and equipment safety (three criteria), with a total of 12 criteria.

For each of the finalized criteria, a guidance form was developed for completing SR safety assessment criteria and to collect accurate and transparent information using a common language. The booklet consisted of seven parts: the main areas of the criteria (one of the six main areas), the sub-areas of the criteria (one of 20 sub-domains), the titles of the criteria, the definition and logic of using the criteria (general explanations about the titles and specific explanations about the importance and necessity of collecting the criteria), the metrics used to measure the criteria (how to measure the criteria; viewing documents, asking people, asking SRs, measuring, etc.), and the measurement levels of the criteria (meaning that in what level or levels the criterion can be calculated or measured).

## 5. Discussion

In the present study, using a comprehensive literature review, opinion polls of experts and stakeholders, and Delphi technique, a framework for assessing SRs' safety in PHC with 71 criteria, six main areas, and 20 sub-areas was designed and validated.

The results of the literature review in the present study showed that there were a few studies and reports on SRs' safety in PHC. This is while a very superficial search in scientific resources and the Internet will yield numerous studies on patient safety in hospitals and specialized care and level three centers. There are numerous barriers to developing and implementing safety procedures in PHC, including the lack of valid scientific evidence on SRs' safety in the provision of PHC services, the existence of challenges in assessing the personal aspects of patient care, the diversity and complexity of medical, psychological, and social issues in the service delivery process, and the problems related to the coordination principles of service delivery in the PHC sector (22, 23). Having a reliable and feasible tool to measure progress in this area is essential because the use of appropriate assessment methods can improve PHC by identifying potential weaknesses, ensuring appropriate responsiveness, and divulging the reasons and mechanisms of safety adverse events during the provision of PHC services (17). One of the main reasons for this can be a misunderstanding of the extent of errors in PHC. On the other hand, the Almaty (Kazakhstan) statement, which was somehow the starting point of PHC, also neglected the safety issue in this area. In the present study, a review of the limited studies available indicated that, first of all, the research field is new, and studies in this field are at the beginning of their journey. Secondly, these studies have not specifically and comprehensively addressed the issue of SR safety in PHC. Therefore, it is necessary that researchers and health organizations, especially the WHO, design and implement a lot of research in this field in cooperation with different countries.

In this study, based on the results of the literature review and experts' opinions, most of the recognized criteria were related to management and leadership. This shows the high importance of principled and appropriate leadership in the PHC sector. Given the breadth of PHC services, effective communications between the society and a large number of PHC providers, officials, and managers need wide and high levels of different capabilities and skills. Therefore, having a capable and effective leadership in this area is vital (24-26). The critical issue of SR safety is no exception to this rule.

Another important area in the safety of SRs in PHC included the SRs and community participation. Given the nature of PHC, which is the first level of health system to contact the public, the issue of public participation in the provision of this type of care is vital. Based on a lot of evidence, remarkable achievements have been attributed to

the participation of the community and people in PHC (27-31). Because of the importance of this area, public participation was considered as one of the four principles of PHC in the Almaty meeting (32). Evidence shows that SRs, as observers, can actively and continuously collect information about the process of health care provision and play important roles in improving safety measures (33, 34). Service recipients can also play important roles in improving health care safety as "conscious partners" or as observers of unsafe processes (35, 36). In this regard, an important issue that should be seriously considered is the low knowledge and information of people and SRs about their rights, especially about safety in PHC. Therefore, it is recommended that serious attention be dedicated to training and informing people and society about safety by officials and health care providers.

In the present study, another important area in SR safety in PHC was identified to be occupational safety, which included three sub-areas: service provider safety, building/structure safety, and equipment safety. Given the nature of PHC that provides services to people on a large scale (i.e., in rural and urban areas, by a large number of staff with different specialties, inside a large number of buildings, and using various tools and equipment), occupational safety is a critically important issue. For instance, PHC has been established in Iran since 1985 in the form of health networks in different cities and villages (37, 38). The performance and pattern of PHC in Iran has an international reputation and has been visited and praised by experts from various international organizations (39, 40). The network currently includes more than 18,000 health houses, 2,500 rural health centers, 2,300 urban health centers, and more than 28,000 Behvarzes, providing PHC services directly to 100% of the country's urban population and more than 86% of its rural population (41, 42). According to the WHO (2007), about 70% of the world's population benefit from PHC services. This is while only about 10% - 15% of service providers work in standard workplaces and under safe conditions (43). The WHO also published a report in 2011, entitled "connecting health and labor: What role for occupational health in primary health care?", which was the output of an important conference emphasizing the significance of occupational safety (44). Also, a considerable number of reports and studies have been published in recent years, reflecting the importance and necessity of paying attention to occupational safety in the PHC sector (45-47). Therefore, the criteria and metrics identified in this study can be used to develop a suitable measurement tool in this field.

Based on reviewing the texts and the researchers' experiences and knowledge, the present study was the first comprehensive and systematic review aiming to present a framework with specific criteria for assessing SR safety in PHC. However, we faced several limitations including the low number of credible references and the lack of enough knowledgeable and informed experts in this field.



## 5.1. Conclusions

In this study, a comprehensive and systematic framework with specific criteria was presented for assessing SR safety in PHC. Given the importance and extent of PHC services and the potential risks that threaten SRs and care providers, the framework proposed in the present study, after some modifications, can be used by policymakers and officials to promote safety in PHC.

## 5.2. Strengths and Limitations of This Study

Based on the results of the texts reviewed and the experiences of the research team, the present study, for the first time, has comprehensively and systematically presented a framework of criteria for measuring the safety of SRs in PHC. However, researchers faced several limitations, including the limited number of credible references and knowledgeable and informed experts in this field.

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