Patient safety assessment manual for primary care

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Foreword

Patient safety is a fundamental principle of quality highlighted in the global health agenda. It is an essential requirement for establishing resilient health care systems. Patient safety was emphasized by the Seventy-second World Health Assembly in resolution WHA72.6 on Global action on patient safety, in May 2019, which endorsed the establishment of an annual World Patient Safety Day to be observed globally on 17 September.

To prioritize patient safety as an avenue to improve the overall quality and safety of health care in the Eastern Mediterranean Region, WHO is looking for innovative approaches. These will not be limited to hospital care but will apply across the care continuum, including primary health care. It is well recognized that until primary care is strengthened, it is not possible to achieve a robust health care system and, thus, universal health coverage.

Building on the success of WHO's Patient Safety Friendly Hospital Framework and the Astana Declaration in 2018, which envisioned "primary health care and health services that are high quality, safe, comprehensive, integrated, accessible, available and affordable for everyone and everywhere, provided with compassion, respect and dignity by health professionals who are well-trained, skilled, motivated and committed", the WHO Regional Office for the Eastern Mediterranean decided to develop standards for patient safety friendly primary care.

The resulting Patient Safety Friendly Primary Care Framework is a WHO-led programme for promoting patient safety practices in primary health care facilities. The framework encompasses different domains, standards and criteria. It introduces a comprehensive set of standards through which primary care facilities will be able to deliver safer patient care. The framework will assess performance from a patient safety perspective; build capacities of staff in patient safety; and actively integrate patients and communities in improving health care safety.

I hope this first edition of the *Patient safety assessment manual for primary care*, which explains how to apply the Patient Safety Friendly Primary Care Framework, will be useful in improving patient safety in primary care facilities in both the public and private sectors. The framework will also support ministries of health, as well as independent organizations and professional bodies, in building technical capacity in primary care.

Dr Ahmed Al-Mandhari
WHO Regional Director for the Eastern Mediterranean

Glossary and acronyms

Accountability: Responsibility and requirement to answer for tasks or activities. This responsibility may not be delegated and should be transparent to all stakeholders.

Action plan: A formalized plan that establishes a facility's overall goals.

Audit: A systematic independent examination and review to determine whether actual activities and results comply with planned arrangements.

Best practice: An approach that has been shown to produce superior results, selected by systematic process and judged as exemplary or demonstrated as successful. It is then adapted to fit a particular facility.

CCTV: Closed-circuit television.

Clinical governance: A framework under which facilities are accountable for continuously monitoring and improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care should flourish.

Community: Individuals, families, groups and organizations that usually reside in the same locality.

Competency: The knowledge, skills, abilities, behaviours, experience and expertise needed to perform a particular task or activity.

Confidentiality: The right of individuals to keep information about themselves from being disclosed.

Culture: The shared attitudes, beliefs and values that define a group or groups of people and shape and influence perceptions and behaviours.

EPP: Emergency preparedness plan.

Ethics: An acknowledged set of principles that guide professional and moral conduct..

FOCUS-PDCA: Find, organise, clarify, understand and select [method], including plan-do-check-act [model]

Goals: Broad statements that describe the outcomes a facility is seeking and provide direction for day-to-day decisions and activities.

Incidents: Event that is unusual or unexpected, may have an element of risk or may have a negative effect on clients, groups, staff or the facility.

Information: Data that are organized, interpreted and used. Information may be paper based or electronic

Information management: The collection, management and distribution of information.

Informed consent: The information given to the patient, ensuring all risks, benefits and potential side-effects are explained, in advance of a procedure and any sedation.

IPC: Infection prevention and control.

LASA: Look-alike, sound-alike [medicines]

Mission: A broad written statement that articulates the facility's purpose and scope.

Objective: A target that must be reached if the facility is to achieve its goal.

Orientation: The process by which staff are introduced to a new role and work environment.

Operations plan: A plan setting out the annual steps and tasks through which the strategic plan will be operationalized; it may also be called an annual plan.

PMP: Preventive maintenance programme

Policy: A written operational statement that formalizes the approach to tasks that is consistent with the facility's objectives.

Polypharmacy: The chronic co-prescription of several drugs. It is associated with a high rate of adverse drug reactions, mainly from drug–drug interactions (the ability of a drug to modify the action or effect of another drug administered successively or simultaneously).

PPE: Personal protective equipment.

Primary care: Health care involving few specialties – mainly internal medicine, obstetrics and gynaecology, paediatrics and general surgery – or just general practice; limited laboratory services are typically available for general, but not specialized, pathological analysis.

Procedure: A written set of instructions conveying the approved and recommended steps for a particular action or series of actions.

Process: A series of actions or steps taken to achieve a particular end.

PSFPC: Patient safety friendly primary care.

Quality improvement plan: A plan that outlines quality improvement initiatives, including the proposed actions, timelines and responsible individuals.

RCA: Root cause analysis

Risk: The probability of danger, loss or injury.

Risk management: A systematic process of identifying, assessing and taking action to prevent or manage clinical, administrative, property and occupational health and safety risks in the facility.

Risk management programme: A set of components that provides the foundation and organizational arrangements for designing, implementing, monitoring, reviewing and continually improving risk management throughout the facility.

SOPs: Standard operating procedures.

Strategic plan: A formalized plan that establishes the facility's long-term goals.

Survey: External peer review that measures the performance of the organization against an agreed set of standards.

Surveyor: An external peer reviewer of organizational performance against agreed standards.

Vision: A declaration of a facility's objectives, intended to guide its internal decision-making.

WASH: Water, sanitation and hygiene.

Preface

This is the first edition of the *Patient safety assessment manual for primary care*, which explains how to apply the Patient Safety Friendly Primary Care Framework. It comprises a set of standards that cover the different domains of patient safety. The Patient Safety Friendly Framework was developed by the WHO Regional Office for the Eastern Mediterranean to assess patient safety at a system level. The framework provides a means to determine the level of patient safety for the purpose of initiating a patient safety or quality improvement programme. The evaluation is voluntary and is conducted through self-assessment and an external peer review survey.

The standards in the Patient Safety Friendly Primary Care Framework are based on international research and evidenced-based practices in primary care. To ensure the standards remain current, revisions will be made every three to four years.

In this edition, the total number of standards is 19, made up of 125 criteria. Standards have been developed with consideration for their alignment with all WHO initiatives to promote safer care.

The Patient Safety Friendly Primary Care Framework is the result of collaborative work between the WHO Regional Office for the Eastern Mediterranean and regional experts.

Introduction

Overview

WHO has long recognized the importance of primary health care. As early as 1978, WHO endorsed the Declaration of Alma-Ata, emphasizing the crucial role of primary care around the world. In 2018, the Astana Declaration reaffirmed WHO's commitment to the role of primary care. The Seventy-second World Health Assembly in 2019, with a renewed focus on safety and quality in primary care after Astana, stated that the opportunity to ensure that the basics – including water, sanitation and hygiene (WASH) services – are in place has never been greater.

The COVID-19 pandemic is the most devastating and destructive virus to hit the human population in the 21st century *(1)*. Primary care's role in the prevention and control of infectious disease outbreaks has never been more important. The sudden outbreak of COVID-19 meant primary care facilities had to rapidly adapt existing emergency plans to manage services and reduce the transmission of infection. Proactive investment in primary care infrastructure and capacity is crucial to respond to pandemics, and improved surveillance, cooperation and communication would ensure that countries are even better prepared *(2)*.

Providing evidenced-based WASH equipment, waste management practices and basic hygienic measures in communities and primary care facilities will help to prevent transmission of the virus that causes COVID-19 *(3)*. COVID-19 has demonstrated the strengths of standards in clinical practice *(1)*.

Building on the success of the WHO Regional Office for the Eastern Mediterranean Patient Safety Friendly Hospital Framework and recognizing the importance of primary care, the WHO Regional Office has developed patient safety standards for primary care. These standards include WASH services and the management of infectious disease outbreaks at the primary care level. Understandably, there is a strong focus on infection prevention and control (IPC).

A literature review was undertaken at the outset to identify any new themes or changes in each of the patient safety domains. This included identifying the relevant updated WHO guidelines to support implementation of the standards. Pilot testing and front-line evaluations of the standards were also sought, collated and analysed, and these – together with the literature review – were used to guide the development of the primary care standards.

Key findings from the literature review included a study by Marchon and Mendes on patient safety in primary care with the objective of identifying methods to evaluate incidents, contributing factors and solutions to make facilities safer *(4)*. The most common type of incident was medication or diagnostic error. Lainer et al. highlighted that medication safety is a major concern in primary care, as drug treatment remains the most important clinical process associated with adverse events *(5)*. Webair et al. emphasized that the solution to maintaining a culture of patient safety is to implement a quality management system *(6)*. These findings were drawn on in developing the standards.

The Patient Safety Friendly Primary Care (PSFPC) Framework and rating scale were pilot tested in five primary care facilities, spanning both the public and private sectors. RUMBA principles ensure the criteria are relevant, understandable, measurable, beneficial and achievable.

This edition of the framework will be available in 2022, and primary care facilities can be assessed against the standards from May 2022 onwards.

PSFPC facility assessment

The patient safety standards in the PSFPC Framework are a set of requirements that are critical for the establishment of a patient safety programme at the primary care level. They enable primary care facilities to assess patient care from a patient safety perspective, build capacity of staff in patient safety, and involve patients and the community in improving primary care services.

These standards are applicable to the whole facility, not just a part of it or a specific service it provides. The assessment is voluntary and is conducted through an external peer review survey. The ultimate goal of the framework is to improve the level of patient safety in primary care facilities by creating conditions that lead to safer care, thus protecting patients and the community from avoidable harm and reducing adverse events in primary care settings.

The PSFPC Framework can be used with other patient safety tools and other forms of external evaluation. The difference between this framework and other external evaluation programmes is that it concentrates on patient safety and emphasizes continual improvement rather than an award.

Role of WHO in patient safety friendly primary care

The WHO PSFPC Framework aims to assist primary care facilities within countries to launch a comprehensive patient safety programme. Ultimately, it is hoped that this framework will be owned by primary care facilities in both the public and private sectors as well as by ministries of health. This framework provides the necessary tools for professional associations; regulatory, accrediting or oversight bodies; and ministries of health to help to improve patient safety. Award of a certificate is at the discretion of the national supervising body, such as the ministry of health or an accreditation body. However, primary care facilities can also use this framework to self-assess and use the gap analysis to form a quality improvement programme to enhance patient safety.

Structure of this document

This document is designed for primary care surveyors and facilities. It is organized into three sections: 1) Overview of the PSFPC Framework; 2) PSFPC standards; and 3) PSFPC assessment tools.

Section 1 contains information on how to use the standards, how the surveyors would conduct the assessment, the rating scale and how the level of achievement is calculated.

Section 2 contains the standards, divided into five domains: leadership and management; patient and community involvement; safe, evidence-based clinical practice; safe environment; and lifelong learning. Each domain comprises several standards, 19 in total. Each standard contains a number of criteria, 125 in total. Criteria can be critical, core or developmental and are distributed among the five domains.

Section 3 contains a list of documents that a facility needs to prepare, a set of structured interview questions, guidelines for observations, a sample survey schedule and a report template.

Section 1

Overview of the PSFPC Framework

Primary care facility

All primary care facilities are invited to participate in the PSFPC Framework, whether public or private. Primary care is usually the first point of access the patient has and can be provided in a single facility or a network of facilities.

It is recommended that a small team of surveyors is tasked with working through the self-assessment process. The team will be responsible for collating all the evidence and identifying any areas for particular attention. At the end of this process, the primary care facility will have a gap analysis, including identified actions where further work is required, and a list of documents that demonstrate the facility's compliance with each criterion.

In this document, after each criterion has been defined, a small list of suggested evidence of compliance is presented. This is suggested evidence only, and primary care facilities may decide to present other evidence that demonstrates their compliance. Evidence should be provided for each criterion and must be in English. If any actions are required to achieve better compliance, these should be clearly documented. All evidence of compliance (documents) should be presented in a user-friendly system that the surveyors can easily navigate.

The facility management team is encouraged to inform the public, staff and patients that PSFPC surveyors will be assessing the primary care facility. The survey dates will be known in advance and can be circulated to the team.

Interpreting the standards

All standards have a set of criteria. Each criterion is followed by a list of documents that can be used to validate compliance to the criterion (Table 1). This is not an exhaustive list, as structures and processes differ in different countries, but should be used as a guide to determine how to validate compliance to a criterion. There are certain documents that all health care facilities should submit as part of a PSFPC assessment (see Section 3). These include corporate documents such as strategic and operational plans, policies and procedures and evidence of measurement and audit.

Table 1: Structure of the standards

Domain A. Leadership and management		
A.1. Leadership and management are committed to patient safety		**Evidence of compliance (examples)**
Critical criteria	A.1.1.1	
	A.1.1.2	
	A.1.1.3	
	A.1.1.4	
Core criteria	A.1.2.1	
	A.1.2.2	
	A.1.2.3	
	A.1.2.4	
Developmental criteria	A.1.3.1	
	A.1.3.2	

Critical criteria have been prioritized as issues that must be urgently addressed for a primary care facility to provide safe care. In this edition, there are 30 in total, and all are based on evidence from the literature of common problems that arise in primary care, such as governance, communication, hand hygiene, staff competency and staff training. Addressing all 30 criteria is good place for a primary care facility to start its quality journey (Table 2).

Table 2: The 30 critical criteria

Critical criteria
A.1.1.1. A recognized leadership system is responsible for operating the primary care facility.
A.1.1.2. The leadership has a long-term strategic plan that includes patient safety as a priority.
A.1.1.3. The leadership provides resources, including an annual budget for patient safety activities, which are documented in an action plan.
A.1.1.4. The leadership has an emergency preparedness plan (EPP) that has been tested and communicated to all staff.
A.2.1.1. The leadership ensures that there is a designated qualified senior staff member with responsibility and accountability for patient safety.
A.4.1.1. The leadership ensures the availability of essential functioning equipment and validated supplies.
A.5.1.1. The leadership ensures the provision of sufficient numbers of competent staff to deliver safe patient care at all times.
A.5.1.2. The primary care facility has a defined process to ensure all clinical staff are registered to practise with an appropriate body.
B.2.1.1. Informed consent is obtained before a proposed procedure and/or treatment by trained staff in a manner and language the patient or authorized person can understand.
B.3.1.1. The identification process used throughout the primary care facility requires at least two ways through which to identify a patient.
B.3.1.2. The primary care facility has a system in place to identify and document allergies.
C.1.1.1. The primary care facility conforms to clinical practice guidelines wherever appropriate, including WHO guidelines where available.
C.1.1.2. The primary care facility maintains effective channels of communication throughout the facility, including for urgent critical results.
C.1.1.3. The primary care facility minimizes use of verbal and telephone orders and transmission of results, and “read back” is practised where verbal communication is essential.
C.2.1.1. The primary care facility has a coordinated IPC programme.
C.2.1.2. The primary care facility ensures proper cleaning, disinfection and sterilization of all equipment.
C.3.1.1. The primary care facility has a system to safely manage medications that addresses patient needs, meets applicable regulations and adheres to WHO guidelines.
C.3.1.2. The primary care facility keeps high-alert medications in a safe place.
C.3.1.3. The primary care facility ensures availability of life-saving medications at all times.
C.3.1.4. The cold chain distribution and storage process remains unbroken for temperature-sensitive medications and vaccines.
C.4.1.1. The leadership conducts a gap analysis of existing services and resources.
C.4.1.2. The leadership has an emergency plan in place for the management and control of outbreaks.
C.4.1.3. The primary care facility has communication systems for monitoring, obtaining and circulating information about public health alerts.
C.4.1.4. The primary care facility has additional IPC systems in place for the treatment of infected patients and the prevention of transmission to staff, other patients and the community.
D.1.1.1. The primary care facility implements a fire safety programme with an evacuation plan.
D.2.1.1. The primary care facility has access to clean water, with reserves of at least three days.
D.2.1.2. Functional hand-washing facilities are available at all points of care and within 5 m of a toilet.
D.2.1.3. The primary care facility conforms to guidelines on waste management, including safe storage, transport and disposal of waste.
D.2.1.4. The primary care facility has a process to safely manage health care waste produced by infectious disease outbreaks.
E.1.1.1. All relevant primary care staff are provided with a patient safety orientation programme.

Core criteria are an essential set of standards with which a primary care facility should comply to become safe for patients. It is not compulsory to meet 100% of the core standards for a facility to be involved in the PSFPC improvement programme. However, the percentage of standards complied with determines the level that the primary care facility attains. Furthermore, the percentage of core standards fulfilled is important for internal benchmarking, to document improvement over time.

Developmental criteria are stretch goals that a primary care facility should attempt to comply with, in accordance with its capacity and resources, to enhance safe care.

Rating scale

The critical criteria are rated either as "met" or "not met". Each criterion receives a score of 1 if it is met and 0 if it is not met.

For core and developmental criteria, a three-point rating scale is used. Each criterion receives a score of 1 if it is met, 0.5 if it is partially met, and 0 if it is not met. If a criterion is not applicable as it is not relevant to the clinical services provided by the primary care facility, then “not applicable” is scored, and the criterion is not considered in the final score. An example of a criterion that might not be applicable is D.1.2.9: the primary care facility has a radiation safety policy, including a designated responsible person. If a facility does not provide radiation-based diagnostic imaging services, this criterion would be rated as “not applicable”. The rating scale is applied at the level of each criterion, not at the standard level.

The PSFPC Framework uses a peer review methodology. Therefore, rating requires experience on the part of the survey team. Ratings should be agreed by the whole survey team. The surveyors should be trained to be able to triangulate data from various sources: First, by reviewing documents, some of which will be reviewed before going on site. Second, by interviewing key members of staff, patients and the community. Finally, by observing the environment and clinical care. All this evidence and the surveyors’ experience are used to determine the final rating and ultimate achievement level.

When applying a rating, the rationale and guidance shown in Table 3 should be used. If necessary, details of the improvements required to achieve a higher rating should be added.

Table 3: Rationale and guidance for ratings

Rating	Score	Rationale	Surveyor action
Met	1	80% or above compliance	Add a recommendation or an opportunity for improvement
Partially met	0.5	31–79% compliance	Add an opportunity for improvement or a recommendation to assist the facility in improving
Not met	0	Less than 30% compliance	Add recommendation and time scale

Survey

The on-site survey team and length of survey will vary according to the profile of the primary care facility (e.g. size, services, locations). However, a consistent approach will be applied to all similar types of facility. Survey teams may have two to three surveyors, depending on the size of the facility and its activities. Survey teams should have a member who is an experienced surveyor with the required competencies to lead the team. The team should comprise a mixture of corporate and clinical expertise.

A schedule of daily activities should be prepared by the country-level facilitator and agreed by the team leader and should be sent in advance of the survey to the facility for its input. The survey will span one to two days.

At the end of each survey, the survey team will discuss the high-level findings with the primary care team. This will be followed by a report and recommendations to aid the primary care facility in making improvements in patient safety. The report will be confidential and constructive and should be used as part of a facility-wide quality improvement programme to improve patient safety. The results of the survey may be made public or remain confidential, at the discretion of the facility management.

Surveyors

Surveyors will be selected by the WHO Regional Office and by the relevant ministry of health or other agency using the framework. All surveyors must be trained in the PSFPC Framework before they can survey at a national level. The role of the survey team is to validate the primary care facility's compliance with the standards in the PSFPC Framework and provide constructive feedback on how to improve. The PSFPC Framework uses a peer review methodology and a philosophy of continual improvement through support and learning. Therefore, the selection of appropriate surveyors is crucial to the success of the framework.

The criteria listed below should be used for the selection of surveyors.

- Experts in the field, with at least 10 years of working experience and graduate studies combined (medicine, governance, nursing and health management).
- Knowledge of the PSFPC standards and survey methodology.
- Knowledge and understanding of:
  - health care systems
  - health care education
  - patient safety methods
  - regulation, accreditation and quality improvement.
- Analytical skills – effective information-handling; understanding and absorbing complex information; decision-making based on evidence; thorough understanding of primary care audit.
- Cultural awareness – demonstrating sensitivity to and understanding of cultural, religious and demographic diversity.
- Professionalism – adhering to high personal ethical standards; prioritizing patient safety; maintaining confidentiality, impartiality and objectivity; being enthusiastic, motivated and committed.
- Interpersonal and communication skills – working collaboratively in a team; working constructively and respecting the views and contributions of others; interacting effectively with colleagues and patients; communicating effectively and courteously.
- Fluent in spoken and written English.
- Good time management.

The criteria listed below should be used for the selection of team leaders, in addition to the criteria above.

- Previous experience of external evaluation surveys in health care or education.
- Team member of at least two previous Patient Safety Friendly Hospital Framework or PSFPC Framework surveys.
- Previous experience leading an external evaluation survey team or similar.
- Ability to chair and lead.
- Conflict management skills.

Assessing and maintaining level of achievement

Primary care facilities are scored as patient safety friendly based on four levels of compliance, with Level 4 representing the highest attainable level (Table 4).

Table 4: Level of compliance based on criteria met

Primary care level	Critical criteria met	Core criteria met	Developmental criteria met
Level 1	100%	Any	Any
Level 2	100%	60–89%	Any
Level 3	100%	≥ 90%	≥ 20%
Level 4	100%	> 90%	≥ 80%

The level of achievement is calculated in three stages.

1. Have all critical criteria achieved a rating of "met"? If yes:

2. What is the percentage of compliance with the core criteria?

3. What is the percentage of compliance with the developmental criteria?

The percentage of compliance is calculated by adding the scores for all criteria within the category (core or developmental) and then dividing by the total number of criteria in that category. If a criterion is deemed not applicable by both the facility and the survey team, that criterion is not considered in the final score.

To calculate the percentage of compliance with the core criteria, each criterion should be scored 1, 0.5 or 0 (corresponding to met, partially met or not met). Assuming that all criteria have been included (none designated "not applicable"), the total numerical score should then be divided by 78.

To calculate the percentage of compliance with the developmental criteria, each criterion should be scored 1, 0.5 or 0 (corresponding to met, partially met or not met). Assuming that all criteria have been included (none designated "not applicable"), the total numerical score should then be divided by 17.

Example: Primary care facility 1

- All 30 critical criteria have achieved full compliance.
- The total score for core criteria is 68:
  - 68/78 = 87%
- The total score for developmental criteria is 5:
  - 5/17 = 30%
- Primary care facility 1 has achieved Level 2.

Example: Primary care facility 2

- All 30 critical criteria have achieved full compliance.
- The total score for core criteria is 73:
  - 73/78 = 93%
- The total score for developmental criteria is 14:
  - 14/17 = 82%
- Primary care facility 2 has achieved Level 4.

Once a primary care facility is recognized for its achievement in PSFPC standards, it is important that this compliance is maintained. Internal evaluation is suggested on a quarterly basis; in addition, external evaluation is suggested on a two-year basis for Level 1 and 2 primary care facilities and on a three-year basis for Level 3 and 4 primary care facilities.

Expansion at national level

Following an initial baseline assessment of one primary care facility, selected by the ministry of health, the following steps are suggested for national expansion.

- The ministry of health expresses commitment to and ownership of the PSFPC programme and selects up to 10 primary care facilities to participate in a launch and training workshop. Each primary care facility is approached by the ministry of health with a briefing on the programme and a description of the process, with emphasis on its key objective, which is to advance patient safety.
- Each primary care facility management assigns a task force, including a nurse and an administrator.
- A workshop on the PSFPC Framework is held.
- The baseline assessment in each of the participating primary care facilities is initiated. Surveyors from the survey team in one primary care facility perform the assessment in another primary care facility.
- The results of the baseline assessment are summarized in a report for each primary care facility (using the report template, provided on page 51). Reports are shared with policy-makers at the ministry of health.
- The results are shared with each primary care facility, and the facility is provided with key suggestions and recommendations for improvement. Technical support materials can also be provided by the WHO Regional Office. The primary care facilities are notified that they will be reassessed after nine months and are assisted in drafting an action plan.
- A workshop is held at the national level to share the results and raise more interest nationwide.

Section 2

PSFPC standards

Introduction

This section contains the detailed standards of the PSFPC Framework. Table 5 shows the number of standards in each of the five domains, along with the number of critical, core and developmental criteria for each standard.

Each standard, with its specific criteria, is detailed individually in a separate table, which also contains guidance on the key evidence of compliance for each criterion.

Table 5: Overview of the standards

Domains	Critical criteria	Core criteria	Developmental criteria	Total criteria in each domain
A. Leadership and management (7 standards: A1–A7)	8	23	6	37
B. Patient and community involvement (4 standards: B1–B4)	3	14	3	20
C. Safe, evidence-based clinical practice (4 standards: C1–C4)	13	25	6	44
D. Safe environment (2 standards: D1–D2)	5	13	1	19
E. Lifelong learning (2 standards: E1–E2)	1	3	1	5
Total	**30**	**78**	**17**	**125**
Total domains: 5. Total standards: 19. Total criteria: 125.				

Domain A: Leadership and management

Explanatory notes

Leadership and management are essential components of a patient safety framework. While primary care can be provided in one clinic or a network of facilities, the principles of governance remain the same. A clear understanding of responsibilities and accountabilities lead to role clarity and will support the implementation of appropriate policies.

Domain A evaluates the leadership's commitment to patient safety and what resources – human, financial, equipment and information management – are made available to support a patient safety programme. Risk management is also included as it is a significant part of any patient safety framework and should include a reporting system. A robust communication policy can mitigate a number of adverse events, and both internal and external systems should be in place.

A workplace health and safety programme is concerned with protecting the safety, health and welfare of people employed in the practice. Staff should be aware of their rights and responsibilities in relation to welfare at work.

Domain A: Leadership and management

Standards	Number of criteria		
	Critical	Core	Developmental
A.1. Leadership and management are committed to patient safety.	4	4	2
A.2. The primary care facility has a patient safety programme.	1	4	2
A.3. The primary care facility uses data to improve safety performance.	0	2	1
A.4. The primary care facility has essential functioning equipment and supplies to deliver its services.	1	3	0
A.5. The leadership ensures the provision of competent staff, including independent practitioners and volunteers, to deliver safe care at all times.	2	1	0
A.6. The primary care facility has an information management system to support safe practices.	0	4	1
A.7. The primary care facility supports a work health and safety programme.	0	5	0
	8	**23**	**6**

A.1. Leadership and management are committed to patient safety

Type of criteria	Criteria	Evidence of compliance (examples)
Critical criteria	A.1.1.1. A recognized leadership system is responsible for operating the primary care facility.	• Organization chart that shows supervision and reporting relationships for all staff and all areas • Documented roles and responsibilities or job descriptions of the primary care manager and/or clinical leads *Note:* Leader may have different titles: manager, medical officer, etc.
	A.1.1.2. The leadership has a long-term strategic plan that includes patient safety as a priority.	• Two- or three-year action plan • Yearly deliverables • Long- and short-term patient safety goals • Population needs of the community identified
	A.1.1.3. The leadership provides resources, including an annual budget for patient safety activities, which are documented in an action plan.	• Action plan • Primary care budget showing designated line for patient safety • Financial resources for: – IPC – staff training
	A.1.1.4. The leadership has an emergency preparedness plan (EPP) that has been tested and communicated to all staff.	• An EPP that documents the risk management, preparations and action to be taken for any situation that causes disruption to the normal functioning of the practice. This includes internal and external emergencies such as: – pandemic and disease outbreaks, such as COVID-19 – natural disasters – internal emergencies, such as power outage, data breech, fire or floods • Evidence of: – testing at least annually – service continuity plans More information is available at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications

Type of criteria	Criteria	Evidence of compliance (examples)
Core criteria	A.1.2.1. The leadership works with the local community to ensure implementation of local and national patient safety programmes.	• List of relevant local or national patient safety programmes; for example: – hand hygiene – use of antibiotics – vaccinations – antenatal and postnatal home visits • Community outreach activities • Public health warnings • Health promotion campaigns • Awareness-raising of risks of smoking
	A.1.2.2. The leadership promotes a culture of patient safety at the practice and community level.	• Evidence of celebrating WHO's: – World Hand Hygiene Day, 5 May – World Patient Safety Day, 17 September • Other patient safety community campaigns • Reports and actions taken • Feedback to staff and community leaders
	A.1.2.3. The leadership measures the culture of patient safety every two years.	• Process to assess patient safety culture, every two years, using a questionnaire (for example, the Agency for Healthcare Research and Quality questionnaire on patient safety culture). • Process to assess patient safety culture before and during patient safety programme implementation
	A.1.2.4. The leadership develops and implements a process to ensure the effectiveness of internal communication.	• Communication strategy for: – staff – primary care network – community – public health regional bodies – provincial and other bodies • Mediums of communication – staff meetings – electronic communication – SMS – religious or tribal leaders
Developmental criteria	A.1.3.1. The primary care facility has mission, vision and value statements that demonstrate a culture of patient safety.	• Detailed short-term action plan for facility level, based on higher level (state/district) strategic plan, with mission, vision and value statements. • Evidence of patient safety within statements
	A.1.3.2. The primary care facility's long-term plans are formed through consultation with patients and stakeholders.	• Evidence of community involvement in the planning of services.

A.2. The primary care facility has a patient safety programme

Type of criteria	Criteria	Evidence of compliance (examples)
Critical criteria	A.2.1.1. The leadership ensures that there is a designated qualified senior staff member with responsibility and accountability for patient safety.	• Job description for patient safety officer or coordinator or equivalent • Designated person responsible for IPC • Organization structure
Core criteria	A.2.2.1. The primary care facility has access to a patient safety expert committee to guide all safety and risk within the facility.	• Terms of reference of the committee for safety and risk management • Members of committee include community representatives • Minutes of bi-monthly meetings
	A.2.2.2. The patient safety officer or medical officer develops a schedule of audits and uses the results to improve primary care services.	• A schedule of safety audits appropriate to the size of the facility • Evidence of clinical and environmental assessments, including PSFPC • Improvements that have been implemented based on findings • Reports delivered to staff every six months
	A.2.2.3. The patient safety officer or medical officer develops a risk management programme used to identify, assess and reduce adverse events, medication errors and other patient safety issues.	• Risk management programme comprising a plan and policy for implementation • Risk register that includes a list of all risks that are prioritized, the person assigned responsibility, and a relevant mitigation plan
	A.2.2.4. The patient safety officer or medical officer develops reports on different safety and risk activities and disseminates them internally.	• Reporting system for adverse events and near misses • Audit results • Patient feedback • PSFPC self-assessment and surveyor reports • Adverse incident reports • Complaints
Developmental criteria	A.2.3.1. The patient safety officer or medical officer develops reports on different safety activities and disseminates them externally.	• Reports on different patient safety activities, disseminated externally to ministry of health (as well as WHO and/or patient safety organizations) • PSFPC survey reports benchmarked against other primary care facilities
	A.2.3.2. The primary care facility has an open disclosure policy and gives feedback on incidents to staff, patients and their relatives.	• Policies on: – open disclosure – collecting feedback • Feedback reports to: – patients/community – staff

A.3. The primary care facility uses data to improve safety performance

Type of criteria	Criteria	Evidence of compliance (examples)
Core criteria	A.3.2.1. The patient safety officer or medical officer measures outcome of care to assess performance, with a special focus on patient safety.	• Patient safety goals • Targets related to patient safety goals • Key performance indicators
	A.3.2.2. The patient safety officer or medical officer acts on results of audits, measures and feedback by implementing patient safety improvement projects.	• Patient safety action plan or quality improvement projects • Reports to leadership • Reports to staff
Developmental criteria	A.3.3.1. The primary care facility compares its patient safety indicator data over time with other PSFPC facilities.	• Reports that benchmark data over time, showing correlation to best international practice and/or other PSFPC Framework participants

A.4. The primary care facility has essential functioning equipment and supplies to deliver its services

Type of criteria	Criteria	Evidence of compliance (examples)
Critical criteria	A.4.1.1. The leadership ensures the availability of essential functioning equipment and validated supplies.	• Process to identify what essential equipment and supplies are required to provide the patient services offered • Asset register for all equipment • Availability of resuscitation equipment • Recall system
Core criteria	A.4.2.1. The primary care facility has a preventive maintenance programme (PMP) to inspect and test all equipment.	• Documented PMP with designated responsible person • Procedures for preventive maintenance of equipment, including tests • Schedule for routine tests and calibration of machines • Preventive equipment maintenance reports
	A.4.2.2. The primary care facility has a system in place to repair or replace broken equipment, including recalls or hazard notices.	• Procedures to replace equipment • Policy to communicate hazard notices to the relevant staff
	A.4.2.3. The primary care facility ensures that staff receive appropriate training for all essential equipment, including resuscitation and other medical devices.	• Training logs that include use of and maintenance of: – resuscitation equipment – medical devices • Evidence that only trained and competent staff handle specialized equipment

A.5. The leadership ensures the provision of competent staff, including independent practitioners and volunteers, to deliver safe care at all times

Type of criteria	Criteria	Evidence of compliance (examples)
Critical criteria	A.5.1.1. The leadership ensures the provision of sufficient numbers of competent staff to deliver safe patient care at all times.	• Human resource plan that identifies numbers, types and qualifications of staff, appropriate for services provided • Designated person responsible for human resource planning • Designated person responsible for IPC – full- or part-time depending on size of facility
	A.5.1.2. The primary care facility has a defined process to ensure all clinical staff are registered to practise with an appropriate body.	• Policies for validating and recording staff qualifications and licences, including designated responsible person • Personnel files with evidence of staff qualifications, professional registrations and licences (registration to practise with an appropriate body).
Core criteria	A.5.2.1. The primary care facility has a system in place to monitor ongoing competency levels for all health care professionals.	• Evidence-based, structured process to monitor competency of all health care professionals, based on qualifications and experience, to provide clinical and technical services and procedures • Terms of reference for medical staff or other relevant committees • Minutes of medical staff committee meetings

A.6. The primary care facility has an information management system to support safe practices

Type of criteria	Criteria	Evidence of compliance (examples)
Core criteria	A.6.2.1. The primary care facility has a process to control all documents and procedures in a consistent manner.	• Policy for development of policies • Template for consistent policies • Document control system
	A.6.2.2. The primary care facility maintains a standardized medical record, with a unique identifier, for every patient.	• Policies on: – content of medical records – generation of unique patient identifier • Validation of patient identification • Audit of: – completeness of medical records – legibility of handwriting
	A.6.2.3. On presentation, a full examination is conducted and treatment plan is recorded in the patients' medical records.	• Medical chart audits
	A.6.2.4. The primary care facility ensures that medical records are secure and easily accessed by care providers whenever needed.	• Audit on availability of medical records
Developmental criterion	A.6.3.1. The primary care facility has an automated information management and electronic medical records system with an appropriate backup system.	• Structure of automated information management system • Policies on creation, management and control of electronic medical records

A.7. The primary care facility supports a work health and safety programme

Type of criteria	Criteria	Evidence of compliance (examples)
Core criteria	A.7.2.1. The primary care facility provides an occupational health and safety orientation programme that addresses staff health and safe working conditions.	• Occupational health and staff safety programme. • Orientation and training on: – fire safety – needlestick injuries – IPC measures to prevent COVID-19 infections among health care workers – safety practices (standard and transmission-based precautions, use of personal protective equipment (PPE), hand hygiene, etc. – security
	A.7.2.2. An ongoing occupational health programme is implemented for all staff.	• Occupational health programme, including: – ongoing workplace assessments – mental health supports – immunizations – personnel records with evidence of occupational health records
	A.7.2.3. Staff are allowed sufficient rest breaks, particularly in 24/7 primary care facilities, to enable them to practise safely and to ensure the facility adheres to national labour laws.	• Policies and procedures for clinical staffing level • Duty rosters for clinical staff, where applicable • Compliance with national labour laws and regulations • Policies and procedures for sufficient rest breaks to enable staff to practise safely
	A.7.2.4. The primary care facility has systems in place to ensure safe injection practice.	• Policies for: – sharps management. – management of needlestick injury – waste management – post-exposure management More information is available at: https://www.who.int/teams/integrated-health-services/infection-prevention-control/injection-safety
	A.7.2.5. The primary care facility has a workplace violence prevention programme.	• Policy on prevention of violence in the workplace

Domain B: Patient and community involvement

Explanatory notes

Domain B evaluates whether patients are aware of their rights. The aim here is to ensure the primary care facility has a people-centred focus, including providing the right information to enable patients/people to make informed decisions about the services they receive.

The views of patients should be sought and analysed. Sources of this information include complaints, compliments and patient feedback surveys. The facility's feedback system needs to be transparent, and the information should be used to make improvements.

Primary care facilities are, for most people, the primary entry point to health care and therefore have a crucial role in promoting health and preventing illness. Patients should be provided with instructions that are clear and relevant to their ethnicity.

Domain B. Patient and community involvement

Standards	Number of criteria		
	Critical	Core	Developmental
B.1. The primary care facility has a programme to protect the rights of patients that includes patient safety.	0	5	0
B.2. The primary care facility builds health awareness in its patients and carers to empower them to share in making the right decisions regarding their care.	1	6	1
B.3. The primary care facility ensures proper patient identification and verification at all stages of care.	2	1	1
B.4. The primary care facility encourages feedback from patients and acts on the patients' concerns and compliments.	0	2	1
	3	**14**	**3**

B.1. The primary care facility has a programme to protect the rights of patients that includes patient safety

Type of criteria	Criteria	Evidence of compliance (examples)
Core criteria	B.1.2.1. The primary care facility has a patient rights statement that is accessible to all patients, families and carers.	• Patient rights statement that is: – visible to patients and carers throughout the primary care facility – documented and approved – supported by policies and procedures
	B.1.2.2. Patient safety is included in the patient rights statement.	• Inclusion of patient safety in the patient rights statement; patient safety includes: – safe care – a safe and secure environment – a clean facility – competent staff
	B.1.2.3. The primary care facility informs patients about their responsibilities while receiving care.	• Patient information leaflets detailing patients' responsibilities in relation to: – safe use of medications – health promotion – follow-up on treatments
	B.1.2.4. The primary care facility has a documented process to deal with patient refusal of treatment.	• Policy and form for patients to sign if they refuse treatment against medical advice
	B.1.2.5. Patients are aware of the process for providing feedback, either positive or a complaint.	• Complaints policy • Comment boxes • Random sample of feedback on how complaints were managed and the changes that have taken place to prevent recurrence of the incident • Feedback to patients at conclusion of complaint • Sharing of correct information

B.2. The primary care facility builds health awareness in its patients and carers to empower them to share in making the right decisions regarding their care

Type of criteria	Criteria	Evidence of compliance (examples)
Critical criteria	B.2.1.1. Informed consent is obtained before a proposed procedure and/or treatment by trained staff in a manner and language the patient or authorized person can understand.	• Policies and procedures for informed consent that include guidance on: – procedures and treatments for which informed consent is necessary – information to be given to the patient, ensuring all risks, benefits and potential side-effects are explained in advance of the procedure and any sedation – how to measure compliance with informed consent policies and procedures • Systematic review of random sample of medical records: informed consent form is completed, signed, dated and timed and is available in patient's medical records
Core criteria	B.2.2.1. The primary care facility provides education that supports patient and family participation in care decisions.	• Educational material including patient information leaflets or posters • Minutes of disease-specific support group meetings with signatures of attendance by patients (and families, where appropriate) • Policies and procedures for health promotion
	B.2.2.2. All patients obtain from their treating clinicians/ health workers complete updated information on their diagnosis and treatment.	• Information leaflets • Copy of care pathway
	B.2.2.3. The primary care facility provides health promotion and preventive services based on the population it serves.	• Systems used to identify risk factors for illnesses that are particularly prevalent in the primary care facility's local community (e.g. cardiovascular disease, maternal and child health, infectious diseases) • Restricted use of antibiotics prescribing • Hand hygiene campaigns • Information on warning signs and symptoms of cancer • Information on harmful effects of smoking
	B.2.2.4. Education methods take into account the patient's culture, language and health literacy level and the functional needs of patients with disabilities.	• Policy on health literacy • Information leaflets in different languages • Interpretation service
	B.2.2.5. Patients are made aware of and encouraged to use their voice in relation to the WHO Global Patient Safety Challenges.	• Examples of WHO Global Patient Safety Challenges are: – Clean Care is Safer Care (hand hygiene) – Medication Without Harm (5 Moments for Medication Safety)
	B.2.2.6. The primary care facility provides patient safety advice to patients and the community through multiple mediums.	• Patient access to primary care facility website • Information leaflets • Social media campaigns • Hand hygiene campaigns in the community
Developmental criteria	B.2.3.1. The primary care facility conducts a population needs and resources analysis of disease prevalence and health care needs within the community it serves.	• Design of health promotion based on results of population analysis • Co-ordination with other facilities in the district or region

B.3. The primary care facility ensures proper patient identification and verification at all stages of care

Type of criteria	Criteria	Evidence of compliance (examples)
Critical criteria	B.3.1.1. The identification process used throughout the primary care facility requires at least two ways through which to identify a patient.	• Policies and procedures for patient identification and verification, including two identifiers, which are known to the patient • The patient identifiers include full name of patient (to third generation of family), date of birth, photograph and primary care number/unique identification number
	B.3.1.2. The primary care facility has a system in place to identify and document allergies.	• Policies and procedures for identification of allergies • System in place to alert regarding allergies
Core criteria	B.3.2.1. The patient's rights to privacy and confidentiality of care and information are respected.	• Policies on: – storage of medical records – restricted access to patient data
Developmental criteria	B.3.3.1. The primary care facility uses bar coding for patient identification.	• Policy on using bar coding to identify patients while administering medications

B.4. The primary care facility encourages feedback from patients and acts on the patients' concerns and compliments

Type of criteria	Criteria	Evidence of compliance (examples)
Core criteria	B.4.2.1. The primary care facility has structures and processes in place to ensure patients' opinions are heard and acted on.	• A system for handling feedback from patients, comprising: – comment boxes – focus groups – questionnaires – analysis of complaints – actions from feedback – scheduled activities
	B.4.2.2. The primary care facility informs patients about how feedback has been used to improve services.	• Patient feedback reports • Changes to services
Developmental criteria	B.4.3.1. The primary care facility has structures in place to ensure feedback is sought from the community and acted on.	• Feedback from community meetings

Domain C: Safe, evidence-based clinical practice

Explanatory notes

Clinical/primary care governance is evaluated in Domain C. Clinical guidelines provide important recommendations for patient care and must be accessible to practitioners. IPC and medication management are two patient safety issues that require specific attention at the primary care level; each have a standard in Domain C.

Standard C.4 is dedicated to the role of primary care in the prevention and control of infectious disease outbreaks. The sudden outbreak of COVID-19 meant primary care facilities had to rapidly adapt existing emergency plans to manage services and reduce the transmission of infection. Criteria in this standard include the importance of forward planning, transparent communication, telephone triage, IPC, staff training and targeted testing. It is important that despite the pressure caused by outbreaks on primary care facilities, essential services continue during this time. Building relationships with other facilities to avoid duplication of services can help maximize resources.

Domain C. Safe, evidence-based clinical practice

Standards	Number of criteria		
	Critical	Core	Developmental
C.1. The primary care facility has effective clinical auditing and oversight that ensures inclusion of patient safety.	3	4	1
C.2. The primary care facility has a functional IPC programme to reduce the risk of health care associated infections.	2	6	1
C.3. The primary care facility has a safe medication system.	4	5	1
C.4. In the event of an infectious disease outbreak, the primary care facility has systems in place to manage and control the emergency.	4	10	3
	13	**25**	**6**

C.1. The primary care facility has effective clinical auditing and oversight that ensures inclusion of patient safety

Type of criteria	Criteria	Evidence of compliance (examples)
Critical criteria	C.1.1.1. The primary care facility conforms to clinical practice guidelines wherever appropriate, including WHO guidelines where available.	• Clinical practice guidelines based on the top five diagnoses and top five high-risk diseases specific to the local community, including WHO guidelines where available • Availability of these and other clinical guidelines • Implementation of guidelines, protocols and checklists relevant to safety
	C.1.1.2. The primary care facility maintains effective channels of communication throughout the facility, including for urgent critical results.	• Communication strategy with: – staff – public – other primary care facilities – national databases • Process for communicating routine and urgent critical results • Use of information technology

Type of criteria	Criteria	Evidence of compliance (examples)
	C.1.1.3. The primary care facility minimizes use of verbal and telephone orders and transmission of results, and "read back" is practised where verbal communication is essential.	• Policies for use of verbal telephone orders, including: – restricting their use – ensuring read back is available
Core criteria	C.1.2.1. The primary care facility manages and coordinates services and programmes to meet the needs of patients and to support safe positive outcomes.	• Range of services is based on the population the facility serves, examples include: – child welfare and vaccination clinics – reproductive health – safe childbirth – developmental clinics – health checks – cancer screening – treatment and prevention of noncommunicable diseases
	C.1.2.2. The primary care facility has systems in place to ensure safe communication of test results to patients and care providers.	• Policies and procedures to ensure safe communication of test results to patients and care providers after discharge • Use of information technology • Use of SMS alerts
	C.1.2.3. The primary care facility maintains a list of approved abbreviations, including symbols and dose designations, for use in primary care.	• List of approved abbreviations
	C.1.2.4. The primary care facility has access to a clinical guidelines committee to ensure the development or adoption of validated clinical guidelines.	• Policies to: – adopt and circulate validated policies – prioritize clinical guidelines, checklists and policies to be developed • Terms of reference for multidisciplinary clinical guidelines committee
Developmental criteria	C.1.3.1. The primary care facility evaluates the effectiveness of its communication strategy on an annual basis.	• Communication strategy • Schedule of communication audits • Results and action plans

C.2. The primary care facility has a functional IPC programme to reduce the risk of health care associated infections

Type of criteria	Criteria	Evidence of compliance (examples)
Critical criteria	C.2.1.1. The primary care facility has a coordinated IPC programme.	• Adherence to WHO's core components guidelines and minimum requirements for IPC • Trained IPC link person, with dedicated time in each primary health care facility • Evidence-based, facility-adapted standard operating procedures (SOPs) based on the national IPC guidelines • IPC training for all front-line clinical staff and cleaners upon hiring • Reporting and alert of outbreaks and health care associated infection surveillance according to national or subnational plans • Multimodal prevention strategies for priority IPC interventions • Monitoring of IPC structural and process indicators, based on IPC priorities identified in the other components • Appropriate systems to reduce overcrowding in the facility and optimize staffing levels • Sufficient and appropriate IPC supplies and equipment More information is available at: https://www.who.int/teams/integrated-health-services/infection-prevention-control/core-components

Type of criteria	Criteria	Evidence of compliance (examples)
	C.2.1.2. The primary care facility ensures proper cleaning, disinfection and sterilization of all equipment.	• Policies for cleaning, disinfection and sterilization of equipment • Adherence to WHO's core components guidelines and minimum requirements for IPC More information is available at: https://www.who.int/teams/integrated-health-services/infection-prevention-control/core-components
Core criteria	C.2.2.1. The primary care facility conforms to evidenced-based guidelines for IPC.	• Guidelines for: – hand hygiene – respiratory hygiene – safe injection – environment cleaning – health care waste management – staff welfare and protection – aseptic techniques – triage of infectious patients Available at: https://www.who.int/teams/integrated-health-services/infection-prevention-control/core-components Strengthening IPC in primary care available at: https://www.who.int/publications/i/item/9789240035249 IPC in primary care toolkit of resources: https://www.who.int/publications/i/item/9789240037304
	C.2.2.2. The primary care facility ensures continuous availability of essential, functioning IPC equipment and supplies.	• Policies and procedures for IPC equipment and supplies, including: – PPE – cleaning and disinfection material – sterilization material – hand hygiene (alcohol-based hand sanitizer or hand washing)
	C.2.2.3. The primary care facility implements policies and procedures for the rational use of antibiotics to reduce resistance.	• Policies and procedures for rational use of antibiotics to reduce resistance • Training records of staff trained in policies and procedures for rational use of antibiotics and antimicrobial stewardship More information available at: https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance
	C.2.2.4. The primary care implements recognized guidelines for hand hygiene, including WHO guidelines.	• Recognized guidelines for hand hygiene, including *A guide to the implementation of the WHO multimodal hand hygiene improvement strategy* and: – 5 Moments for Hand Hygiene – How to Handwash Available at: https://apps.who.int/iris/handle/10665/70030 https://www.who.int/campaigns/world-hand-hygiene-day
	C.2.2.5. Staff are screened before employment and, as best practice indicates, afterwards for colonization and transmissible infections.	• Staff health records • Staff screening policy and procedures
	C.2.2.6. The primary care facility acts to protect staff from health care associated infections, including by provision of hepatitis B vaccination.	• Policies and procedures for protection of staff and volunteers from health care associated infections
Developmental criteria	C.2.3.1. Patients and the community are involved in hand hygiene campaigns.	• Process to involve patients • Examples of community campaigns for hand hygiene

C.3. The primary care facility has a safe medication system

Type of criteria	Criteria	Evidence of compliance (examples)
Critical criteria	C.3.1.1. The primary care facility has a system to safely manage medications that addresses patient needs, meets applicable regulations and adheres to WHO guidelines.	• Medication safety programme • Patient information leaflets
	C.3.1.2. The primary care facility keeps high-alert medications in a safe place.	• Policies and procedures for removal of high concentrations of electrolytes, including potassium chloride, potassium phosphate and sodium chloride, from service areas and storage in a safe place
	C.3.1.3. The primary care facility ensures availability of life-saving medications at all times.	• Availability of life-saving medications based on needs of the facility
	C.3.1.4. The cold chain distribution and storage process remains unbroken for temperature-sensitive medications and vaccines.	• Availability of refrigeration • Quality control process for fridges and medications • List of temperature-sensitive medications, such as: – vaccines – insulin
Core criteria	C.3.2.1. The primary care facility ensures legible handwriting when prescribing or writing physicians' orders.	Policies and procedures to ensure legible handwriting when prescribing or writing physicians' orders.
	C.3.2.2. The primary care facility ensures medication reconciliation at every visit.	• Safe medication policies and procedures that cover: – all transitions of care – polypharmacy and prescribing – advice from clinical pharmacist
	C.3.2.3. The primary care facility ensures patient (or carer) education about medication.	• Process to educate patients and their carers about efficient and safe use of medication, any expected side-effects, potential interaction with other drugs and/or food, and pain management • Medical records that reveal patient (or carer) education about medication • Policies and procedures for patient (or carer) education about medication at discharge • Implementation of WHO's 5 Moments for Medication Safety
	C.3.2.4. The primary care facility standardizes and limits the number of medication concentrations.	• Process to standardize and limit the number of medication concentrations throughout the primary care facility, with special emphasis on: – labelling and storage of high- risk medications, such as potassium chloride, heparin and insulin – labelling and storage of look-alike, sound-alike medicines (LASA) – disposal of unused or expired medications
	C.3.2.5. The primary care facility has a policy and procedure to manage medication errors.	• Policy and procedure to manage medication errors
Developmental criteria	C.3.3.1. The primary care facility has access to a clinical pharmacist or dispenser to support its medication management system.	• Availability of clinical pharmacist or dispenser or clear guidance document for remote contact if such personnel are not available on site

C.4. In the event of an infectious disease outbreak, the primary care facility has systems in place to manage and control the emergency

Type of criteria	Criteria	Evidence of compliance (examples)
Critical criteria	C.4.1.1. The leadership conducts a gap analysis of existing services and resources.	• Documentation of gap analysis that includes: – risk analysis – assessment of surge capacity – mapping of vulnerable populations
	C.4.1.2. The leadership has an emergency plan in place for the management and control of outbreaks.	• Emergency plan for the management and control of outbreaks • Hand hygiene practices • Triage of patients
	C.4.1.3. The primary care facility has communication systems for monitoring, obtaining and circulating information about public health alerts.	
	C.4.1.4. The primary care facility has additional IPC systems in place for the treatment of infected patients and the prevention of transmission to staff, other patients and the community.	More information is available at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/infection-prevention-and-control/
Core criteria	C.4.2.1. The primary care facility uses WHO guidelines to investigate cases and clusters and to refer for isolation, contact tracing and quarantine of contacts.	• Adherence to guidelines, including: – surveillance to detect case within 48 hours of onset of symptoms – testing with 24 hours of detection – follow-up of patients More information available at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications
	C.4.2.2. The primary care facility reports notifiable infectious diseases to the relevant authority; cases are confirmed by laboratory.	• Policy on management of notifiable diseases
	C.4.2.3. The primary care facility has access to a competent laboratory with the capacity to provide services based on WHO guidelines.	• Use of accredited or government-approved laboratory services • Specimen collection and procedures that adhere to WHO guidelines and are functional. More information is available at: https://apps.who.int/iris/handle/10665/331509
	C.4.2.4. The primary care facility increases community awareness and education on preventive public health measures, respiratory etiquette, hand hygiene and physical distancing.	• Brochures or posters to increase public awareness More information is available at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/guidance-for-schools-workplaces-institutions/
	C.4.2.5. The primary care facility has systems in place to manage staff welfare during an outbreak.	• Use of health worker safety monitoring and reporting systems, such as key performance indicators

Type of criteria	Criteria	Evidence of compliance (examples)
	C.4.2.6. The primary care facility's physical environment can be adapted to adhere to WHO guidelines to reduce the spread of the disease.	More information is available at: https://www.who.int/publications/i/item/WHO-HIS-SDS-2018.10 https://apps.who.int/iris/handle/10665/96340
	C.4.2.7. The primary care facility has a system for telephone triage to advise patients of the most suitable treatment.	
	C.4.2.8. The primary care facility has processes in place to identify vulnerable groups within the community that may require extra support.	• Process to identify vulnerable groups, which could include: – the elderly – pregnant people – care and residential home residents – residents in densely populated settings (e.g. refugee camps) – people experiencing homelessness – humanitarian settings
	C.4.2.9. The primary care facility has essential supplies or the capacity to quickly increase access to the necessary resources and equipment.	• Procurement policy • Stock control policy • Knowledge of market access • WASH procedures • Adequate PPE supplies • Availability of soap and hand sanitizer • Availability of cleaning materials
	C.4.2.10 The primary care facility identifies and maintains essential health services that must continue during an outbreak.	• Encourage patients to continue to seek treatment for essential non-outbreak services, such as: – newborn welfare – antenatal care More information is available at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/maintaining-essential-health-services-and-systems
Developmental criteria	C.4.3.1 There are systems in place for primary care facilities to work across organisational boundaries to manage pressure points and deliver essential services.	• Liaise with communities • Data sharing • Patient record sharing
	C.4.3.2 The primary care facility can establish a monitoring system based on indicators as defined in the COVID-19 Monitoring and Evaluation (M&E) Framework.	• The COVID-19 M&E Framework lists key public health and essential health services and systems indicators to monitor preparedness, response, and situations during the COVID-19 pandemic Available at: https://www.who.int/publications/i/item/monitoring-and-evaluation-framework
	C.4.3.3 The primary care facility can support the requirements of special needs patients during an outbreak.	• Communications such as lip reading if face masks are used • Use of interpreters • Wheelchair access

Domain D: Safe environment

Explanatory notes

Domain D evaluates whether the primary care facility's physical environment is fit for purpose and supports safe services. Fire safety, security and planned preventive maintenance programmes (PMPs) are some of the topics covered. Whether the facility takes into account environmental sustainability when managing and using its supplies should also be considered.

Providing a safe environment is dependent on access to safely managed WASH services, particularly for vulnerable communities. Ensuring evidenced-based and consistently applied WASH and waste management services in primary health facilities and communities is even more pertinent in times of an outbreak such as COVID-19.

Domain D. Safe environment

Standards	Number of criteria		
	Critical	Core	Developmental
D.1. The primary care facility has a safe and secure physical environment for patients and staff.	1	9	0
D.2. The primary care facility has access to WASH and waste management services.	4	4	1
	5	**13**	**1**

D.1. The primary care facility has a safe and secure physical environment for patients and staff

Type of criteria	Criteria	Evidence of compliance (examples)
Critical criteria	D.1.1.1. The primary care facility implements a fire safety programme with an evacuation plan.	• Fire safety policies and procedures • Tour of environment; see Section 3
Core criteria	D.1.2.1. The primary care facility has a designated person in charge of environmental safety.	• Organization structure • Terms of reference of the environmental safety team
	D.1.2.2. The primary care facility has a PMP for its physical environment	• Minutes of meetings of environmental safety team • Records of PMP for physical environment
	D.1.2.3. The primary care facility implements a security programme and uses secure areas whenever appropriate.	• Security policies and procedures, validated during the primary care tour, that cover: – secure medical records – secure medication – closed circuit television (CCTV)
	D.1.2.4. The primary care facility ensures that staff display personal identification.	• Policies and procedures with regard to staff wearing a visible identification badge and an appropriate uniform

Type of criteria	Criteria	Evidence of compliance (examples)
	D.1.2.5. The primary care facility develops and tests plans for internal and external emergencies.	• Internal emergency plan • External emergency plan • Reports following drills required by external and internal emergency plans • Disease outbreaks
	D.1.2.6. The primary care facility provides mechanisms to ensure a backup supply of electricity.	• Uninterrupted power supply or generator
	D.1.2.7. The primary care facility has a documented PMP in place for inspecting, testing and maintaining medical and emergency equipment.	• Planned preventive maintenance checklist • Maintenance contracts
	D.1.2.8. The primary care facility has an implemented smoke-free policy.	• Smoke-free policy • Tour of environment; see Section 3
	D.1.2.9. The primary care facility has a radiation safety policy, including a designated responsible person.	• Designated person with responsibility for staff and patient safety during X-ray procedures • Radiation safety policies and procedures • Warning signs • Radiological waste • Tour of environment; see Section 3

D.2. The primary care facility has access to WASH and waste management services

Type of criteria	Criteria	Evidence of compliance (examples)
Critical criteria	D.2.1.1. The primary care facility has access to clean water, with reserves of at least three days.[1]	• Tour of the environment demonstrates: – clean running water – water testing reagents – adequate stocks of chemical additives – contract with water suppliers
	D.2.1.2. Functional hand-washing facilities are available at all points of care and within 5 m of a toilet.	• Availability of: – wash hand basins with soap and water – alcohol (60–80%) hand sanitizer More information is available at: https://www.who.int/teams/integrated-health-services/infection-prevention-control/hand-hygiene/tools-and-resources

[1] https://apps.who.int/iris/bitstream/handle/10665/311620/9789241515504-eng.pdf.

Type of criteria	Criteria	Evidence of compliance (examples)
	D.2.1.3. The primary care facility conforms to guidelines on waste management, including safe storage, transport and disposal of waste.	• Guidelines (including WHO guidelines) on management of waste and sharps • Policy for disposal, storage and management of waste, including domestic, medical, chemical and infectious • Waste is locked in a designated area, which is temperature controlled and animal proof • Contract with external company to collect and dispose of waste • Management of sharps
	D.2.1.4. The primary care facility has a process to safely manage health care waste produced by infectious disease outbreaks.	• Policy on waste management during an infectious disease outbreak • Linen management For more information: https://www.who.int/publications/i/item/WHO-2019-nCoV-IPC-WASH-2020.4
Core criteria	D.2.2.1. The primary care facility implements regular environmental cleaning and disinfection practices.	• Housekeeping policies and procedures • Policy on cleaning practices • Tour of environment; see Section 3: • All spaces within the facility are clean and in good repair More information is available at: www.washinhcf.org
	D.2.2.2. The primary care facility has separate toilet facilities for staff and patients, and to accommodate persons with disabilities.	• Tour of environment; see Section 3 • Depending on the services provided, at least two toilets are available: one for staff and one for patients
	D.2.2.3. The primary care facility has a process for safe disposal of dirty water and faecal waste.	• Policy on sanitation • Availability of plumbing services For more information: https://www.who.int/publications/i/item/9789241515511
	D.2.2.4. The primary care facility segregates waste according to hazard level and colour codes.	• Policies and procedures for waste segregation according to hazard level and colour coding • Waste is safely segregated into at least three bins • Infectious waste is treated and disposed of safely
Developmental criteria	D.2.3.1. The primary care facility aims to recover or recycle as much material as possible to reduce the need for waste treatment and disposal.	• Green policy • Policy to recycle paper and plastics

Domain E: Lifelong learning

Explanatory notes

Staff need to be trained on patient safety issues at the onset of employment and at regular intervals during their employment. Orientation, both organizational and role specific, should be provided to all new staff. Staff learning and professional development needs specific to primary care should be identified, documented and addressed.

Participation in and/or contribution to research projects within the primary care facility or community is an advantage. The primary care facility should foster a culture of continuous quality improvement and support projects appropriate for the facility's size, structure and circumstances.

Domain E. Lifelong learning

Standards	Number of criteria		
	Critical	Core	Developmental
E.1. The primary care facility has a staff professional development programme with patient safety as a cross-cutting theme.	1	1	0
E.2. The primary care facility conducts research and quality improvement projects in patient safety on an ongoing basis.	0	2	1
	1	**3**	**1**

E.1. The primary care facility has a staff professional development programme with patient safety as a cross-cutting theme

Type of criteria	Criteria	Evidence of compliance (examples)
Critical criteria	E.1.1.1. All relevant primary care staff are provided with a patient safety orientation programme.	• Patient safety orientation programme that includes: – fire safety – manual handling – hand hygiene – IPC – use of PPE – risk management and use of reporting system – needlestick injury
Core criteria	E.1.2.1. The primary care facility provides ongoing training and education for all staff.	• Process to: – ensure identification of staff training needs – address these needs through ongoing training for all staff to ensure safe patient care and respect for patient rights • Refresher training for topics covered in orientation programme

E.2. The primary care facility conducts research and quality improvement projects in patient safety on an ongoing basis

Type of criteria	Criteria	Evidence of compliance (examples)
Core criteria	E.2.2.1. All research is approved and monitored by the relevant research ethics committee and conducted to meet the needs of the primary care facility.	• Terms of reference of research ethics committee • Examples of research studies • Evidence of health systems research/health policy and systems research
	E.2.2.2. The primary care facility conducts quality improvement projects to promote patient safety activities.	• Process to train staff on the use of quality improvement tools (e.g. plan–do–study–act) (PDSA)/FOCUS-PDCA) • Evidence of quality improvement projects
Developmental criteria	E.2.3.1. The primary care facility conducts quality improvement projects in the community to promote patient safety.	• Evidence of quality improvement projects in the community and/or with other primary care facilities

Section 3

PSFPC assessment tools

Introduction

This section assists the primary care facility and the survey team in the collection of data through document reviews, observation and interviews. These assessment tools offer suggestions rather than specific instructions to be followed. The survey will vary depending on the size of the primary care facility. A survey of a primary care facility with one doctor can be conducted in one day; a network of three primary care facilities may take two days. Titles of documents can vary depending on the country; for example, an operational plan maybe called an annual plan. It is the responsibility of the peer review team to triangulate as much evidence as is required to fairly and consistently assess each criterion. It is the responsibility of the facility to be transparent and provide useful documents and data that validate compliance with each criterion. It is suggested that the facility present documents in a logical sequential manner for ease of use.

This section has five subsections: (a) brief information to be gathered about the facility; (b) a list of key documents to be reviewed across the five domains; (c) a proposed agenda for surveys and sample interview tools, including several questionnaires to help to gather specific information from facility staff or patients during the survey; (d) guides to assist observation in clinical and non-clinical areas; and (e) a survey report template.

Primary care in brief

1. List the types of services provided by the facility.
2. Provide some statistics relevant to these services; for example:
   - annual visits
   - average daily visits
   - annual number of vaccinations
   - annual number of births.
3. List disciplines and numbers of staff employed.
4. List services provided anywhere other than in the facility (e.g. home visits, schools visits).
5. List any contracted (outsourced) services.
6. Provide a site description. List all rooms and/or buildings affiliated with the facility.
7. Provide details of any incident over the last 12 months that affected patient care and would be relevant to share with the peer review team.

List of documents

The following lists of documents are organized into five groups, one for each domain. One document may cover a number of criteria. To help the survey team become familiar with the primary care facility being surveyed, the documents marked with an asterisk (*) should be sent to the team at least two weeks before the survey is scheduled.

In general, policies, procedures and guidelines must all be evidenced based, dated and authorized by a person in authority, and their circulation should be controlled. Evidence should be available of a distribution list, relevant training of personnel and evaluation of compliance. They should be available in all facilities in soft or hard copy.

All documents should be dated and signed by the relevant responsible person. Documents will be examined at the start of the survey and their use validated through interviews and observations. The PSFPC Framework is not intended to become overly bureaucratic, with excessive documents; therefore, it is advised to focus on validating compliance with the criteria through the use of data.

Domain A: Leadership and management

Document	Evidence to include
Long-term strategic plan	• Patient safety activity • Identification of population needs • Services to be developed over the next two to three years
*Short-term operational plan and budget	• Annual goals • Funding for patient safety • Targets achieved
*Organization structure	• Responsibility and reporting lines for all positions that show who is responsible for – the facility (overall) – patient safety – IPC
Budget for patient safety	• Budget line as part of another programme (e.g. infection control, staff training) or a standalone budget line
Emergency preparedness plan (EPP)	• EPP that documents the risk management, preparations and action to be taken in any situation that causes disruption to the normal functioning of the practice. This includes internal and external emergencies, such as: – infectious outbreaks, natural disasters, earthquakes or floods – internal emergencies, such as power outage, data breech or fire
Policy to measure the culture of patient safety	• Assessment by a validated tool (Agency for Healthcare Research and Quality or equivalent) or through patient safety questionnaires and qualitative approaches • Results of culture survey within the last two years
Participation in local and national patient safety campaigns	• Flyers from public meetings • Health promotion information leaflets (e.g. no smoking, balanced diet) • Supporting and celebrating WHO patient safety days, such as: – World Hand Hygiene Day, 5 May – World Patient Safety Day, 17 September – World Antimicrobial Awareness Week, 18–24 November
*Risk management programme	• Process to identify and mitigate risks, including: – a risk register template or spreadsheet designed to systematically track and evaluate risks, define risk priority and potential impact, and document mitigation strategies – an adverse incident reporting system and a process to communicate feedback on risk to all staff – plan for training of staff on incident reporting process
Communications strategy	• Relevant sections containing information on: – key responsible person – internal and external policies – process to measure effectiveness
*Patient safety programme	• Relevant sections containing information on: – named responsible person – schedule of clinical and environmental audits – action plans

Document	Evidence to include
Terms of reference for patient safety committee *Note:* title of committee may vary and could be: Patient safety & risk management Infection prevention and control Environmental safety	• Relevant sections containing information on: – committee members – minutes of meetings – samples of case reviews and actions taken
Preventive maintenance programme (PMP) for equipment	• Asset register of all equipment • Schedule of routine tests and calibration • Process to replace faulty equipment • Staff training logs
Human resource plan	• Numbers of staff required to provide services • Policy on validating staff credentials and qualifications • Professional development programme • Example of staff file
Occupational health programme	• Manual handling training programme • Vaccination and screening records • Violence prevention programme • Implementation of staff wellness measures, such as: – safe injection practices – rostered breaks – mental health supports – workplace assessments
*Policy on control and development of policies	• System for consistent approach to policy development • Documentation control system, including review date, publication date, person responsible, and authorization by person in authority
Medical records	• Policies on: – content of medical records (examination record and treatment plan) – approved abbreviations – generation of unique patient identifier – validation of patient identification – requests from patients for information • Audit of: – completeness of medical records – legibility of handwriting – chart availability • Records securely stored either in soft or hard copy

* Documents should be sent to the survey team at least two weeks before the survey is scheduled.

Domain B: Patient and community involvement

Document	Evidence to include
Documented and approved patient and family rights statement in which patient safety is incorporated	• Patient rights statement that includes the rights to: – access to care in the primary care facility – respect for patients' cultural and spiritual beliefs and personal preferences – be informed and involved in all medical decisions during care – provide feedback or complaints – refuse treatment – security, privacy and confidentiality – have pain managed – access information about a patient's own primary care services and outcomes
Policy on informed consent	• List of procedures for which informed consent is required that includes invasive procedures and minor surgical procedures • Informed consent forms that are available in all facilities • Informed consent forms that are completed, signed, dated and timed and are available in patients' medical records
Policy on patient identification	• Process for identification using two identifiers before administration of medication, performance of any procedure, and any minor surgery procedures • Patient identification and verification policies and procedures that contain special emphasis on high-risk groups (e.g. newborn infants, vulnerable patients) • Patient identification process that includes full name of patient (to third generation of family), date of birth, photograph and primary care number or unique national identification number, and which is used consistently throughout the primary care facility
Policy for patient engagement	• Strategy for engagement and empowerment of patients in patient safety activities • Evidence of patient involvement in areas that may include patient identification, hand hygiene and single use of injections • Educational material and/or written or verbal information provided to patients that empowers them to play an active role and become partners in shared decision-making • Reports or minutes of meetings that include engagement of patients/community and their carers in setting policies and suggesting quality improvement and patient safety projects
Patient education programme	• Educational material, including patient information leaflets and posters in reception • Minutes of community-based disease-specific support group meetings • Policies and procedures for health promotion: – restricted use of antibiotic prescribing – hand hygiene – warning signs and symptoms of cancer – harmful effects of smoking, drugs and alcohol
Complaints process	• Process that includes: – person responsible for acknowledging and acting on complaints – how patients are to be communicated with • Log of complaints and actions over previous 12 months • Open disclosure and complaints policies

Document	Evidence to include
Engagement of the community in patient safety campaigns	• Hand hygiene campaign material • Minutes of meetings with civil defence • Media campaign materials
Patient services programme	• Availability of patient advocate • Health promotion programme • Education and information leaflets • Primary care facility website • Social media campaigns
Patient feedback	• Measuring of patient experiences • Satisfaction surveys • Patient-reported outcome measures

Domain C: Safe, evidenced-based clinical practice

Document	Evidence to include
Job description of medical officer	• Description of person responsible for clinical guidance, oversight and evaluation of effectiveness of all clinical care
Policy for communicating routine and critical results	• Policies for: – providing results or orders by telephone, including "read back", whereby the verbal or telephone message is written down completely by the receiver, who then reads it back and has it confirmed by the person who gave the result or order – reporting critical results – recording critical and urgent results in the medical record
*Schedule of audits and related action plans	• Examples of such audits and actions plans: • Hand hygiene • Use of antibiotics • Medication safety
Process to identify which clinical policies are required and their implementation	• Terms of reference of clinical guideline committee • Process to sign off and distribute clinical policies • Policies, which could include: – safe surgery – safe childbirth
Care pathways	• Evidence of defined pathways for: – child development – safe childbirth – safe surgery – reproductive health – health checks – treatment for noncommunicable disease
Assessment tools to manage and mitigate patients at risk	• Assessment tools in place, which could include tools for: – vulnerable patients – suicide or domestic violence – clinical risk

Document	Evidence to include
IPC programme	• Clear IPC workplan • IPC SOPs • Staff training • Audit schedule • Availability of supplies and equipment • Staff screening and vaccinations • Policies (WHO or alternative validated source) on at least the following areas: – hand hygiene – PPE – aseptic techniques – safe injection practices – transmission-based precautions – environmental cleaning and disinfection – waste management – decontamination of equipment – respiratory and communicable disease screening and triage – notification of communicable diseases
Medication safety	• Access to a clinical pharmacist or dispenser • Patient education leaflets • System for monitoring and mitigating medication errors • Availability of life-saving medication • Policies on at least the following areas: – procurement, availability and storage of medicines – limited access and standardization of high concentrations and risk substances – polypharmacy and prescribing – reconciliation on discharge – use of controlled substances – storage of temperature-sensitive medication – rational use of antibiotics

* Documents should be sent to the survey team at least two weeks before the survey is scheduled.

Domain D: Safe environment

Infectious disease outbreak preparedness plan	Evidence of a gap analysis and EPP that is tested on an annual basis
Emergency preparedness plan (EPP)	• EPP that covers: – emergency management team – documented responsibilities – criteria that will trigger the emergency plan – communication strategy – robust workforce planning – contact list and mobile numbers – plan to surge staff capacity – role in national plan – access to supplies – plan to coordinate community services – changes to facility environment – policy for telephone triage – staff training requirements – staff welfare – access to laboratories

Document	Evidence to include
Terms of reference for environmental safety committee or equivalent *Note:* This could be the same committee that covers other patient safety issues, such as IPC	• Terms of reference related to: – organization structure – name of person responsible for environmental issues – names of committee members – minutes of meetings and actions taken – radiation safety programme – name of person responsible for radiation safety
Fire safety programme	• Schedule of fire training and evacuation drills • Safety checklists of equipment, extinguishers and fire hoses • No smoking policy • Fire exit signage
Security programme	• Staff identification policy • Policy for safeguarding patients and staff • Controlled access to delivery rooms
PMPs for equipment and environment	• Physical environment: – records of PMP – minutes of meetings of environmental safety team • Equipment safety: – schedule of tests and calibrations – process for managing recalls – availability of backup equipment
Internal and external emergency plan	• A major emergency or disaster plan that: – defines the roles and responsibilities of the staff during any internal or external emergency – aligns with the WHO Strategic Framework for Emergency Preparedness and WHO policy on emergency preparedness
Waste management plan	• Plan that includes: – WHO guidelines on management of waste and sharps – linen management – disposal, storage and management of waste, including domestic, chemical and infectious – management of sharps
Contract for safe disposal of waste	• Safe disposal contracts that include: – domestic waste – clinical waste – infectious waste *Note:* WHO waste type definitions used

Domain E: Lifelong learning

Document	Evidence to include
Staff orientation programme	• Staff orientation programme on patient safety, which covers: – fire safety – manual handling – hand hygiene – IPC standards and transmission-based precautions – use of PPE – risk management and use of reporting system – needlestick injuries
Professional development programme	• Training and education schedule for staff • Sign-in sheets for training sessions
Quality improvement programme	• Documentation of quality improvement projects • Publications and/or posters

Observation guides

The observation guides in this section cover the priority patient safety areas common to all primary care facilities.

1. Environmental safety of the facility and all clinical areas
2. Fire safety
3. Medical records
4. Radiology
5. Pharmacy

Each primary care facility surveyed will have its general environment and clinical areas observed for patient safety issues. If the facility has its own pharmacy and/or radiology services and laboratory services, they too will be evaluated. The observation guides are only one part of the survey, and findings must be triangulated with documents and interviews.

1. Environmental facility and clinical areas

Observation
External signage indicating primary care facility
Parking for people with disabilities
Reception: • visible statement of patient rights, with patient safety documented • secure and confidential storage of patient information • patient waiting rooms comfortable, with gender separation if appropriate • comment boxes
Environment: • tidy • well maintained • free of rust, dust, dirt, debris, spillages, blood or body substances
No smoking signs
Security: • CCTV • staff name badges • security personnel • controlled access
Equipment maintenance: date machines were last tested, asset number
Policies and procedures available in the facility
Continuous supply of electricity, including a backup generator
Availability of storage space: • safe storage of hazardous substances • separate housekeeping cupboard or room

Private clinical area(s):
- resuscitation equipment, including trolley and defibrillator, and life-saving medication
- validated equipment for point-of-care testing
- PPE

WASH services:
- clean water
- handwashing basins and hand sanitizer
- WHO posters: 5 Moments for Hand Hygiene and How to Handwash
- separate toilets for patients and staff
- safe disposal of sanitary waste
- cleaning and disinfection solutions

Waste and linen management:
- sharps boxes
- separate colour-coded bags for domestic, clinical and infectious waste
- secure and temperature-controlled waste storage room, if applicable

2. Fire safety

Observation
Fire evacuation plan posted throughout the primary care
Fire alarms present and in working order
Clear fire exits and stairways
Fire hoses in working order
Flammable liquids stored securely and their use restricted
Exit signs clearly marked and sufficiently lit, and all exit doors fire resistant
All fire extinguishers have current labels, dated and signed
All gas cylinders: • are chained or safely secured • are stored in shade and correct temperature away from direct sunlight • have valve protection cap in place when oxygen cylinder is not in use • full and empty oxygen cylinders stored separately in upright position
Records of fire training for staff available

3. Medical records

Observation
Chart audits
Personal identification number
Archiving system
Standardized coding of diseases

Content of medical record: • completeness • allergies documented • continuity of care, diagnosis, treatment and follow-up • medication reconciliation
Accessibility of medical records
Consent form (if relevant): • information on risks and benefits of consented procedures on consent form • form signed as per practice policy
Legible handwriting
Nurses' notes
Physicians' notes

4. Radiology

Observation
Radiation safety programme
Patient identification
Quality control of results
Appropriate handling and storing of hazardous material
Warning signs marking unsafe areas
Lead aprons
Radiation monitoring system
Warning signs regarding pregnancy

5. Pharmacy

Observation
Process for: • storage • ordering • preparing and dispensing • administration and follow-up
Appropriate storage of: • concentrated solutions • look-alike, sound-alike medicines (LASA) • hazardous material
Patient (or carer) information leaflets about medication safety, including WHO's Medication Without Harm (5 Moments for Medication Safety)
System for reporting and managing medication errors

Interviews and on-site schedule

The survey schedule will differ depending on the services the primary care facility provides and the number of surveyors on site. There must be at least two surveyors to agree on ratings and the final outcome with recommendations. Some primary care facilities can be surveyed in one day, some may take three days, but the majority will probably take two days. The aim of the on-site survey is for the peer review team to seek information to rate a primary care facility's compliance to the PSFPC standards. They must ask the questions "Are patients safe?" "How can I as an expert in patient safety assist this facility to mitigate safety issues?" and, finally and most importantly, "Is there a safety issue that warrants direct intervention before I leave?"

After the suggested survey schedules, there is a list of example key questions for interviews. As primary care facilities differ, interviews should be adaptable and take into account that job titles can differ. In smaller primary care facilities, one person may hold many responsibilities and one or two committees can cover a number of specialties. In networks, there may be a team of staff available to manage patient safety and quality improvement.

Suggested survey schedules

Solo primary care facility, day 1

Time	Activity	Primary care staff
08.00–08.15	PSFPC briefing and agenda review	WHO representative, survey team, facility manager, patient safety manager
08.15–08.45	Overview presentation of primary care services	Facility leadership
08.45–10.45	Document review and coffee All documents should be gathered in one room for surveyors to review	One facility staff member to be available to survey team
10.45–11.45	Surveyors 1 & 2 Interview with facility leadership focusing on Domains A & E	Any or all members of facility senior management team (director, practice manager) who can answer questions regarding Domain A
11.45–12.45	Surveyor 1 Interview with patient and/or community representatives	Group of patients and community stakeholders
11.45–12.45	Surveyor 2 Tour and interview regarding Domain D. Tour of environment to include clinical rooms, fire safety, equipment, WASH services and storage of medical records	One facility staff member to be available to survey team
12.45–13.30	Lunch	
13.30–14.30	Surveyors 1 & 2 Interview with facility staff focusing on Domain C and management of outbreaks	
14.30–15.15	Document review Surveyors team meeting, identifying issues and any clarifications required	Infection control lead
15.15–16.00	Feedback to leadership and staff	

Network of primary care facilities, day 1

Time	Activity	Primary care staff
08.00–08.15	PSFPC briefing and agenda review	WHO representative, survey team, facility manager, medical officer, patient safety manager
08.15–08.45	Overview presentation of primary care services and its network	Facility leadership
08.45–12.00	Document review and coffee All documents should be gathered in one room for surveyors to review	One facility staff member to be available to survey team
12.00–12.45	Surveyors 1 & 2 Interview with facility leadership, focusing on Domain A	Any or all members of facility senior management team (director, facility manager, medical officer) who can answer questions regarding Domain A
12.45–13.15	Lunch	
13.15–14.15	Surveyor 1 Interview with facility staff, focusing on Domains B and E.	Members of team could include staff, patient representative, professional development officer
13.15–14.15	Surveyor 2 Tour of environment to include clinical rooms, fire safety, equipment, WASH services, storage of medical records, and radiology (if available)	One facility staff member to be available to survey team
14.15–15.00	Documentation review	
15.00–15.30	Surveyor 1 Interview with infection control officer, focusing on Domain C	
15.00–15.30	Surveyor 2 Interview with environmental safety team, focusing on Domain D	Staff members could include engineer, fire safety officer, waste manager, patient safety officer
15.30–16:30	Surveyor 1 Interview with a sample of staff	Occupational health officer, professional development officer
15.30–16:30	Surveyor 2 Interview with patient and community representatives	Representatives from patient and community group
16.30–17.00	Surveyors team meeting, identifying issues and any clarifications required	

Network of primary care facilities, day 2

Time	Activity	Primary care staff
08.00–09.00	Travel to primary care facility 2	WHO representative, survey team, facility manager, medical officer, patient safety manager
09.00–10.00	Surveyor 1 & 2 Tour of facility 2, including clinical and environmental spaces	Facility manager
10.00–10.30	Document review	
10.30–12.00	Surveyors 1 & 2 Interview with multidisciplinary clinical staff, focusing on Domain C	Will depend on services provided at the facility and could include doctor, nurse, occupational therapist, physiotherapist, pharmacist, members from infection control, or medical officer
12.00–13.00	Lunch	

Time	Activity	Primary care staff
13.00–13.45	Surveyor 1 Interview with patient safety officer	Patient safety officer or other person responsible for risk management and patient safety
13.00–13.45	Surveyor 2 Interview regarding management of outbreaks	Facility leadership, infection control officer
13.45–14.15	Clarification of outstanding issues	
14.15–14.45	Feedback to leadership	
14.45–15.15	Feedback to staff	

Suggested interview questions

Interview with facility leadership

- Explain the organizational structure and lines of reporting within the facility or network.
- Who is the designated senior staff member with responsibility, accountability and authority for patient safety?
- Does the primary care facility have a strategic plan with patient safety as a priority? What evidence do you have of this plan being implemented?
- Does the primary care facility have an annual budget for patient safety activities?
- What does the patient safety and risk management programme consist of?
- How are risks identified and what proactive actions are taken to improve patient safety within the facility or network?
- Is the facility involved in research or quality improvement projects?
- Does the facility follow a code of ethics, for example in relation to research or resuscitation?
- Does the leadership assess staff attitudes towards patient safety culture? How often?
- Are qualified clinical staff, both permanent and temporary, registered to practise with an appropriate body?
- How does the primary care facility manage the development and control of policies and procedures?
- Does the primary care facility have campaigns on patient safety?
- How does the primary care facility involve its community in patient safety activities?
- Are patient safety and adverse incidents reported and analysed? Does the prevailing culture allow for ease of reporting?
- Is there a committee that oversees patient safety?
- Are external stakeholders involved in the patient safety committee?
- What are the current patient safety improvement projects?
- Does the primary care facility develop reports on different patient safety activities, and does it disseminate them?
- What are the measurable targets related to patient safety?
- Are patient safety reports shared with the national organization responsible for oversight of patient safety?
- Does the primary care facility obtain feedback from patients and their carers?
- What is the process of complaints?
- How is staff feedback obtained?

- Does the patient safety task force use scientific tools e.g. root cause analysis (RCA) and improvement tools (e.g. plan-do-study-act/FOCUS-PDCA models)?
- How did the primary care facility adapt during the COVID-19 pandemic?
- Does the primary care facility have external or internal disaster plans? If so, how frequently are they rehearsed?
- Does the primary care facility have a preventive and corrective building safety programme?
- Does the primary care facility require a security programme?
- Does the primary care facility have an effective utility system plan comprising a preventive maintenance and backup plan in case of failure or interruption?

Interview with medical officer

- Does the leadership support staff involved in patient safety incidents as long as there is no intentional harm or negligence?
- What communication process do doctors use to transfer patient information between colleagues?
- In your opinion, is there an open, non-blaming, learning and continually improving patient safety culture at all levels of the primary care facility?
- Does the primary care facility ensure that staff receive appropriate training in patient safety solutions?
- Does the primary care facility conform to clinical practice guidelines where appropriate, including WHO guidelines where available?
- What invasive or minor surgery procedures are provided? Is there a system in place to ensure that invasive procedures are carried out safely and according to standard guidelines?
- What pathways of care does the primary care facility use?
- Does the primary care facility commonly screen patients to identify those vulnerable to harm (e.g. suicide, malnutrition or infection)?
- Does the primary care facility maintain a list of approved abbreviations?
- How are patient laboratory and diagnostic imaging results checked, reported to patients, actioned and recorded?
- Does the primary care facility have access to a guidelines committee that selects, develops and implements patient safety policies?

Interview with IPC officer or medical officer

- Does the primary care facility have a functional IPC programme?
- What are the infection control objectives?
- Does the primary care facility conform to recognized SOPs for IPC? Give examples.
- Is there a policy for the rational use of antibiotics?
- What procedures and what surgical instruments and medical devices are used in the primary care facility?
- Are there single-use disposal medical devices at the primary care facility? How does the facility ensure they are not reused?
- Does the primary care facility have policies for sterilization of surgical instruments? How are the instruments sterilized?

- Does the primary care facility have sufficient supplies to ensure prompt decontamination and sterilization?
- How are staff protected from health care-associated infections, including by hepatitis B vaccination?
- What training do the staff receive on IPC? How often?
- Does the primary care facility have an inventory and sufficient stock of essential infection control equipment and supplies?
- Has the primary care facility conducted outbreak investigations?

Interview with patient(s)

- How do you access your doctor?
- Were you briefed about the patient and family rights policy of the primary care facility?
- Is the patient and family rights statement visible throughout the primary care facility?
- Did you obtain from your treating physician complete updated information on your diagnosis, treatment or prognosis?
- Do you participate in making decisions regarding your health care?
- Do you give signed consent before any procedure?
- Did you receive patient education concerning your case and diagnosis upon discharge?
- Have you ever taken part in a patient experience survey? Did you receive the results?
- In general, do the primary care staff treat you with care and respect?
- Are there any improvements you would like the primary care facility to make to either services or physical environment?

Interview with staff

- What systems are in place to ensure safe injection practices (e.g. hand hygiene, isolation measures)?
- Were you provided with a patient safety orientation programme? What were the topics?
- Is there ongoing training for all staff to ensure safe patient care?
- Are you familiar with the reporting procedure and steps to be taken during or after an adverse event?
- What happens if equipment breaks or malfunctions?
- Were you trained in relevant equipment use, decontamination and sterilization?
- Do you brief patients about the patient and family rights policy of the primary care facility?
- Does the primary care facility have a staff professional development programme with patient safety as a major theme?
- Does the primary care facility monitor professional qualifications and competencies for all health care staff?
- What was your role in the recent COVID-19 pandemic?
- Did you have PPE as required?

Report template

1. Executive summary

Objective

To perform an external assessment of FACILITY NAME, against the WHO Patient Safety Friendly Primary Care (PSFPC) standards, 1st edition.

Settings

FACILITY NAME is a PUBLIC/PRIVATE primary care facility situated in TOWN, COUNTRY. It provides primary care services for a population of 0000. The facility provides a wide range of services including .....There is/are 00 facility(ies) in this network.

Methodology

The PSFPC framework comprises 19 standards, which are prioritized into critical, core and developmental criteria. The 19 patient safety standards are organized into five domains.

Domain A: Leadership and management

Domain B: Patient and community involvement

Domain C: Safe, evidence-based clinical practice

Domain D: Safe environment

Domain E: Lifelong learning

This assessment involved multiple approaches that were triangulated to gain the results. Documents were reviewed, interviews were conducted and site visits to 000 primary care facilities were conducted.

Due to the size of FACILITY NAME, a team of 000 PSFPC surveyors conducted the assessment over 000 days, DATE.

Findings

FACILITY NAME achieved 000% compliance with the critical standards. The facility was assessed against 000 core criteria, as 0 were deemed not applicable by the survey team. The facility achieved a 00% compliance rate to the 00 core criteria. FACILITY NAME was assessed against 00 developmental standards and achieved a compliance rate of 00%.

Among the five domains, DOMAIN NAME scored first, with a total score of 00%. DOMAIN NAME scored second with 00%, followed by DOMAIN NAME at 00%. DOMAIN NAME scored fourth with 00%. In last place was DOMAIN NAME, with 00%. The overall compliance rate for critical, core and developmental criteria in the five domains was 00%.

Conclusions

As the primary care facility meets 00% of the critical criteria, 00% of the core criteria and 00% of the developmental criteria, FACILITY NAME, is assigned “Level 00” compliance with the PSFPC standards.

2. Introduction to the PSFPC Framework

3. Introduction to FACILITY NAME

4. Assessment methodology for FACILITY NAME

Based on the WHO *Patient safety assessment manual for primary care*, 1st edition, the following assessment methodology was applied in FACILITY NAME.

An external evaluation survey team were on site for two days, DATE. The team comprised:

- NAME, COUNTRY
- NAME, COUNTRY

The assessment involved review of documents, interviews with key stakeholders and observational visits to key departments; see Appendix 1 (FACILITY NAME Agenda). The staff of the FACILITY NAME are to be commended for their openness and can-do attitude, witnessed during the assessment. Documents were clearly indexed and easy to find.

5. Findings

5.1. Domain A: Leadership and management

5.1.1. Strengths

5.1.2. Opportunities for improvement

5.2. Domain B: Patient and community involvement

5.2.1. Strengths

5.2.2. Opportunities for improvement

5.3. Domain C: Safe, evidence-based clinical practice

5.3.1. Strengths

5.3.2. Opportunities for improvement

5.4. Domain D: Safe environment

5.4.1. Strengths

5.4.2. Opportunities for improvement

5.5. Domain E: Lifelong learning

5.5.1. Strengths

5.5.2. Opportunities for improvement

6. Conclusions

7. Recommendations

7.1. Short term

7.2. Long term

References

1. Berwick DM. Choices for the “new normal”. JAMA. 2020;323(21):2125–6. doi:10.1001/jama.2020.6949.

2. Wu Z, McGoogan JM. Characteristics of and important lessons from the coronavirus disease 2019 (COVID-19) outbreak in China. JAMA. 2020;323(13):1239–42. doi:10.1001/jama.2020.2648.

3. Water, sanitation, hygiene, and waste management for the COVID-19 virus. Interim guidance 2020. Geneva: World Health Organization; 23 April 2020 (https://apps.who.int/iris/bitstream/handle/10665/331846/WHO-2019-nCoV-IPC_WASH-2020.3-eng.pdf).

4. Marchon SG, Mendes WV, Jr. Patient safety in primary health care: a systematic review. Cad Saude Publica. 2014;30(9):1815–35. doi:10.1590/0102-311x00114113.

5. Lainer M, Vögele A, Wensing M, Sönnichsen A. Improving medication safety in primary care. European Journal of General Practice. 2015;21 Suppl:14–8. doi:10.3109/13814788.2015.1043124.

6. Webair HH, Al-assani SS, Al-haddad RH, Al-Shaeeb WH, Bin Selm MA, Alyamani AS. Assessment of patient safety culture in primary care setting, Al-Mukala, Yemen. BMC Family Practice. 2015;16:136. doi:10.1186/s12875-015-0355-1.

7. Hensher M, Price M, Adomakoh S. Referral hospitals. In: Jamison DT, et al., editors. Disease control priorities in developing countries. Washington (DC): World Bank; 2008:1229–44.