



Design and Validation of the First Electronic Registry System for Reporting Medical Errors in the Primary Health Care System in Iran

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Abstract

Introduction: Patient safety is one of the priorities in all care systems in the world. Unsafe care can cause harm to patients and increase the mortality and morbidity rate. Establishing an error reporting system is one of the initial steps toward improvement in the quality of care in primary health care. The aim of this study was to set and validate the first electronic reporting system for primary care in Bandar Abbas, Iran.

Methods: To design and create an electronic error reporting system, we designed a data collection form and validated it by the experts; then, the tool was designed and revalidated to capture the errors and design automatic report forms. Finally, the modifications were made in the software. The software had been implemented in selected comprehensive health centers in Bandar Abbas for 8 months.

Results: The registry is designed to include two main sections, including general information on medical errors (demographic information, type of event, error severity, error occurrence location, pre-error training, preventable error, causes of error, error identification source, and error detection time) and classification of medical errors (care errors, vaccination errors, environmental and occupational health errors, laboratory errors, and imaging errors).

Conclusion: Managing medical errors successfully needs the establishment of a voluntary reporting system and addressing barriers to reporting errors. This innovative error registry system of primary care was created to collect, analyze, and disseminate information about the frequency, types, and causes of medical errors in primary health care.

Keywords: Medical errors, Patient safety, Primary health care, Registries

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Introduction

Patient safety is one of the priorities in all care systems in the world (1). Setting a system to capture medical errors and standards for patient safety improves the quality of care, allows for learning from errors, and provides opportunities for change that may lead to engineering solutions (2). Medical error is defined as failure to do something that needs to be done or use of an improper method occurs by the medical team and can lead to injury to the patient (3). Primary care, which is part of

outpatient care, is very important in both developed and developing countries (4). Compared to inpatient services, outpatient services have considerable differences, including a wide range of services that will be extended in a long, continuous manner, and the prolonged relationship between patients and service providers compared with the outpatient (5). The outpatient system consists of a wide range of service providers and various centers which are under the supervision of different organizations and do not have a single management (5). This system has

a longitudinal nature, so that an agent cannot cause harm, but it may have several factors and a long time to cause harm (5).

Medical errors are among the top ten leading causes of mortality, morbidity, and patient injury worldwide during health care. Studies reveal that medical errors will result in the loss of vital resources, risk of people's wellbeing and safety, and imposition of many economic costs to the health system. Despite the importance of the topic, research in the field of medical errors in the primary health care system is in preliminary stages (6).

Harms are caused by medical errors in primary health care, causing an annual hospitalization rate of 7 million people in the Organization for Economic Co-operation and Development (OECD) countries (7). It is estimated that more than 5% of adults (about 12 million people) in the United States are affected by medical errors each year when receiving primary care (8). In a US study of medical malpractice complaints over 25 years, the most frequent ones (61.8%) were outpatient errors, and the highest payment (67.6%) was for outpatient compensation. However, mortality and disability rates were higher in hospitalized wards (9). Literature shows that the errors in primary care may cause frequent returns of the patients to the health care system, errors that may affect the long-term health status of the patients, e.g. errors in vaccination, or impairment in maternal and child health (10).

Considering the importance of medical error management, different studies reported the implementation of medical error reporting systems in different settings including the Portuguese Primary Health Care (PHC) units in Madeira Island/Portugal (11) or the National Medication Error Reporting System in Malaysia (12). Iranian researchers also developed reporting error systems in one of the pediatric hospitals in Tehran (13) and hospitals affiliated with Iran University of Medical Sciences (14).

To the best of our knowledge, there is no error reporting system in the primary health care system in Iran. The objectives of this paper are twofold: providing the protocol steps toward designing an electronic registry for medical errors in primary care, and piloting the designed system in the primary health care clinical setting in Bandar Abbas, south of Iran. The designed system is meant to develop quality safety system in primary health care.

Material and Methods

This exploratory research was conducted with the aim of creating a medical error registration system in

primary healthcare and piloting the designed system in the clinical setting of Bandar Abbas, Iran, 2019.

As the first step, to reach the objectives of this research, using the findings from the literature, (15-21), Iran national care guidelines (22-27), and expertise consult, the team designed an error collection form to collect and classify medical errors in primary health care.

This form was used to set up an error reporting system that collects error and near-error reports and identifies defects in the system to prevent frequent errors. The project was designed and implemented in 3 phases including designing an error registry form (phase 1), developing the software (phase 2), and performing a pilot study of the designed system (phase 3).

In phase 1, the literature searches and focus groups were done to design an appropriate and validated electronic error reporting data collection tool. As the first step, various international and national studies in the fields of classification of medical errors among family physicians, outpatient setting, primary health care centers, and vaccine adverse event reporting systems, as well as national primary care guidelines and surveillance system assessment reports were reviewed (22-27). The first draft of data collection and classification of errors (Appendix) was developed based on 8 documents. (15-21).

The drafted data collection and classification of medical errors tool in the primary health care was distributed by email among 35 primary health care experts including health service management specialists, family physicians, dentists, nurses, midwives, psychologists, nutritionists, environmental and occupational health experts, laboratory experts, public health experts, and health providers for their professional review and advice; we used purposeful sampling method. Thirty participants responded in the first round and five others after the follow-up. The suggestions were then incorporated back into the tool. The revised draft was then again reviewed and finalized during a three-hour focus group session attended by field experts and authors (MA, AZ). The final draft was then used in designing an error registry.

Phase II- Software development: This registry system, designed by a programmer, is web-based software based on PHP server technology version 5.6, MySQL database and the global HTML5 standard, and Ajax technology, based on the MVC standard architecture. The access level for different employees was specified in the software.

Phase III- Finally, the desired modifications were

made for the software. The software was implemented in selected comprehensive health centers in Bandar Abbas for 8 months.

Results

The developed registry is the first of its kind in Iran to efficiently collect, analyze, and intervene and is meant to reduce errors and improve patient safety in Bandar Abbas, Iran. Figure 1 illustrates how the designed registry system works.

The registry is designed to include two main sections, including general information on medical errors (demographic information, type of event, error severity, error occurrence location, pre-error training, preventable error, causes of error, error

identification source, error detection time) (Table 1) and classification of medical errors (care errors, vaccination errors, environmental and occupational health errors, laboratory errors, imaging errors) (Table 2).

Discussion

Although the majority of health care services are provided by primary and outpatient care, most research on medical errors is focused on the inpatient sectors, and investigating medical errors in primary health care in the world is in the early stages (28). The use of reporting systems in primary health centers provides safe health services, despite the intricacies of primary care (29).

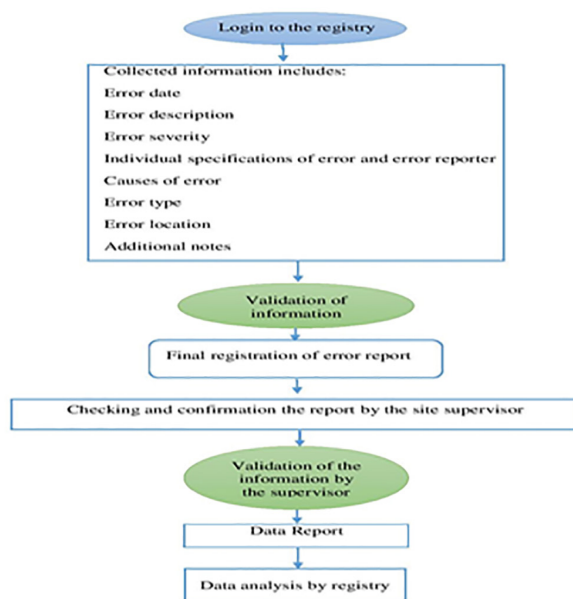


Figure 1: Description of the designed registry system

Table 1: Medical errors information on the error reporting system in primary health care

Medical errors information		
Demographic information	Type of event	Error severity
Sex	Near miss event	Sentinel event
Education level	No harm even	Non-sentinel event
Work experience	Harmful event	
Occupation		
Error occurrence Location	Pre-error training	Error preventable
Rural Health house or urban health base	Yes	Yes
Urban or rural health center Border Care Base District health care	No	No
Causes of error	Error identification	Error detection time
Lack of power	Error	Before the error occurred
Fatigue	Patient or referred	During error
Bustle of center	Supervisor Expert	After the error is done
Novice Staff	Unit staff	After causing the effects
Lack of proper communication with the patient	Students	
Failure to track cases		
Lack of awareness		
Bug on equipment		

Table 2: Classification of various medical errors in error reporting system in primary health care

Classification of various medical errors	
Care errors	
Prevention errors	<ul style="list-style-type: none"> ● Incorrect IUD sharing technique ● Wrong prescription of contraceptive ● Distribution of supplements and contraceptives destroyed or outdated ● Lack of prescription or wrong prescribing pharmaceutical supplements ● Non reporting of the outbreaks and reportable cases ● Lack of active case finding of high-risk groups in communicable diseases ● Incorrect education or counseling in age-group cares ● Lack of counseling or training in age-group care
Diagnostic errors	<ul style="list-style-type: none"> ● Unnecessary or incorrect procedures and tests ● Lack of required laboratory tests ● Failure to detect disorders ● Lack of close contact with the patient ● Mistake or delay in diagnosis ● Improper interpretation of diagnostic tests ● Lack of history and careful examination of the patient ● No follow-up for next care
Treatment errors	<ul style="list-style-type: none"> ● Failure to implement DOTS strategy ● Failure to provide emergency services ● No urgent referrals ● Failure to follow urgent and non-urgent referral ● Continued treatment unnecessary ● Delay or error in treatment
Vaccination errors	<ul style="list-style-type: none"> ● Wrong technique in vaccination ● Wrong technique in vaccine reconstruction ● Low quality vaccines, solvents or syringes ● Improper storage of the vaccine ● Vaccination in contraindication of vaccination ● Wrong path of vaccination ● Vaccination in the wrong place ● Vaccination or distribution of past vaccines ● No hand washing before injection ● Wrong vaccine injection ● Vaccination with improper doses Failure to observe the cold chain ● Vaccination in inappropriate time or age ● Failure to report complications of vaccination ● Non-registration of cold chain information ● Lack of sterilization of the injection site
Environmental and occupational health errors	<ul style="list-style-type: none"> ● Inadequate monitoring of sewage and waste disposal ● Non-formation of health Council meetings ● No legal deal with health offenders ● Insufficient training of food center operators ● No daily chlorination ● No dealing with reported complaints ● Insufficient sampling of water and food ● Non-assessment of workplace harmful factors ● Inadequate or incomplete inspection of sensitive food supply and distribution centers ● Inadequate monitoring of workshops
Administrational errors	<ul style="list-style-type: none"> ● Past or degraded date items ● Equipment Downtime ● Non-standard equipment ● Lack of appropriate equipment ● Defects in guidelines ● Defects in the registry system ● Lack of personal protective equipment ● Non-safe physical spaces

Medication errors	<ul style="list-style-type: none"> ● Prescription or distribution of the drug with inappropriate repeated and timing ● Prescription or distribution of medication to the wrong patient ● Drug administration or distribution with incorrect shape ● Drug in the wrong dose Inadequate storage of drugs ● Prescription or distribution of the wrong medication ● Drug interactions ● Non-prescription drug distribution ● Distribute or inject the damaged or expired drugs ● Use of the wrong technique of drug injection ● Mistakes in drug preparation ● No drug consultation ● Wrong on the way medicine enters the body
Laboratory errors	<ul style="list-style-type: none"> ● Use of past materials and supplies for sampling ● No or incorrect labeling ● Non-observance of sterile conditions during and After sampling ● Incorrect sampling technique ● Defects or errors in admission forms or test requests ● Improper transfer of samples Delayed Sample Analysis ● Low volume sampling ● Sampling of wrong patient ● Use non-standard or expired kits ● Lack of sufficient time for analysis ● Missing result ● Use of undesirable sample for testing ● Announcement of the result without testing ● Error recording test results ● Incorrect sending of patient test results ● No set up devices
Imaging errors	<ul style="list-style-type: none"> ● Lack or incorrect marking ● Lack of using proper protection devices ● Wrong techniques in performing graphic ● Improper dose of radiation ● Improper patient preparation ● Use of non-standard or past dates emergence materials ● Improper patient position ● Do radiographs from the wrong position

Literature shows that the error reports are even neglected in the hospitals, and there is a lack of evidence on the error reporting system for primary care (30). Accordingly, the proposed medical errors reporting system in primary health care was designed and launched for the medical errors from all primary health care units and programs including age groups care; immunization of children and certain groups; diagnosis and treatment; midwifery; dentistry; nutrition; psychology consultations; pharmaceutical, laboratory, radiology, environmental and occupational health; and school health. The errors are collected and analyzed through the reporting system to reduce the recurrence and increase the patient safety.

In this project, instead of designing a paper reporting system, a web-based system was launched to report the errors. As shown in the literature, using an electronic reporting system is more time-efficient and accurate for recording the information. This results in easier data collection and analysis, increases the quantity and quality of reporting, and provides data for informed decisions by the field leaders (31).

Setting up a reporting system for medical errors in primary health care has restrictions. The main limitation of such a system registry is the fear of legal actions against the individual reporting of the error (32). Such fear may result in under-reporting. A survey of the emergency department of an educational hospital showed that only 10% of the errors had been reported in the hospital (33). We also expect that the designed registry system in this project to suffer from underreporting due to similar reasons. Therefore, we found out that implementation of such a system requires to be accompanied by promoting the culture of error reporting, as well as providing appropriate legal and professional support for the primary health care staff. Such an intervention has been designed to prevent underreporting and used effectively in the design of the error reporting system at Duke University and the European Immunization Errors registry system, at least for 10 years until the error report reached an acceptable level (15, 34). Appropriate culture for reporting errors in health centers has not been performed in Iran. Therefore, still the health care workers fear reporting and its

legal, social, cultural, and financial consequences. On the other hand, reporting medical errors is not considered an issue of necessity in the laws of Iran.

By designing this registry and creating a system for reporting medical errors in primary care and using the feedback for error prevention, the health care errors will reduce. This will result in the escalation of the quality of care and patient safety. Due to the lack of an error reporting system in primary health care, it is recommended that this reporting system should be piloted in one of the regions of the country and then expanded throughout the country. Future research related to this study could address the ways to increase reporting errors and patient safety in primary health care. It is suggested that the effectiveness and efficiency of this software should be evaluated in future studies.

Conclusion

Due to the lack of a national error-reporting system in health care centers in Iran and the existence of different barriers to reporting errors in health centers, not reporting mistakes is very common. Therefore, medical errors continue to occur, and patients' safety is endangered. Managing medical errors successfully needs the establishment of a voluntary reporting system and addressing barriers to reporting errors. This innovative error registry system of primary care was created to collect, analyze, and disseminate information about the frequency, types, and causes of medical errors in primary health care.

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Authors' Contributions

Abdoljabbar Zakeri: acquisition, and analysis of data, drafting the work, final approval, agreement to be accountable for all aspects of the work; Mahatsi Khakpour: conception or design of the work, revising the work, final approval, agreement to be accountable for all aspects of the work; Mina Danaei: interpreting the data, revising the work, final approval, agreement to be accountable for all aspects of the work; Mohsen Momeni: interpreting the data, revising the work, final approval, agreement to be accountable for all aspects of the work; Ardalan Askarian: acquisition of data, drafting the work, final approval, agreement to

be accountable for all aspects of the work; Mehrdad Askarian: conception or design of the work, revising the work, final approval, agreement to be accountable for all aspects of the work

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Ethics approval and consent to participate

This study was approved by the vice-chancellor of research and technology, as well as the local ethics committee of Shiraz University of Medical Sciences (IR.sums.med.rec.1397.526).

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Appendix: Draft Form for Collecting and Classifying Medical Errors in Primary Health Care

Date of occurrence				
Error description				
Error leads to	Patient injury Damage to equipment and facilities	Injury to staff	Without causing harm	
Error severity	Sentinel event	Non-essential event		
Type of event	Near miss event	No harm event	Harmful event	
The cause of the error	Lack of staff	Novice staff	Lack of awareness	
	Ignorance of reading and executing commands	The hustle and bustle of the center	Fatigue	
	The non-transparency of the handwriting	Failure to follow the principles of medication	Error in calculating the dose	
	Lack of proper communication with the patient	Lack of correct diagnosis	Neglect	
	Failure to follow up on required	Lack of medical services	Low sleep	
	Failure to provide services to other employees	Failure to provide nursing services	Long shift	
	Failure to follow the principles of infection control	Lack of patient identification	Employee job diversity	
	The lack of staff insufficient staff training	Defective equipment	Inadequate layout	
	Formal or nominal similarity of the drug	Others		
	Was the incident preventable?	Yes	No	
Have you been trained to prevent this error before?	Yes	No		
Error detection by	Error	The person accompanying the client	Client	
	Environmental supervisor	Employees of the same unit	Staff Supervisor	
	Employees of other units	Students		
Level of error reporting education	High school	Diploma	Associate Degree	
	Bachelor	MA	Doctorate	
Level of error education	High school	Diploma	Associate Degree	
	Bachelor	MA	Doctorate	
Error detection time	Before an error occurs	While making an error	After making an error	
	After complications			
Employment status of error reporter	Official	Contractual	Manpower plan	
	Private company			
Error reporting work experienceyears			
Error work experienceyears			
Error gender	Male	Female		
Error Reporting Job	Family physician	Dentist	Dentist assistant	
	Nurse	Nurse assistant	Health care	
	Behvarz	Supervisor expert	Psychologist	
	Nutritionist	Environmental Health Expert	Professional health expert	
	Radiology expert	Laboratory technician	Laboratory technician	
	Midwife	Disease control expert	Admissions Officer	
	Medical Statistician	Public affairs director	Servant and janitor	
	Guard	University student	Head of the Center	
	Head of Staff Unit	Administrative and Financial expert		
	Error job	family physician	Dentist	Dentist assistant
		Nurse	Nurse assistant	Health care
		Behvarz	Supervisor expert	Psychologist

	Nutritionist	Environmental health expert	Professional health expert
	Radiology expert	Laboratory expert	Laboratory technician
	Midwife	Disease control expert	Admissions Officer
	Medical Statistics Expert	Public Affairs director	Servant and janitor
	Guard	University student	Head of the Center
	Head of Staff Unit	Administrative and Financial Expert	
Error location	Health House / Rural Health Base	Rural Health Center	Urban Health Base
	Behavioral disease Counseling center	Pre-marriage counseling center	Urban health center
	Vulnerable women's counseling center	Children's development center	Border care base
	Pulmonary center	medical laboratory Dental clinic	Staff units
	Harm reduction center		
	Vaccine and rabies Vaccination unit	Cold chain unit and vaccine distribution	
Error time	Morning	Evening	the night
Type of errors	Diagnosis and treatment errors		
	Failure to perform tests with indications	Doing the wrong procedure on the patient	Misdiagnosis
	Performance of unnecessary procedures and tests	Use unconventional methods for diagnosis	Delay in patient treatment
	Initiation or continuation of unnecessary treatment for the patient	Failure to provide emergency services to the patient	Delay in diagnosis
	Performance of the procedure in an inappropriate physical space	Perform the procedure in the wrong position	
	Failure to follow the principles of infection control during the procedure	Others	
	Nursing errors		
	Incomplete medications and other supplies in the emergency room	Existence of expire date drugs in the emergency room	Delay in following the doctor's order
	Failure to provide emergency services to the patient	The equipment is not ready for use in emergencies	Others
	Performance the procedure in an inappropriate physical space	Performance of the procedure in the wrong position	
	Failure to follow the principles of infection control during the procedure	Doing the wrong procedure on the patient	
	Drug errors		
	Improper storage and storage of drugs	Prescribing the wrong medicine	Wrong drug distribution
	Improper prescription of time and frequency of drug use	Wrong prescription of drug form for patient	Wrong distribution of drug form
	Distribution of destroyed drug or expired date	Prescription of an inappropriate dose of medication	Mistakes in drug preparation
	Drug distribution more or less than the prescribed amount	Prescribing drugs with drug interactions	Others
	Distribution of medication to the wrong patient	Prescription of medication to the wrong patient	
	Distribution of drugs without prescription	Injection of destroyed drug or expired drug	
	Wrong way of drug administration	Use of the wrong drug injection technique	
	Laboratory errors		
	Failure to comply with sterile conditions during and after sampling	Sterile conditions during and after sampling	Sampling from another patient
	Failure to receive a sample from the patient	Inadequate sampling of the patient	No sampling from the client
	Patient conditions are not appropriate prior to sampling	Attachment of the wrong label on the sample container	No labeling container sampling

Use of expired materials and equipment for sampling	Use of inappropriate sampling techniques	Wrong sampling of the patient
Failure to complete or defect in test and sampling application forms	Improper transfer of samples to the laboratory	Missing sample
Use of an unfavorable or inappropriate sample for analysis	Avoidable delays in analyzing the sample	Human errors
Error recording information by receptionists when delivering sample	Errors due to laboratory materials	Instrumental errors
Failure to notify critical results as soon as possible	Incorrect sending of patient test results	Missing test results
Defects in the software or hardware system	Avoidable delays in sending test results	Error recording test results
Others		
Imaging errors		
Lack of using a marker to determine the location	Mistake in placing a marker in the right place	Incorrect patient position
Failure to record the patient's exact profile in imaging	Use of expired materials for emerging	Improper dose of radiation
Failure to use appropriate protective equipment for the patient	Lack of accurate history of the patient	Wrong technique in imaging
Lack of proper patient preparation	Others	
Administrative errors		
Lack or lack of proper equipment to provide service	Non-calibration of equipment	Non-standard equipment
Existence of contaminated drugs and biological substances	Existence of past date or destroyed consumer items	Equipment failure
Uncovered wires and unsecured switches and sockets	No emergency power when needed	Others
Non-standard physical space and its input and output		
Vaccination errors		
Improper storage of vaccine	Distribution of past date vaccines	Improper vaccine packaging
Unclear name of the vaccine or solvent	Inappropriate needle of syringe	Improper syringe
Wrong technique in vaccine regeneration	Vaccine injection in the wrong place	Contamination of vial vaccine
Incorrect route of vaccine injection	Wrong technique in vaccine injection	Reuse of disposable vaccine
Vaccine injections in cases of vaccination	Injection of the vaccine at the wrong time	injection past date vaccine
Injection of the wrong vaccine into the client	Not washing your hands before injection	Vaccine injection at a lower dose
Injection of several high-dose vaccines	Repeated injections of a vaccine by mistake	Vaccine injection at higher doses
Injecting the wrong vaccine into another client	Failure to record the opening date of the vials	not sterilization the injection site
Use of ready-made vials after expiration date	Failure to record cold chain information	Vaccine injection at the wrong age
Injection of vaccines without ensuring that they are healthy	Incorrect recording of vaccine refrigerator temperature	Others
Failure to comply with the cold chain during vaccine transmission	Failure to register vaccination information in the registry	
Storage of the vaccine or solvent in the vaccination refrigerator	Incorrect training and consulting to clients after vaccination	
Failure to register vaccination information on the vaccine card	Failure to report vaccine complications in a timely manner	
Type of Vaccine		
OPV	IPV	MMR
MR	HB	DTP
Td	BCG	Pentavalent

DT	Rabbis	Meningitis
H.Inf	Influenza	
Care errors		
Lack of accurate assessment of danger signs in care	Failure to take a detailed history	Lack of careful examination
Lack of measurement of vital signs and other indicators of care	Misdiagnosis of disorders in healthy people	Incomplete care
Wrong measurement of vital signs and other indicators of care	Lack of referring the patient in emergencies	Lack of identification of disorders
Failure to follow up on non-urgent referrals	Failure to follow up on urgent referrals	Wrong IUD placement technique
Failure to follow up for the client's next visit	Record information without taking care	Using past date IUD
Failure to register information in the system in case of care	Incomplete registration of care information	Incomplete treatment of patients
No prescription supplements for age groups	Incorrect registration of care information	Improper training in age group care
Wrong prescription of pharmaceutical supplements	Prescribing destroyed or past date drug supplements	Lack of human sampling in outbreaks
Prescription of an inappropriate dose of medication supplements	wrong prescribing of contraceptives	improper behavior with customer
Improper prescription of time and frequency of drug supplements	Distortion of samples taken or tests performed	
Distribution of destroyed or expired contraceptive items	Wrong technique of testing and sampling	
Lack of testing and sampling required in the care of age groups	Improper maintenance of samples taken	
Use of expired devices and kits to perform tests and sampling	Improper transfer of samples taken to the laboratory	
Lack of active case finding of high-risk groups of infectious diseases	Improper interpretation of rapid diagnostic tests	
Lack of direct treatment under the supervision of a health expert in TB	Treat patients with expired medications	
Lack of immediate reporting of outbreaks and cases that can be reported	Lack of assessment of the patient relatives	
Delayed epidemiological investigation of outbreaks	Improper counseling in the care of age groups	
Failure to intervene in time for the spread of infectious diseases	Lack of necessary training in the care of age groups	
Failure to comply with confidentiality of client information	Others	
Lack of sampling of water and food in water and food outflows		
Lack of necessary advice in the care of age groups according to the instructions		
Existence of destroyed or past date drugs and supplements		
Improper storage of medications, supplements, and contraceptives		
Type of care program		
Neonate	Children	Adolescents
Patient	Young	Elder
Pregnant mother	Patient	

Suggestion