Institutionalization of Patient-Centered Tuberculosis (TB) Treatment in Armenia

Result Area 1: Strategy for improved quality and safety of TB service delivery at PHC level endorsed by stakeholders

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EXECUTIVE SUMMARY

Strengthening TB services in all levels is an important step toward improving quality of provided services and patients' life, decreasing TB morbidity and mortality. In 2019, the Zvart Avedisian Onanian Center for Health Services Research and Development (CHSR) of the Turpanjian School of Public Health, American University of Armenia in collaboration with the National TB Control Center of the RA Ministry of Health and with financial assistance from the USAID implemented a project which included an evaluation of the needs and services in the outpatient TB settings in Armenia based on the best internationally accepted standards. The aim of this subcomponent of the project was to work with stakeholders and develop a strategy to improve quality and safety of TB services delivery at the Primart Health Care (PHC) level.

The study team (1) reviewed and summarized the literature on quality assessment of outpatient TB facilities, (2) qualitatively explored practices of TB healthcare professionals at PHC level and ambulatory treatment experience of TB patients and their family members, (3) assessed the documentation, staff practices and environmental conditions of outpatient TB facilities using standardized checklists, (4) evaluated compliance level of TB diagnostic and treatment practices with internal policies and procedures, national and international guidelines and standards, (5) made recommendations to the National TB Control Center (NTCC – currently renamed to National Center of Pulmonology) based on the findings, and (6) developed core quality indicators for establishing a continuous quality improvement system in outpatient TB centers at the PHC level in Armenia.

The study showed that several processes were not standardized and consistent throughout the PHC facilities and required continuous improvements. It also provided a roadmap for prioritizing the needs and developing a strategy to address the existing mismatches between protocols/guides and practice. Furthermore, it highlighted areas where training of healthcare providers can lead to effective and sustainable changes, while reinforcing the strength of the system. The set of core quality initiatives for establishing long-term programs targeting integration of a patient safety and quality assurance system into outpatient TB centers in Armenia included:

(1) continues quality improvement program, (2) continuous professional development program, (3) patient and family rights program, (4) data management program, (5) hand hygiene program, and (6) laboratory and radiation safety program.

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BACKGROUND

Tuberculosis

Tuberculosis (TB) is an infectious disease caused by the *Mycobacterium tuberculosis*.[1] Between five to ten percent of the 1.7 billion people infected with TB acquire the disease during their lifetime. Ninety percent of TB cases are adults, with male to female ratio of 2:1.[1] Even though TB has been known as the "disease of the past", given the decrease in morbidity and mortality rates in Western Europe and North America, it still remains a major epidemic and public health challange in many countries.[1] Globally, 10 million people develop TB disease each year and TB is among top 10 causes of death worldwide. TB is also number one cause of death from single infectious agent, outranking HIV/AIDS.[1] Globally, TB mortality and incidence rates have been decreasing by 3% and 2% per year, respectively.[1] In 2018, Armenia had a TB incidence rate of 33 per 100,000 population and a mortality rate of 1.8 per 100,000 population.[1] In 2014-2015, WHO and UN committed to the global goal of ending TB epidemic and set milestones for years 2020, 2025, 2030, and 2035.[1]

TB disease development and poor TB care are affected by several risk factors.[2] At the same time TB itself is a risk factor and can cause complications for other health conditions. Hence, early identification of comorbidities is crucial for early diagnosis of TB and management of comorbidities. The most common risk factors for developing TB are HIV, diabetes, poor nutrition, tobacco smoking, and harmful use of alcohol. People living with HIV are 26-31 times more likelily to catch TB. People living with diabetes are 3 times more likely to develop TB than people without diabetes. Malnutrition and TB are mutual risk factors. Tobacco smoking can double or triple the risk of developing TB and is associated with poor TB care and treatment results. Harmful alcohol use can affect TB treatment adherence and triple the risk of catching TB.[2]

WHO separates three tests for TB diagnosis: rapid molecular tests, sputum smear microscopy, and culture-based methods. Rapid molecular tests can present results in less than two hours.[1] It is recommended both for adults and children and is much more accurate than sputum smear microscopy. Sputum smear microscopy includes testing of patients' sputum samples by a

microscope to check for bacteria's presence. Culture-based methods demand more sophisticated laboratory accommodations to come-up with results; this process can take up to 12 weeks.[1]

Drug-resistant tuberculosis (DR TB) is a worldwide public health threat and can jeopardize TB treatment and management globally. Drug-resistance is caused by inappropriate antibiotics utilization during chemotherapy among drug-susceptible TB patients. This inappropriate usage can arise due to various factors, such as incorrect management of treatment procedure and failure to assure full completion of treatment. Drug resistance mostly happens in regions with poor TB services and programmes.[3] According to WHO 2018 data, there were about 0.5 million new cases of rifampicin-resistant TB, of which 78% had multidrugresistan TB (MDR TB).[4] Armenia also faces challenges with DR and MDR TB.[5] In 2017, the prevalance of new MDR TB cases reached 16% and among retreated cases 44% in Armenia.[1]

The most effective way to prevent DR TB is taking medication as prescribed by health care workers.[6] Dosages should not be missed and treatment should be continued until the end of the treatment course. TB patients should have a proper communication with their health care providers to ensure that their doctors are informed in case they are having difficulties with taking their medication. The role of health care providers in preventing DR TB evolves around prompt case diagnosis, strictly following proposed treatment guidelines, following-up on patient's response to medication and overall treatment, and ensuring that treatment is completed. DR TB is more difficult to cure. Improper monitoring of treatment can result in life-threatening consequences, including depression, hearing loss, hepatitis, kidney impairment among patients, etc. The higher the resistance, the bigger potential life-threatening causations and the costlier the treatment.[6] In the US, cost for drug-susceptible TB treatment can average around $18,000 compared to $513,000 for DR TB treatment with no count on the lost income by patients during their treatment.[6]

National Tuberculosis Control Center (NTCC) in Armenia

In Armenia, the National Tuberculosis Control Center (NTCC) organizes and coordinates both inpatient and outpatient TB services through TB prevention and treatment at three levels:

- Central level – responsible for direct coordination and professional assistance of all services.
- Hospital level – responsible for diagnosis and inpatient care during intensive phase of TB treatment for sputum smear positive (SS+) patients.
- Primary level – responsible for outpatient care during intensive phase of TB treatment for sputum smear negative (SS-) patients and all TB patients during continuation phase of TB treatment.[7]

Until 2018, inpatient TB services were functioning through two specialized TB dispensaries (one located in Abovyan city with a total 300 TB hospital beds, serving about 90% of all TB patients from Armenia (around 3,000 TB patients annually) and another one located in Yerevan city with a total 48 TB hospital beds serving mainly Yerevan residents) and four departments in regional hospitals in Gyumri, Vanadzor, Kapan, and Goris (with a total 110 TB hospital beds).[7] After optimization, all facilities providing inpatient TB services in Armenia were consolidated into a single hospital in Abovyan city. Currently, outpatient TB services are functioning through 59 outpatient TB centers including regional 50 PHC level facilities and nine in Yerevan.[7]

According to the WHO, starting 2014, Armenia has been working on improving and transforming its health system through launching vital changes (e.g., "new financing mechanisms for hospital TB services and updated hospitalization and discharge criteria in an attempt to execute TB prevention and more people-centered care").[8]

Role of Primary Health Care (PHC) in TB Management

The effectiveness of the care provision is directly associated with the primary health care setting with active screening and strong alignment with the admission and discharge criteria. Outpatient facilities and the PHC providers are particularly important in Tuberculosis (TB) management and control given that they are usually the first ones most of the TB patients refer to.[9] According to WHO, a PHC system cannot be considered appropriate if it does not engage in TB control.[9] The importance of PHC in many countries, including Central and Eastern Europe and Commonwealth of Independent States (CIS), is growing.[9] The overall goals of TB control are to

reduce mortality, morbidity, and disease transmission, and prevent development of DR-TB in community.[9–11]

TB services and PHC are mostly connected at the district level.[9] The functions of PHC regarding TB services include examining the patient, taking medical history, ordering smear examination and x-ray, or refering the patient to providers who are qualified to carry out these tests. PHC facilities, under the management of TB control services, can also provide directly observed treatment to the patients during the continuation of TB treatment, checking adverse reaction to medications, referring patients for regular check-ins and monitoring with the TB physician, and ordering sputum microscopy examination during the treatment period.[9] If these were to happen, PHC providers should ensure ongoing collaboration and systematic communication with TB services concerning patient's treatment advancement and other problems that could occur. The cooperative relationship between PHC and TB services produces higher level of TB care for the patient.[9]

PHC providers also have the ability to provide education to the TB patients and use its compatibility with patients to encourage them to continue the TB treatment and provide mental and emotional support, which is proven to be critical in TB treatment.[12,13] Due to different social factors influencing the disease and multiple needs of TB patients, favorable TB control and management requires a multidisciplinary approach.[13] Multidisciplinary teams, implementing versatile and patient-centered care, are involved in TB control and management in several countries like the United Kingdom (UK) and Norway. It often involves professionals (TB lead physician, case manager, general practitioners, social worker, specialized doctors per patient need, a peer supporter and a psychologist) with a variety set of skills to ensure the needs of TB patients are met, especially more complicated are MDR TB cases who demand supplementary psycho-emotional and clinical support.[13 9,14,15]

Even though the functions of PHC may differ depending on regions and countries, the basic components of the system can be common, including the link between TB services and PHC providers.[9,13] Some countries stress improving patient follow-up and reinforcing diagnostic capacity at the PHC level (Norway, UK, Taiwan), while other countries include arrangement of

directly observed therapy (DOT) and sub-divisions of case-management in the role of general practitioner (Romania, Turkey, India).[13] Latent TB screening practices at PHC facilities have been noticed recently in high income countries. [10,16,17]

Considering the best international practices and concepts and following the WHO's people-centered model of TB care, the Ministry of Health of Armenia is working on the optimal model development for TB prevention and care in the country providing TB patients in district level the diagnostic services, directly observed treatment, control of adverse reactions from TB drugs, and TB counseling.[18] The Ministry of Health also specifies three stages of infection monitoring and management within PHC facilities: administrative, environmental, and personal respiratory protection.[9,19] The goal of the administrative control is to decrease patient exposure to droplet nuclei transmission. At this stage, PHC is responsible for rapid detection of possible TB infected patients and proceeding to isolating these patients from general public, refer to in-patient facilities for quick initiation of proper treatment, and finally to follow infection control plan of the facility. The goal of environmental control is to decrease the concentration of infectious droplet nuclei. PHC is responsible for escalating natural ventilation and controlling direction of airflow in TB patient areas and when collecting sputum. Personal respiratory protection goal is to protect health care workers in places where concentrations of droplet nuclei cannot be properly decreased by administrative or environmental levels. PHC providers are supposed to be aware of usage of proper clothing, instruments to protect health care workers from inhaling infectious droplet nuclei and that usage of respirators need to be done in restricted cases such as high-risk scenarios.[9,19]

Quality of Care and TB

The WHO End TB Strategy, that the Government of Armenia has also joined for 2016-2022 years, acknowledges the shortage of access to high-quality preventive, diagnostics and treatment services and introduces three pillars to ensure: 1) integrated, patient-centered care and prevention; 2) bold policies and supportive systems; and 3) intensive research and innovations.[19] High-quality TB care provision is essential to prevent suffering and death from TB and cut its transmission. It increases the likelihood of desired health outcomes. Mistrust in the healthcare caused by poor quality services impedes their utilization and challenges disease control efforts.

[20,21] Introduction of international standards and guidelines for TB care provides opportunity to ensure access to high-quality TB services, serving as a comparison benchmark for the national program's performance assessment. [20]

Assessment of adherence of diagnostic and treatment services delivery to the standards is one of the core components for defining quality of provided care and can guide developing quality improvement programs targeting the identified gaps and constraints.[20,21] The WHO defines quality of care as a conjunction of six dimensions: effectiveness, efficiency, accessibility, acceptability, equitability, and safety.[22] Best practice of care will try to address all these dimensions.

Another approach defines quality of care by differentiation of roles and responsibilities through identifying three perspectives of the concept of quality of care: perspective of a patient, service provider, and health facility manager. Service provider's perspective of quality, including TB service providers, incorporates capacities such as competence, confidence, being respectful, educating patients, application of management core principles, team working ability, motivation and proper documentation of treatment outcomes. Facility managers in their turn shall offer services that satisfy patients, and properly monitor the indicators.[22,23]

Joint Commission International Accreditation Standards for Ambulatory Care, developed by the Joint Commission International (JCI) target to measure the quality of services being provided in the primary healthcare (PHC) facilities to improve the performance and the outcomes of the ambulatory services. [24] The assessment of quality of service provided in the PHC level is conducted through functions, standards and measurable elements. The JCI Accreditation Standards for Ambulatory Care 3rd edition identifies 16 functions grouped into two major sections: International Patient Safety Goals, Access to Care and Continuity of Care, Patient and Family Rights, Assessment of Patients, Care of Patients, Anesthesia and Surgical Care, Medication Management and Use, Patient and Family Education, Quality Improvement and Patient Safety, Prevention and Control of Infections, Governance/Leadership and Direction, Facility Management and Safety, Staff Qualifications and Education, Management of Communication and Information.[24]

The International Standards for TB Care (ISTC) developed by the Tuberculosis Coalition for Technical Assistance has been proposed as a tool describing the level of care to be achieved by the providers in order to facilitate high-quality care provision to all forms of TB patients.[24] High-quality TB care provision is an important step toward improving medical practice and patient outcomes to eventually decrease the disease incidence. [22,25] The improvement of the quality of TB services is possible through adherence to international standards adapted for the country. TB services delivery should incorporate mechanisms to assure, monitor, and continually improve quality. Identification of gaps in TB service delivery through assessing its effectiveness, safety, people-centeredness, timeliness, equity, integration of care and efficiency is the first step in this process, followed by the implementation of evidence-based approaches addressing identified gaps and constraints. [23]

In 2016, the American University of Armenia (AUA) developed and assessed the needs of the National TB Control Center's (NTCC) inpatient diagnostic and treatment services of the largest TB hospital in the country located in Abovyan city that provides inpatient care to around 3,000 TB patients annually. The assessment was performed using the JCI Accreditation Standards for Hospitals, International Standards for TB Care, and WHO framework for conducting TB program reviews, targeting to measure the quality of inpatient TB services.[26]

STUDY OBJECTIVES

In 2019, the Zvart Avedisian Onanian Center for Health Services Research and Development (CHSR) of the Turpanjian School of Public Health, American University of Armenia in collaboration with the National TB Control Center of the RA Ministry of Health and with financial assistance from the USAID implemented a project which included an evaluation of the needs and services in the outpatient TB settings in Armenia based on the best internationally accepted standards. The aim of this subcomponent of the project was to work with stakeholders and develop a strategy to improve quality and safety of TB services delivery at the Primart Health Care (PHC) level. This project started with an initial needs assessment evaluating different aspects of NTCC's diagnostic and outpatient operations, including both clinical and administrative functions. The specific objectives of the needs assessment were:

- Review and summarize literature on quality assessment of outpatient TB facilities.
- Qualitatively explore practices of healthcare professionals of outpatient TB facilities and outpatient treatment experience of TB patients and their family members.
- Using standardized checklists assess the documentation, staff practices and structural conditions of outpatient TB facilities.
- Assess the compliance level of outpatient TB diagnostic and treatment practices with the internal policies and procedures, national and international guidelines and standards.
- Make recommendations to the National TB Control Center based on the assessment findings for further improvement in the provision of TB diagnostic and treatment services delivery at PHC level.

METHODS

Study design and participants

The quality of TB diagnostic and treatment services in outpatient TB cabinets was assessed using a mixed methods study design. We integrated qualitative and quantitative methods by triangulating results from all data collection instruments and methods[27] that included standardized checklists for observations, documents and medical records review, in-depth interviews (IDIs) and focus group discussions (FGDs). Observations facilitated the research team to objectively evaluate the compliance with standards. Documents review helped to check the availability of local policies and procedures as a formal ground for PHCs' and outpatient-TB facilities' functioning. With medical records' review, we were able to assess how patients' health information gather during provider-patient encounter is documented. In-depth interviews and focus group discussions identified participants' insights and perspectives on their daily practices with respect to the standards being assessed.

The research team have identified key informants from the PHC facilities with outpatient TB services in Armenia, using purposive and convenient sampling methods to provide pertinent information for the assessment, based on their experience and expertise in the outpatient care. The key informants recruited for the study included1) PHC managers, 2) TB physicians/nurses, 3) family physicians, 4) radiologists, 5) TB laboratory physician/technician, 6) TB patients and 7) TB patients' family members.

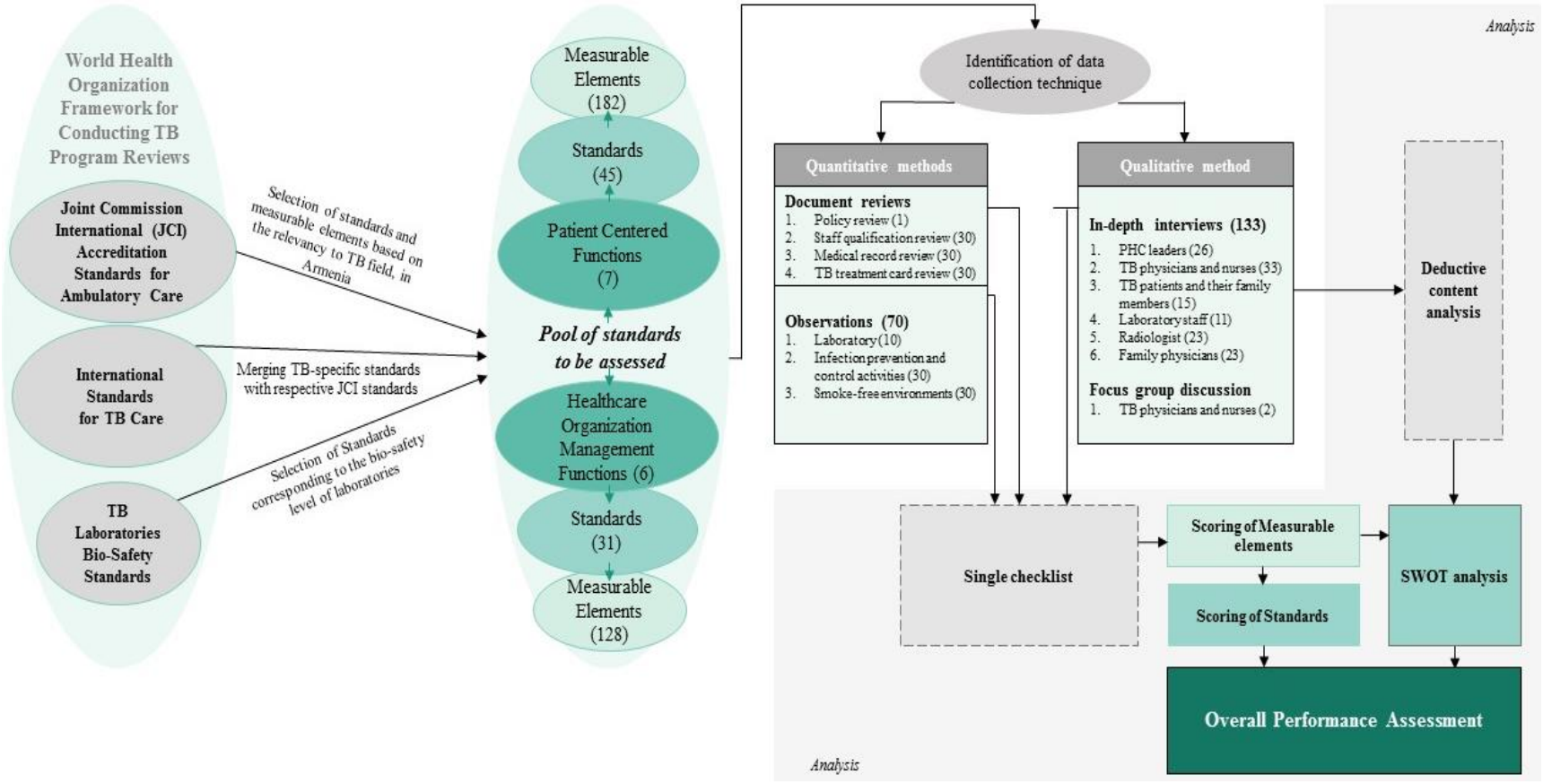
Study Instruments

Joint Commission International Standards for Ambulatory Care, International Standards for TB Care, and WHO framework for conducting TB program reviews, served as a framework for quality assessment[24]. Overall, 13 functions of international standards for ambulatory care in general and for the TB care in specific, including standards for laboratory biosafety, TB-Tobacco control, and the waste management practices were developed. These standards were divided into two main sections consisting of seven Patient Centered Functions and six PHC Management Functions, including the TB-Tobacco Control function[27] (using WHO recommendations for integration of TB and tobacco control measures[28]). All these Functions have their specific Standards, each of Standards consists of several Measurable Elements (Table 1, Figure 1).

Table[VP1] **1.** JCI Functions and the number of assessed Standards and the Measurable elements.

JCI Functions	Standards	Measurable Elements (ME)
Patient-centered Functions		
1. International Patient Safety Goals (IPSG)	3	9
2. Access and Continuity of Care (ACC)	7	21
3. Patient and Family Rights (PFR)	9	29
4. Assessment of Patients (AOP)	13	71
5. Care of Patients (COP)	3	17
6. Medication Management and Use (MMU)	4	15
7. Patient and Family Education (PFE)	6	20
PHC Management Functions		
8. Quality Improvement and Patient Safety (QPS)	6	21
9. Prevention and Control of Infection (PCI)	3	15
10. Governance, Leadership and Direction (GLD)	8	33
11. Staff Qualifications and Education (SQE)	6	22
12. Management of Information (MOI)	5	23
13. TB-Tobacco Control (TBTC)	3	14
Total	**76**	**310**

Figure 1. Flowchart of data collection instruments, data management and analysis.



The JCI and WHO standards and measurable elements were incorporated into the study instruments when appropriate for the assessment to develop checklists and open-ended questions for the in-depth interview and focus group discussion guides (Appendix 1). All the study instruments were developed in English and translated into Armenian. The quantitative checklists were pretested before data collection; the qualitative guides were continuously improved as needed during the process of data collection.

Sampling and data collection

PHC facilities were sampled using clustering approach. Each of the 10 marzes and the capital city Yerevan served as a cluster (11 clusters in total). Within each cluster, 50% of PHC facilities having outpatient TB centers were randomly selected to be included in the assessment. In total, 30 outpatient TB centers were selected (Appendix 2).

Data collection lasted February-April 2019. Two data collection teams, each consisted of one CHSR researchers and two interviewers were formed to simultaneously visit the selected outpatient TB facilities for the data collection according to a predetermined timeline. Prior to the start of the data collection, the teams receivedextensive training on the study purpose, the data collection methods and the study instruments.

During each visit to PHC facilities, the research team attempted to approach the manager of the facility, TB physicians and nurses, family physicians, radiologists, TB laboratory physicians or technicians (if available), and TB patients and their family members and to employ all study instruments. In the scope of policy review the National Guideline on TB diagnosis and treatment, serving as a national criterion and guiding TB management processes across the country, was reviewed against the JCI standards. In total, the study team completed 70 observational checklists, reviewed 91 documents, conducted 133 in-depth interviews, and two focus group discussions (Figure 1).

<u>Documents review</u>

Policy documents' review was conducted to understand what were the formal documents regulating the PHC facilities daily practices regarding TB treatment and diagnosis. Reviewed

documents included: organizational chart of the NTCC, internal disciplinary rules of the organization, and internal regulations of different structural units. We also reviewed several guidelines and national regulations, such as hand-hygiene guideline, medical waste and expired materials' disposal guideline, methodological guide for TB infection control, and the national standard for TB treatment and diagnosis. The staff qualification document review was designed to evaluate compliance of relevant professional experience, qualifications and credentials required for job duties and responsibilities of staff.

Medical records review included reviews of medical records and TB treatment cards of TB patients admitted for TB outpatient treatment two months prior to the assessment. We selected two months prior to the assessment to have adequate time to review the full range of medical records per patient (medical history, TB treatment card, and MDR-TB treatment files). TB treatment cards are transferred to TB outpatient centers from inpatient facilities after patients' discharge. All clinical departments that did not admit new TB patients during the data collection period were asked to provide all records they had from 2018.

Observations

Observations using standardized checklists were designed to explore several environmental condition indicators and daily practices of healthcare providers in TB treatment and diagnosis. To evaluate the quality of diagnostic laboratory services, we observed laboratory staff's daily practices, considering the degree of compliance with the WHO bio-safety standards of TB laboratories[29] and radiology department. We used a standardized checklist to assess smoking practices and strategies to eliminate indoor smoking based on observation of behaviors of healthcare providers and patients/family members.

In-depth interviews and focus group discussions

The study team identified key informants from PHC facilities clinical staff and administration using purposive sampling to optimize information acquisition and convenience sampling for those willing to participate, given optimal utilization of available resources. All stakeholders of outpatient TB services were included to ensure validity. In-depth interviews included seven key informant groups/sampling units: 1) PHC managerial leaders, 2) TB physicians/nurses, 3) family

physicians, 4) radiologists, 5) TB laboratory physician/technician, 6) TB patients and 7) family members.They were further categorized as 1) administration 2) healthcare providers, and 3) TB patient and family members to protect their confidentiality and to provide 'data triangulation'.[27] TB health care providers were physicians and nurses with professional experience working in the PHC facilities. To ensure full coverage, at least one representative from each sampling unit across all 30 assessed PHC facilities had participated in the study. Participating TB patients (their family members) had completed their TB treatment. To recruit TB patients, we collaborated with TB outpatient center physicians who made the initial contact with patients to share their contacts with the research team and after obtaining their agreement, passed patients' contact information to the research team.

Data management and analysis

All data collected through document/medical record review and observations were double-entered into a single datasheet using SPSS 21 software. The qualitative data were first verbatimly transcribed and then analyzed using Nvivo 12 pro software and utilizing deductive content analysis with a structured matrix.[30–32] The research team utilized a predefined structure of initial coding which comprised of the measurable elements of the selected standards (Figure 1). After verbatim transcription of the data, two researchers reviewed all transcripts and using 'investigator triangulation' started the analysis. 'Data triangulation' was applied across the different data sources.[27]

To integrate qualitative and quantitative results in measureing levels ofcompliance to the standards, we developed a single checklist comprising of all assessed standards with their measurable elements. The measurable elements assessed were scored and the percentages of positive compliance were derived. Utilizing this checklist, we applied integrated 'methodological triangulation' across both quantitative and qualitative results.[27]

Next, we developed a scoring system, setting the maximum score for each standard at ten. Applying weighted scores to measurable elements within each standard, we calculated the score of the assessed standards by summing the scores of their measurable elements. The number of measurable elements for each standard ranged from two to ten, with four on average, depending

on the standards' complexity. We based our evaluation of compliance to NTCC's daily practices on the obtained scores (scored from 0 to 10) for each assessed standard.

After developing the coding scheme, and the scoring system we conducted a SWOT analysis, grouping all the findings into Strengths, Weaknesses, Opportunities, and Threats for each of the 76 standards.[33] The findings include both a scoring table of each of the standards plus a SWOT analysis for each of the standards. The scoring table and SWOT analysis were supported by direct quotes from respondents, which reduced the influence of biases of the study team and enhanced the findings for improved communication to a wider audience.

Further, to measure the overall performance of TB outpatient services in meeting the 13 assessed functions, we calculated a 'function mean score'. We calculated this score based on a scoring systemthat identifies the level to which standards of each function were met. The score ranges were defined using the standard deviation calculated from the mean,[32] with the minimum score equal to zero and maximum score equal to ten. These numeric values were further transformed as a function scale, with categories of 'Not met' (0) 'Minimally met' (0.1 - 3.3), 'Partially met' (3.4 - 6.6), 'Satisfactory met' (6.7 - 9.9), and 'Fully met' (10). To view findings on meeting the standards, we have converted the scores to corresponding percentages.

Finaly,levels to which the standards were met serves as a basis for recommendations for developing a Continuous Quality Improvement strategy at the PHC level and a specific action plan that included a continuous self-assessment mechanism for further improvements of PHC facilities' daily practices and their work environment helping to identify consistencies and deviations from the standards after the project ends.

Ethical Considerations

The Institutional Review Board of the American University of Armenia approved the study for compliance with locally and internationally accepted ethical standards (Appendix 3). All participants were informed that their participation was voluntary, that they could stop participation at any time and refuse to answer any question they chose, and that the confidentiality of the provided information was fully respected. After being informed of their

rights, all those who chose to participate provided their verbal informed consent. Audio-recording and observations were possible only with permission of all participants; if a participant did not want to be audio-recorded, only written notes were taken. Transcripts and the final report do not contain respondents' names, positions, or any other details that could identify the participants.

RESULTS

1. International Patient Safety Goals (IPSG)

1.1 IPSG. Identify patients correctly. The ambulatory care organization develops and implements a process to improve accuracy of patient identifications.

The ambulatory care organization develops and implements a process to improve accuracy of patient identifications. Errors in identifying the right patients happen essentially in all phases of diagnosis and treatment. At least two identifiers are needed for the process such as the name of the patient, birth date, bar-coded wristband or patient's identification number. Patient's room number or rooms location shall not be used as identifiers.

Measurable elements	Max. score	Obtained score
1. Patients are identified using two patient identifiers, not including the use of the patient's room number or location	**3.4**	**3.4**
2. Patients are identified before providing treatment and procedures	**3.3**	**3.3**
3. Patients are identified before any diagnostic procedures.	**3.3**	**3.3**
Total score	**10.0**	**10.0**

Strengths. The medical records review showed that in all outpatient TB facilities patients were identified through several identifiers, including name and surname, date of birth and the sequential number in the TB-03 form. In each medical record reviewed, the copy of the official passport and the social number were found. For DR patients the DR committee generates and assigns a code that serves as an identifier. In none of the facilities the room numbers were used as identifiers. During the observations the research team noticed that patients are identified before administering medications and before taking blood for clinical testing.

Weaknesses. Not identified

Opportunities. N/A

Threats. N/A

1.2 IPSG. Improve effective communication

Appropriate, precise, comprehensive effective communication can lessen the errors and provides a better patient safety outcome. Three types of communications can be performed,

written, verbal or electronic. The circumstances of patient care that can be unfavorably affected by inadequate communication are handover communications, patient care orders verbally or by the telephone, and verbal or telephone communication of crucial test results. The following safe practices are used for effective communication: using standardized content of communication between the caregiver and the patient or its family, including use of standardized methods, forms, or tools during patient handovers, decreasing verbal medication prescription in critical scenarios, developing guidelines for emergency basis test result requesting and receiving processes, etc.

Measurable elements	Max. score	Obtained score
1. The complete verbal order is documented and read back by the receiver and confirmed by the individual giving the order.	**3.4**	**3.4**
2. The complete telephone order is documented and read back by the receiver and confirmed by the individual giving the order.	**3.3**	**3.3**
3. The complete test result is documented and read back by the receiver and confirmed by the individual giving the result.	**3.3**	**3.3**
Total score	**10.0**	**10.0**

Strengths. TB healthcare providers have established processes to ensure that orders for laboratory tests and their results are confirmed and documented. According to the policy review TB physicians fill in the "laboratory referral form" (TB-05) for placing orders for sputum examinations. Other laboratory test orders are made through referrals developed within the PHC facilities. The results of sputum examinations are written down in a separate form, specifically designed for reporting the laboratory test results (TB-06). The medical record review confirmed that both TB-05 and TB-06 forms are implemented and attached to the medical cards. The National Guideline defines how both forms should be implemented and specifies the healthcare providers responsible for writing up in those forms.

Weaknesses. Not identified

Opportunities. N/A

Threats. N/A

1.3 IPSG. The ambulatory care organization adopts and implements evidence-based hand-hygiene guidelines to reduce the risk of health care–associated infections

Healthcare associated common infections are catheter-associated ones such as pneumonia, bloodstream and urinary tract infections. Proper hand hygiene is the most effective preventive method in this scenario.

Measurable elements	Max. score	Obtained score
1. The organization has adopted or adapted currently published and generally accepted hand-hygiene guidelines	**3.3**	**1.2**
2. The organization implements an effective hand-hygiene program	**3.4**	**1.6**
3. Hand-washing and hand-disinfection procedures are used in accordance with hand-hygiene guidelines throughout the ambulatory care organization.	**3.3**	**1.2**
Total score	**10.0**	**4.0**

Strengths. PHC staff reported having appropriate hand-hygiene practices, according to the National Guideline, and have various sanitizers. Some of physicians mentioned that they are knowledgeable about the correct hand-washing technique referring to the educational posters displayed on the walls.

Weaknesses. However, the policy review showed that outpatient TB facilities are lacking to have internal hand-washing guidelines and established hand-hygiene programs. Most of the healthcare providers erroneously considered the use of sanitizers as a hand-hygiene program. Furthermore, some healthcare providers mentioned that they just wash their hands with soap several times a day and use the instructions of sanitizers as hand-washing guides.

> *Yes we have* [hand-washing guideline]. *Each sanitizer has its own instructions.*
>
> **Healthcare provider 1, IDI**
>
> *No special actions. We just wash our hands several times a day.*
>
> **Healthcare provider 2, IDI**

Opportunities. The NTCC has developed hand-washing guidelines that should be shared with the management of outpatient TB facilities. The latter can be used as an example for adaptation and development of the local ones.

Threats. Not identified

2. Access and Continuity of Care (ACC)

2.1 ACC. Patient flow in the ambulatory care organization is designed to provide efficient care and uniform access based on the needs of the patient.

Alliancing patients' needs with the health care organization's goal and capacity is ensured usually during the first contact with the patient through collecting information on the patient's needs and health through screening. It is essential that arrangements for transferring, treating or referring a patient are made only after the results of screening evaluations are ready.

Measurable elements	**Max. score**	**Obtained score**
1. The ambulatory care organization uses decision criteria to prioritize patients with immediate needs	**3.4**	**2.4**
2. The patient registration and treatment process is designed to give priority to those who are sick or those with urgent needs	**3.3**	**2.4**
3. Patients with appointments and patients who walk into the organization without an appointment are managed in a consistent manner	**3.3**	**2.4**
Total score	**10.0**	**7.2**

Strengths. Almost all healthcare providers listed several decision criteria for patient prioritization among those who are sick or have immediate health needs. In particular, TB suspects who can be infectious (sputum smear positive TB) are at highest priority, therefore they are admitted first. Then, the priority is given to children, TB patients with severe health problems and urgent cases. For those TB patients who routinely receive DOT, a schedule of visits is developed, for avoiding queues.

A TB suspect should not wait. S/he should be admitted first, as s/he can have SS+ form of TB.
Healthcare provider 1, IDI

We have a time schedule for DOT patients. TB suspects are checked earlier.
Healthcare provider 2, IDI

Weaknesses. Patient prioritization practices were failing in outpatient TB facilities with the lower patient load. In fact, prioritization of patients is not addressed in any of the policies reviewed, and the implemented actions are merely based on healthcare providers' initiative.

I have a few TB patients, that is why here we don't have queues and thus I don't have issues with setting priorities among patients.

Healthcare provider, IDI

Opportunities. Policies and/procedures should be developed to define decision criteria for prioritization of patients with acute needs.

Threats. Not identified.

2.2 ACC. The ambulatory care organization designs and carries out processes to provide continuity of patient care services in the ambulatory care organization and coordination among health care practitioners.

Patient's treatment process usually involves multiple health care practitioners making decisions and serving patient's needs to match those with the resources of the health care organization. Having a supported, coordinated system that ensure practitioners working together in harmony, agreeing on decision making processes and implementation of the care provided is an essential attribute to ensure high quality continuation of care.

Measurable elements	Max. score	Obtained score
1. The leaders of departments and services design and implement processes that support continuity and coordination of patient care	**3.4**	**3.4**
2. The patient's record(s) is up to date and available to those practitioners who are authorized to have access and need it for the care of the patient	**3.4**	**3.4**
3. Continuity and coordination of care processes are supported by the use of tools and techniques, such as care plans, guidelines, case managers, and other such methods	**3.2**	**3.2**
Total score	**10.0**	**10.0**

Strengths. The majority of PHC leaders indicated that a care provided in their facilities is a product of a coordinated team work between various departments within the multidisciplinary teams. In case of need, patients are referred for consultation to various specialists or hospitalized, ensuring continuity of their care. TB physicians stated that patients' health information is always updated in the medical records and that the information is always available to healthcare practitioners in case of need.

As far as the policlinic is a multidisciplinary facility, there are various specialists and if there is a need for consultation or examination by narrow specialists, it can be easily organized, for example electrocardiogram, ultrasound examination, we also refer patients for inpatient treatment.

Administration 1, IDI

It is a team work [coordination of patient care], *as well as internally coordinated procedures. The same applies to TB patients' care.*

Administration 2, IDI

Yes, when patients are referred for examinations medical records are available.

Healthcare provider, IDI

The National Guideline is a unique criterion for TB diagnosis and treatment in Armenia which guides the process of TB care within and between inpatient and outpatient TB facilities. The document serves as a tool that defines and supports the coordination and continuity of TB care.

Weaknesses. Not identified

Opportunities. N/A

Threats. N/A

2.3 ACC. The ambulatory care organization develops and implements a process to refer patients to other health care practitioners, other health care settings, or other organizations to meet their continuing care needs.

Patient's health status and their need for treatment continuation and health care services defines the procedure of patient referral to another practitioner, health care organization or setting. The person responsible for the patient's care (usually the practitioner) selects the type of referral needed.

Measurable elements	Max. score	Obtained score
1. There is an organized process for referring patients	**3.3**	**3.3**
2. The ambulatory care organization refers patients when the organization is unable to meet patients' continuing care needs	**3.4**	**3.4**
3. The referral ensures the availability of services to meet patients' continuing care needs	**3.3**	**3.3**
Total score	**10.0**	**10.0**

Strengths. The National Guideline has several algorithms that describe the processes for identification of TB suspects, diagnosis of TB and provision of treatment to sputum smear positive and negative patients, and referral to other healthcare facilities, when TB is rejected. All algorithms define the stages and processes of patients' referrals from outpatient to inpatient TB

facilities and backwards. These processes are implemented in all assessed outpatient TB facilities.

Weaknesses. Not identified

Opportunities. N/A

Threats. N/A

2.4 ACC. The ambulatory care organization develops and implements a process to transfer patients to another organization to meet their continuing care needs.

A transfer of the patient is based on the patient's status, lack of ability to self-transport, or other factors. Criteria help to identify when a transfer is necessary in order to ensure that the patient's needs are met. The ambulatory care organization defines the types of patients and the conditions that require a transfer. The transfer process addresses:

- how responsibility is transferred between health care practitioners and settings;
- criteria as defined by the ambulatory care organization for when transfer is necessary to meet the patient's needs;
- who is responsible for the patient during transfer; and
- and what is done when transfer to another source of care is not possible.

Measurable elements	Max. score	Obtained score
1. Transfers of patients are based on criteria developed by the ambulatory care organization to address patients' needs for continuing care	**2.5**	**2.5**
2. The process addresses how responsibility for continuing care is moved to another practitioner or setting	**2.5**	**2.5**
3. The process addresses who is responsible for the patient during transfer	**2.5**	**0**
4. The process addresses the situations in which transfer is not possible	**2.5**	**0**
Total score	**10.0**	**5.0**

Strengths. The policy review showed that Algorithms 3, 4 and 5 of the National Guideline define the criteria of patients' transfers for further diagnosis and treatment provision to the inpatient TB facilities. When patients are transferred for hospitalization, the accepting facilities are responsible for continuing patients' care.

Weaknesses. No policies or procedures identify the responsible individual or body for patients during the transfer or during situations when a transfer is impossible.

Opportunities. Policies that capture the process of patient transfer should be replenished with the missing points, in accordance with the standard.

Threats. Not identified.

2.5 ACC. Information about the care and services that the patient will need when he or she is referred by the ambulatory care organization is communicated to the patient, family, and continuing care practitioner and/or setting.

Ambulatory care organizations frequently refer patients to further care and services based on patients' continuing health care needs. The ambulatory care organization informs patients and their families about the patient's ongoing health needs and the types of care and services that the patient should seek in the future. The continuing care site to which the patient is referred receives a written summary of this information. When the patient's visit to the ambulatory care organization was by referral from another health care practitioner, the ambulatory care organization provides a copy of the summary to that practitioner.

Measurable elements	Max. score	Obtained score
1. The ambulatory care organization has a process through which it communicates to patients and patients' families about their ongoing health needs and needed care and services	**3.3**	**3.3**
2. A written summary is used to convey information to a continuing care setting and contains, as appropriate, a medication list, significant diagnoses and treatments, follow-up instructions, and test results	**3.4**	**3.4**
3. When a patient is referred to the hospital or other ambulatory care organization by an individual health care practitioner, a summary of the care provided by the hospital/ambulatory care organization is provided to the referring health care practitioner	**3.3**	**3.3**
Total score	**10.0**	**10.0**

Strengths. TB physicians communicate with patients the information on care they need and about the planned treatment. They also explain how the treatment is organized and that they should visit outpatient TB facility on daily basis. During the data collection, physicians also highlighted the work they do with patients' families as TB contacts. In fact, they invite the TB contacts and inform about the disease, necessity of check-ups among TB contacts and

importance of receiving the treatment. Furthermore, according to them, patients, usually, receive the most part of the information in the inpatient facility, during their hospitalization.

Of course we talk with patients in advance, informing them about the duration of treatment. We also tell what ongoing examinations are planned, and how the monitoring of treatment is conducted. It is important for patient to be aware of his upcoming months. **Healthcare provider 1, IDI** *We explain patients how the treatment will be organized, what stages the treatment includes and that they* [patients] *are obliged to come to take medications every day.* **Healthcare provider 2, IDI**

Policy review identified that for transferred patients, physicians fill in the TB-08 form. Medical records review confirmed that the TB-08 form contains the information about patient's identification, diagnosis, and the category of TB treatment, TB medications and other notes for receiving healthcare facility.

Weaknesses. Not identified

Opportunities. N/A

Threats. N/A

2.6 ACC. Patient follow-up instructions are given in a form and language the patient can understand.

For patients not directly transferred to another health care practitioner or organization, clear instructions on where and how to receive continuing care. The ambulatory care organization provides the instructions to the patient and, as appropriate, his or her family in a simple, understandable manner and these instructions include information when obtaining of the urgent care is needed. The instructions are provided in writing or in the form most understandable to the patient when the patient is not able to understand written instructions.

Measurable elements	Max. score	Obtained score
1. Patient follow-up instructions are provided in writing and in a form and language that the patient can understand	**3.4**	**0**
2. The instructions include any return for follow-up care	**3.3**	**0**
3. The instructions include when to obtain urgent care	**3.3**	**0**
Total score	**10.0**	**0**

Strengths. Not identified.

Weaknesses. In outpatient TB facilities, healthcare providers did not provide patients with instructions about follow-up visits.

Opportunities. Procedures should be developed to address the gap in the process of informing patients about care they should receive in the future including informing about follow-up and urgent care and provision of follow-up instructions.

Threats. Not identified

2.7 ACC. The process for referring or transferring the patient evaluates the need for transportation.

During patients' transfers and referrals, the organization should consider patients' needs for transportation based on patient's health conditions and status. It is the outpatient facility's responsibility to ensure with transportation those patients who need it.

Measurable elements	Max. score	Obtained score
1. The process for referring patients evaluates the need for transportation.	**5.0**	**0**
2. The process for transferring patients evaluates the need for transportation.	**5.0**	**0**
Total score	**10.0**	**0**

Strengths. Not identified

Weaknesses. During the discharge, referral or transfer patients' transportation needs are not considered and therefore are left unmet. In fact, patients themselves are responsible for transportation to inpatient TB facility (unless there is an emergency health need, which is covered by the basic benefit package) or back home.

Opportunities. For improving quality of care TB patients receive, transportation during patients' referrals and transfers could be considered.

Threats. Additional financial resources are associated with provision of transportation services that can hinder its implementation.

3. Patients and Family Rights (PFR)

3.1 PFR. The ambulatory care organization is responsible for providing processes that support patient and family rights during care

The leadership need to know and understand patient and family rights and the organization's responsibilities as identified in laws and regulations. The ambulatory care organization respects the right of patients, and in some circumstances the right of the patient's family, to have the prerogative to determine what information regarding their care would be provided to family or others, and under what circumstances. For example, the patient may not wish to have a diagnosis shared with family.

Thus, policies and procedures are developed and implemented to ensure that all staff members are aware of and respond to patient and family rights issues when they interact with and care for patients throughout the organization.

Measurable elements	Max. score	Obtained score
1. The ambulatory care organization respects the right of patients, and in some circumstances the right of the patient's family, to have the prerogative to determine what information regarding their care would be provided to family or others, and under what circumstances	**5.0**	**4.4**
2. All staff are knowledgeable about patient rights and can explain their responsibilities in protecting patient rights	**5.0**	**5.0**
Total score	**10.0**	**9.4**

Strengths. The majority of healthcare providers agreed that it is the patients' right to choose whether the information regarding their health status or care should be disclosed to others. TB physicians and nurses universally mentioned that they are knowledgeable about patients' rights and that it is a key function of their work. They further elaborated that after inpatient treatment when patients are transferred for the continuation phase of treatment, they come already knowledgeable about their rights. If patients initiate their treatment in outpatient TB facility, then it is the TB physician's responsibility to inform them of their rights and responsibilities. Following this further, TB healthcare providers explained how they understand patients' right:

I always check with my patients if they agree their family members to know about his/her disease. I had patients who hided the diagnosis from their family members.

Healthcare provider 1, IDI

It is their right to treat the disease or not, but we talk to them, convince and educate.

Healthcare provider 2, IDI

Of course, we tell them [the patients], *it is the part of our work.*

Healthcare provider 3, IDI

First and foremost, it is the patient's right to choose receive the treatment or not, but I am obliged to explain him the consequences of disease if left untreated. S/he is informed that the treatment is free of charge, everything is free of charge, and that they become eligible for disability group and for social assistance.

Healthcare provider 4, IDI

Weaknesses. One of TB healthcare providers expressed disagreement with the patient right to choose to receive the treatment or not, to decide inform others about the disease or not, explaining that there are cases when healthcare providers fail to convince patients to receive the treatment, as a result family members also fall down with TB. The healthcare provider shared his/her point of view that the right should be given to patients only with exceptions.

Patient has the right to choose to receive the treatment or not, which is very bad, as far as some patients remain unconvinced.

Healthcare provider, IDI

Opportunities. All TB healthcare providers should share the common understating about patient rights and that the rights should be respected unconditionally. Patients' treatment acceptance should not occur in expense of their rights to choose to receive the treatment or not. Therefore, healthcare providers should make more efforts to properly educate patients and their families, to ensure high rate of acceptance of treatment. This should be continuously highlighted by the NTCC.

Threats. Working with non-adherent patients tending to refuse to treat TB is tough which can compromise healthcare providers' determination in respecting patient rights.

3.2 PFR. The patient's rights to privacy and confidentiality of care and information are respected.

Patients may desire privacy, particularly during clinical interviews, examinations, procedures/treatments, and transport from other staff, from other patients, and even from family members.

The policies and procedures reflect information that is released as required by laws and regulations. Staff respect patient privacy and confidentiality by not posting confidential information on the patient's door or at the nursing station and by not holding patient-related discussions in public places. Patients are also informed about when and under what circumstances information may be released and how their permission will be obtained.

Measurable elements	Max. score	Obtained score
1. Staff members identify patient expectations and needs for privacy during care and treatment	**2.5**	**2.5**
2. A patient's expressed need for privacy is respected for all clinical interviews, examinations, procedures/ treatments, and transport	**2.5**	**2.3**
3. Confidentiality of patient information is maintained according to laws and regulations	**2.5**	**0**
4. Patients are requested to grant permission for the release of information not covered by laws and regulations	**2.5**	**0**
Total score	**10.0**	**4.8**

Strengths. TB healthcare providers highly valued patient's needs for privacy agreeing that in general patients expect their health-related information to remain confidential. According to healthcare providers, they do their best in maintaining patients' privacy which sometimes cause inconveniences. Some patients hide their health status from family members which hinders the TB contact investigation. For other patients who live in small communities it is even harder to maintain their health conditions privately. A physician shared an example of a TB patient who decided to receive the treatment in another city, to avoid his/her community become aware of his/her disease. In case of military conscripts, TB physicians are obliged to inform authorized persons requesting that information. However, despite difficulties TB physicians stated that patients' needs for privacy are respected in their outpatient TB facilities.

We always keep the privacy. If not we will have troubles.

Healthcare provider 1, IDI

We always try to maintain patient information in privacy especially considering that our city is small, everybody know each other. We try to be maximally confidential.

Healthcare provider 2, IDI

Naturally, we maintain patient's private information. There is separate entrance to the TB cabinet. It is

a small city, people notice and ask questions. In most of the cases we tell that patient has pneumonia and came for the diagnosis.

Healthcare provider 3, IDI

Patients value the privacy protection the most, even in their families they keep that information in secret, daughters-in-law from mothers-in-law, husbands from wives. These are very troublesome cases as we don't know how to investigate family members. We try to find other ways to bring the family members and examine them.

Healthcare provider 4, IDI

Patients' privacy is always maintained. But in case of a conscript, if there is a request regarding health information, we have to tell that patient was ill during a certain time. We tell this only to the authorized persons.

Healthcare provider 5, IDI

With regards to patients' privacy protection during clinical interviews, healthcare providers mentioned that they cannot hide that information from generalists and other specialists as patients' medical records are available to them. But other than those healthcare providers, no one knows about patients' health condition.

We can hide patients' information from other healthcare professionals, as far as patients for electrocardiogram, ultrasound examination, and consultation of other specialists. Moreover, patients take with them their medical records, where the diagnosis is mentioned. There is no other practice we can follow.

Healthcare provider 1, IDI

That information never leaks from our cabinets, except for the generalists, from whom we can hide as if patient does not have TB. Moreover, there is 002 form, where all comorbidities and treatments patients received are mentioned. It will be wrong to hide this from the generalist, but other healthcare professionals are not informed, for instance about patient's HIV status. I would not go and tell that patient is a HIV positive. Let them maintain infection prevention and control procedures with all their patients. I am not allowed to inform healthcare professionals.

Healthcare provider 2, IDI

Weaknesses. During interviews with patients, some of them told that they have not been informed about the confidentiality of their personal information and how it will be ensured. Some TB physicians reported that there are no procedures and guidelines to follow for patients' confidentiality protection. Also, there are no procedures for receiving patients' permission for the release of information not covered by laws and regulations. However, the policy review showed that the national law on health care provision (Հ O-42) states that it is the patients' rights to request privacy and confidentiality protection and that it is healthcare professionals' responsibility to maintain them accordingly

No, we don't have specific procedures and guidelines.

Healthcare provider 1, IDI *There are no guidelines. We follow our medical intuition.* **Healthcare provider 2, IDI** *I have not been informed* [of privacy and confidentiality issues]. *I don't know.* **Patient/FM, IDI**

Opportunities. PHC facility leaders should raise the awareness about policies and regulations within their facilities for ensuring that all healthcare providers have equal basis with regards to patient privacy and confidentiality protection. Procedures should be developed for patients who are expected to provide such information that is not covered by laws.

Threats. Not identified.

3.3 PFR. Vulnerable populations are identified and protected from additional risks.

The ambulatory care organization clearly identifies who are vulnerable groups of patients and specific protective processes are stated for them. Children, disabled individuals, the elderly, and others identified by the organization are protected and the staff members aware on their responsibilities on how to protect vulnerable groups of patients.

Measurable elements	Max. score	Obtained score
1. The ambulatory care organization develops and implements a process to identify vulnerable patient groups at additional risk and protect them from these risks to safety.	**5.0**	**2.0**
2. Staff members understand their responsibilities in the protection processes	**5.0**	**4.5**
Total score	**10.0**	**6.5**

Strengths. The National Standard defines criteria for socially vulnerable patients who should receive the treatment through home visits. The criteria cover the following population groups: elderly, children under 5 years, a TB patient who is a main caregiver of child under 5 years, pregnant TB patients, a multiparous TB patient whose children do not have other caregivers, patients with movement disabilities, and TB patients with epilepsy or other psychiatric disorders.

According to TB healthcare providers, vulnerable patients are those with alcohol and substance abuse, those with diabetes, and migrant workers, listing the conditions that increase patients' vulnerability towards TB disease.

We have lists for vulnerable patients, regarding the diseases that according to the guideline are considered vulnerable. Generalists have participated in trainings and they know regarding which patients they should be very attentive and whom should refer to our cabinet. It is diabetes, etc.

Healthcare provider 1, IDI

Vulnerable groups are patients with diabetes, those with substance abuse, migrant workers and penitentiary patients.

Healthcare provider 2, IDI

Our patients love to drink. We always try to involve patients' families and help them to quit drinking.

Healthcare provider 3, IDI

Psychiatric patients, diabetes patient, children who are main contacts of patients, elderly are vulnerable patient groups. We always guide vulnerable patients. We tell to other physicians to refer diabetes patients to our cabinet in case of any suspicion. Physicians refer other vulnerable patients to our cabinet for examinations.

Healthcare provider 4, IDI

Weaknesses. There was a discrepancy between healthcare providers understanding of vulnerability (mainly focusing on vulnerable TB patient groups) and the National Standard that refers to socially vulnerable patients. The PHC facilities have developed their own definition of vulnerable patients. Moreover, some TB physicians could not even retrieve any criteria of vulnerability. This is a result of absence of a unique definition of vulnerable patients.

We don't have many vulnerable patient groups. We don't have many patients to set priorities between each other, therefore we try to solve their problems equally, in order to not have any complaints and to solve all problems.

Healthcare provider, IDI

Opportunities. A definition of vulnerable patients should be developed that will include both socially vulnerable patients, and patients with certain health conditions that have increased vulnerability to acquire TB.

Threats. Not identified

3.4 PFR. The ambulatory care organization provides care that is respectful of patients' and families' personal values and beliefs and supports their rights to participate in the care process.

All patients and families are encouraged to express their beliefs in ways that respect the beliefs of others. Thus, each health care practitioner seeks to understand the care and services he or she provides within the context of the patient's values and beliefs. The ambulatory care organization supports and promotes patient and family rights and involvement in all aspects of care. Patients and families participate in the care process by making decisions about care, asking questions about care, and even refusing diagnostic and treatment procedures. Management, clinical staff, and others participate in developing policies and procedures that support patient participation

The policies and procedures address at least the following patient and family rights:

a) The right to refuse or discontinue care

b) The right to withhold resuscitation services and to forgo or withdraw life-sustaining treatments

c) The right to receive appropriate assessment and management of pain

d) The right to access and participate in the organization's process to receive and act on complaints and

to resolve conflicts and differences of opinion about care

All staff members are trained on

e) the policies and procedures;

f) how to identify and respectfully support a patient's values and beliefs; and

g) their role in supporting patients' and families' rights to participate in the care process.

Measurable elements	Max. score	Obtained score
1. Patients' values and beliefs are identified	**2.5**	**2.3**
2. Processes that address at least a) through d) in the intent are developed and implemented to support and promote patient and family participation in care processes	**2.5**	**2.5**
3. Clinical staff are involved in developing the processes that support patient and family rights to participate in the care process	**2.5**	**2.5**
4. Staff are trained on at least e) through g) in the intent	**2.5**	**0**
Total score	**10.0**	**7.3**

Strengths. The majority of TB physicians stated they learn patients' values and beliefs, even when patients seem to be hostile in the beginning. Physicians indicated that each patient is approached differently, depending on his/her educational level, lifestyle, and general values.

They further elaborated that during continuous encounter, patients become so close to TB physicians and nurses that they share their feelings and entrust their problems to them. Physicians also mentioned that they try to adjust the care they provide to meet all the needs that patients may have.

Of course we approach every patient differently, depending on his/her educational level, lifestyle, and general values and considering all these we try to talk to them. We focus on all of these, how we can we approach them similarly. Some patients should be approached gently, others harshly to ensure he remains in the treatment. We differentiate all these in the process.

Healthcare provider 1, IDI

They [patients] *talk and share with us. We spend lot of time with them. It is not the case when they just come to take the medications. Patients become very close with nurses, they share their personal issues with us, they come and have conversations with us, tell about themselves, their families, about their personal problems, just everything. If they become shy of physicians, they speak with nurses, and only then nurses tell us. We address every, even not significant problems.*

Healthcare provider 2, IDI

Patients humanly share and tell [their concerns] *and we manifest individual approach towards the patients.*

Healthcare provider 3, IDI

TB physicians reported that they try to involve patients' families in the process of care right from the beginning of the treatment. According to them, families' involvement is a pledge for a successful completion of the treatment. Furthermore, because of the nature of disease, families should be involved as contacts of TB patients, as they should come for examinations.

Naturally, families should be present from the beginning. We examine them and explain them the whole process of treatment, their role. If families support patients and remain a buttress for them [patients], *then the patients will succeed in their treatment.*

Healthcare provider 1, IDI

Family members should necessarily know [about TB], *especially those of DR patients. Because their [DR patients] treatment is very long and during that process patients may become tired of taking so much medications, it is not that easy. Families should always be near to support them [patients]. We talk to family members, and explain that TB is curable. However efforts should be taken to make sure that the patient eats well, with a regimen, that he/she is taken care of. Family members should do everything, for patient to complete the treatment. In most of the time it helps. Patients need care.*

Healthcare provider 2, IDI

While asking patients and families about their experiences with this regard, most of them pointed out that TB healthcare providers were very attentive, they valued patients' preferences and beliefs, meanwhile acknowledging that TB patients are a hard population to work with. One of

family members told that healthcare providers should consider patients values and beliefs in order to keep working.

> *Yes, physicians consider* [beliefs and values]. *My physician and nurse are very attentive. I take medication in front of them every day. They trust me.*
>
> **Patient/FM 1, IDI**
>
> *If they did not consider* [beliefs and values], *I think that they would not work.*
>
> **Patient/FM 2, IDI**

Weaknesses. Despite the efforts the healthcare providers take, they have never been trained or guided on how to act with patients in order to be considerate of their values and beliefs and what those values and beliefs may include. Therefore, healthcare providers' practices can vary depending on their own personal beliefs, values and points of view. One of TB patients shared the experience of setting his/her communication with the physician, who initially was behaving in a way physicians usually work with "hard" TB patients. However, later when s/he got to know the patient better, their communication settled down.

> *Physicians should communicate with patients, in order to understand them. This disease is typical to people from a specific segment, those generally from prisons. And one day you come as a patient and may face them* [physician] *looking at you that way* [like on prisoner with TB]. *But later after talking to patients, physicians realize that this patient is somehow different, that s/he understands and even knows the alphabet* [speaks with irony]. *They start to behave differently. This is a matter of time, and it is natural and understandable. I have never felt bad.*
>
> **Patient/FM, IDI**

Opportunities. The NTCC should be make sure that all TB healthcare providers act similarly with their patients in identification patients' values and beliefs regarding their process of care. The appropriate practices could be achieved through special trainings that will focus on the items described in the intent statement.

Threats. Not identified

3.5 PFR. The ambulatory care organization identifies patient and family responsibilities in the care process.

Each organization identifies those responsibilities through a process that involves patients, their families, health care practitioners, and other appropriate individuals. The patient and family responsibilities identified include at least:

a) the full disclosure of health information by the patient;

b) cooperation during examinations and procedures;

c) respect for the organization's staff and other patients;

d) respect for the organization's policies and procedures related to smoking, infection prevention and control, and environmental care; and

e) compliance with instructions for self-care by the patient, including taking medications and attending follow-up appointments.

Measurable elements	Max. score	Obtained score
1. The organization identifies patient and family responsibilities in the care process	**4.0**	**0**
2. The process to identify patient and family responsibilities involves patients, their families, health care practitioners, and others as appropriate	**3.0**	**0**
3. The responsibilities identified include at least a) through e) in the intent	**3.0**	**0**
Total score	**10.0**	**0**

Strengths. Not identified

Weaknesses. When TB healthcare providers were asked about how they inform patients about their responsibilities, the majority of them mentioned that some patients sign contract during the inpatient treatment and that they start the outpatient phase already well-informed. PHC facilities have not formally identified patients' responsibilities during the treatment and therefore the processes are not consistently implemented.

Opportunities. The PHC facilities along with the outpatient TB cabinets should outline and summarize patients' responsibilities during outpatient treatment phase. The responsibilities should include the list from 'a' to 'e'. Healthcare providers should make sure to involve patients and their families in the process of identification of patient and family responsivities.

Threats. Not identified.

3.6 PFR. All patients are informed about their rights and responsibilities in a manner and language they can understand.

Seeking and receiving care and treatment at an ambulatory care organization can be frightening and confusing for patients, making it difficult for them to act on their rights and understand their

responsibilities in the care process. Thus, the organization prepares a written statement of patient and family rights and responsibilities that is given to patients when they register for the first time. The statement is posted within the organization or is available at all times from staff. The statement is appropriate to the patient's age, understanding, and language. When written communication is not effective or appropriate, the patient and family are informed of their rights and responsibilities in a language and manner that they can understand.

Measurable elements	Max. score	Obtained score
1. Information about patient rights and responsibilities is provided in writing to each patient when registering for the first time	**4.0**	**1.6**
2. The statement of patient rights and responsibilities is posted or otherwise available from staff at all times	**4.0**	**0**
3. The organization has a process to inform patients of their rights and responsibilities when written communication is not effective or appropriate	**2.0**	**1.5**
Total score	**10.0**	**3.1**

Strengths. The majority of healthcare providers reported that only DR TB patients are provided with their rights and responsibilities in writing, as they sign a contract before initiation of the treatment to agree that they are aware of the major side effects, consequences of interruption of treatment, and that they agree to receive TB treatment. The DR patients' medical records review confirmed that the signed contracts are attached to the medical records.

Most of the TB physicians stated that DS TB patients are informed about their rights and responsibilities in the NTCC, mainly verbally, and that the process is not accompanied with a written document.

No, we do that [inform about rights and responsibilities] *orally, except for DR patients. For these patients we have a special program developed. We ratify that* [acceptance of treatment] *through a document.*

Healthcare provider 1, IDI

We don't have such things [written forms for informing about rights and responsibilities]. *We sign contracts only with DR patients. The remaining patients are informed only orally. The NTCC sends the documents related to patients' contracting.*

Healthcare provider 2, IDI

Only those patients who receive Bedaquiline [DR patients] *we have a specific form* [rights and responsibilities].

Healthcare provider 3, IDI

My rights and responsibilities were presented to me in a writing form and I have signed that, agreeing to necessarily take medications, and for maintenance of stuff.

Patient/FM 1, IDI

Yes, I received that paper in Abovian when I was being discharged from the hospital. This is mostly for DR patients. I did not read that. The contract is made mainly in the inpatient facilities, for treatment and hospitalization. We don't have a similar contract in outpatients.

Patient/FM 2, IDI

Weaknesses. Policy review disclosed that the procedures guiding provision of information on patients' rights and responsibilities in a written format are missing. The observations showed that statements on patient rights and responsibilities are not displayed in TB facilities. In outpatient TB facilities no additional work is initiated by the healthcare providers for provision of information on patients' rights and responsibilities. On top of this, healthcare providers wait for patients to ask questions, making the process more patient-driven and not guided by formal procedures. If during such conversation patient refuses from certain procedures, he signs under a respective statement in his/her medical record. In fact, some TB patients told that they were not informed about their rights and responsibilities at all.

If there is a need, or patients have questions, they ask and we reply to them. If there are no questions, we don't specifically ask if they are aware of their rights or that they have responsibilities. Honestly speaking we don't specifically mention that.

Healthcare provider, IDI

I asked about that [rights and responsibilities] *ashamed in the inpatient facility. When I asked, they answered and explained me.*

Patient/FM 1, IDI

No, there wasn't such thing [discussion on patient rights and responsibilities].

Patient/FM 2, IDI

Opportunities. The process should be formalized through development and enforcement of local policies that will be driven from the respective national law. The experience of DR TB patients should be extended to DS TB patients as well. All outpatient TB healthcare providers should be educated on provision of similar healthcare (in the context of patient rights protection) to all TB patients.

Threats. Failing to provide patients with their rights and responsibilities might result on increasing levels of 'treatment failure' and 'lost to follow-up'.

3.7 PFR. Patient informed consent is obtained through a process defined by the organization and carried out by trained staff in a language the patient can understand.

To consent, a patient must be informed of those factors related to the planned care required for an informed decision. Consent may be obtained at several points in the care process. When a general consent is used, the patient is made aware that additional consents will be required before certain procedures or treatments for which the risk is high. The consent process is clearly defined by the organization in policies and procedures. Relevant laws and regulations are incorporated into the policies and procedures.

Measurable elements	Max. score	Obtained score
1. The ambulatory care organization develops and implements a clearly defined informed consent process	**2.0**	**1.0**
2. Designated staff are trained in the informed consent process and obtain consent in a manner and language that the patient understands	**2.0**	**0.8**
3. Patients give informed consent consistent with the process	**2.0**	**0.5**
4. When a general consent for treatment is used by the organization, patients are aware of those tests, procedures, and treatments that require a separate informed consent	**2.0**	**0.0**
5. There is uniform recording of informed consent	**2.0**	**1.6**
Total score	**10.0**	**3.9**

Strengths. Almost all TB physicians stated that they implement the informed consent process. Almost half of the reviewed medical records contained information about informed consent or parnetal assent.

> *Yes we present them, tell* [informed consent]. *Besides we talk to TB contacts as well to receive their consent.*
>
> **Healthcare provider, IDI**

Weaknesses. According to the physicians, there is no specific structure for informed consent process and that the patients are just informed about their future care before the start of treatment. Some physicians stated the procedures are present only for DR patients, yet the DS patients are being informed about the treatment in the inpatient facility.

No there is not specific format. We just tell them and then the treatment starts.

Healthcare provider 1, IDI

We have an informed consent process for DR patients. DS patients are being informed about their treatment in the inpatient facility.

Healthcare provider 2, IDI

Not all healthcare providers shared a common comprehension of the purpose and the importance of informed consent process. Some of them stated that they provide all the information to patients in order to secure themselves from future misunderstandings with them. Some healthcare providers confused the informed consent process with the process of informing about the disease and the treatment.

Yes, we sign a contract with them, in order to avoid problems in the future. As far as patient may come and tell that we have not understood them correctly and etc.

Healthcare provider 1, IDI

I necessarily explain the patient that the disease is curable if s/he is conscious and is aware of treatment and adheres to all instructions and etc.

Healthcare provider 2, IDI

Only small amount of healthcare providers reported that they have been trained on the informed consent process. The majority of TB patients interviewed, stated that they have not provided their informed consent for the treatment. None of the patients was informed about procedures and tests that require additional informed consent. In those facilities were medical records did not contain any information on informed consent, notes were made by the healthcare providers that the process is not applicable to the outpatient facilities and that the process is being carried out in the NTCC.

Opportunities. A uniform informed consent process should be developed and introduced in outpatient TB facilities. All healthcare providers should be trained on acquisition of informed consent and correct documentation of the process in the medical records. This will help to structure already existing practices and will guarantee the uniformity of the process across all outpatient TB facilities.

Threats. Not identified

3.8 PFR. The organization establishes a process, within the context of existing law and culture, for when others can grant consent.

The ambulatory care organization has a process on grant informed consent that respects law, culture and custom. In some cases, other individuals granting consent are noted in the patients' record.

Measurable elements	Max. score	Obtained score
1. The ambulatory care organization has a process for when others can grant informed consent	**4.0**	**2.0**
2. The process respects law, culture and custom	**3.0**	**0**
3. Individuals, other than the patient, granting consent are noted in the patients record	**3.0**	**1.5**
Total score	**10.0**	**3.5**

Strengths. Some TB physicians indicated that they acquire informed consent from people other than the patient in case of children TB patients and psychiatric TB patients. In some medical records of children TB patients, there were notes that the parent has provided the consent.

> *If the patient has mental problems, then the family members, either wife, sister or brother provide the consent. We explain to them as much possible as they are close to the patients.*
>
> **Healthcare provider, IDI**

Weaknesses. Even though some TB physicians stated that there is a process for acquiring an informed consent from other people, still the process is implemented only in inpatient facilities. Policy review did not find any formal description of the process. The process is implemented merely based on TB healthcare providers' personal understanding. It is not possible to assess if the process is respectful of the law, culture and custom.

> *If the patient is a child, the parent provides the consent. Still is done in the inpatient facility. Also in case of unconscious patients and those with psychiatric disorders the family member should necessarily provide the consent.*
>
> **Healthcare provider, IDI**

Opportunities. The process of when others can grant consent should be defined and incorporated into the practice. A separate policy should guide the process.

Threats. Not identified.

3.9 PFR. Patients and families receive adequate information about the illness, proposed treatment(s), and health care practitioners so that they can make care decisions.

Staff members clearly explain any proposed treatment(s) or procedures to the patient and the family. The information provided includes

a) patient's condition;

b) proposed treatment(s);

c) name of the person providing the treatment;

d) potential benefits and drawbacks;

e) possible alternatives;

f) likelihood of success;

g) possible problems related to recovery; and

h) possible results of nontreatment. (*Also see* PFR.4.1)

The ambulatory care organization needs to have a process to respond when patients request additional information about their health care practitioners.

Measurable elements	Max. score	Obtained score
1. Patients are informed of elements a) through h) in the intent as relevant to their condition and planned treatment	**4.0**	**4.0**
2. Patients know the identities of the physicians and other health care practitioners responsible for their care	**3.0**	**3.0**
3. The ambulatory care organization develops and implements a process to respond to a patient's request for additional information on the health care practitioner responsible for his or her care	**3.0**	**0**
Total score	**10.0**	**7.0**

Strengths. All interviewed patients and family members mentioned that they were informed about their condition, proposed treatment, the healthcare providers responsible for their treatment, benefits of treatment and consequences of non-adherence, that TB is curable, and etc. Some patients mentioned the organization Medicine Sans Frontier that was implementing educational activities with DR patients. As the patient-provider encounter is long lasting TB patients definitely know their physicians and nurses and even establish close contact with them.

When I learned about my disease, by asking reading I realized what type of disease it is. Later MSF described what is TB when I was already hospitalized. I can tell that I know more that 90% information about TB. All points that you listed have been discussed.

Healthcare provider, IDI

Weaknesses. The policy review did not reveal any mechanism regarding how patients should request additional information about their healthcare providers.

Opportunities. Procedures should be developed to guide the process of patients to request additional information about their healthcare providers.

Threats. Not identified

4. Assessment of Patients (AOP)

Patients' admission to the outpatient facilities is based on the assessments to be conducted in order to identify whether the patients' health needs are going to be met if admitted. Continuously throughout the treatment the patients should be reassessed to check if the health needs are satisfied in the ambulatory and to make adjustments in the treatment regimen. Reassessment data should continuously support and justify the treatment the patient is receiving in the clinic.

4.1 AOP. An initial assessment process is used to identify the health care needs of all patients and the scope and content of that assessments is defined in writing and based on applicable laws and regulations.

The ambulatory care organization establishes policies, procedures, or protocols to define and guide an effective and consistent initial assessment process for all patients. The organization identifies who can perform which assessments, such as physicians, nurses, and other clinical disciplines, and defines the initial assessment process for those patients whose needs do not match the organization's mission and resources and who may require a referral or transfer to another organization.

Measurable elements	Max. score	Obtained score
1. The ambulatory care organization develops and implements an initial assessment process to identify the health care needs of TB patients	**2.0**	**2.0**
2. The ambulatory care organization identifies who performs which assessments	**2.0**	**1.0**
3. The scope and content of initial assessments conducted by each clinical discipline are defined in writing	**2.0**	**2.0**
4. Only qualified individuals permitted by licensure, applicable laws and regulations, or certification perform the assessments	**2.0**	**1.9**
5. The ambulatory care organization identifies the assessment process for those patients whose needs do not match the organization's mission and resources and who require a referral or transfer to another organization	**2.0**	**2.0**
Total score	**10.0**	**8.9**

Strengths. The TB outpatient policy document and staff qualification document review has proved that all practicing physicians have qualification, including the licensure and certifications,

to perform the appropriate procedures to diagnose TB. IDIs with healthcare providers of different profiles (TB, family, radiology, and laboratory doctors) confirmed that all patients admitted to the TB cabinets undergo a defined set of examinations. The policy review confirmed the presence of an algorithm that defines the required set of examinations that each specialist performs in their own clinical discipline.

Weaknesses. The policy document does not specify in detail the exact roles of health care providers while performing initial assessments for their patients.

Opportunities. Formalization of daily activities regarding the organization of assessments will be achieved through development of policies and procedures.

Threats. Not identified.

4.2 AOP. Assessment findings are integrated and documented in the patient's record and readily available to those responsible for the patient's care. There is an established reassessment process for patients requiring additional services or ongoing care.

In ambulatory care, when there are multiple assessments by different clinical disciplines, the assessment findings are integrated to appropriately plan for care and services. The assessment findings are documented in a uniform manner and uniform location in the patient's record and the patient's record is readily available to those responsible for the patient's care.

Patients provided additional or continuous services have their needs reassessed through an established process that identifies the scope and content of the reassessment and who is permitted to conduct the reassessments. The reassessment process for special patients is adapted to reflect their needs.

Measurable elements	Max. score	Obtained score
1. Assessment findings are documented in a uniform manner and uniform location in the patient's record	**2.0**	**1.2**
2. Those caring for the patient can easily retrieve assessments as needed from the patient's record or other standardized accessible location	**2.0**	**2.0**
3. The scope and content of reassessments conducted by each clinical discipline are defined in writing	**2.0**	**1.0**

4. Only qualified individuals permitted by licensure, applicable laws and regulations, or certification perform the reassessments	**2.0**	**2.0**
5. The reassessment process for special patient groups and populations is modified to reflect their needs	**2.0**	**2.0**
Total score	**10.0**	**8.2**

Strengths. The TB physicians confirmed that the patients' records are accessible to all of the health care providers working with the TB patients. The staff qualification review showed that all practicing physicians have qualification, including the licensure and certifications, to perform the appropriate reassessments during the TB treatment. Planned reassessments are important for assessing the overall dynamic to TB treatment and are conducted continuously in PHC facilities. Those reassessments are led by the National Standards, the international standards of TB treatment and guided by the patients' health conditions. Based on the reassessments findings the decision is made to discharge/transfer the patient to the inpatient treatment.

For the drug resistant TB cases the continuous treatment is planned by a special committee. I plan the regular patient's [drug sensitive] *continuous treatment according to the guidelines based on their x-ray and sputum examinations. If there are issues related to the treatment, I definitely discuss it with NTCC and then only plan the treatment.*

Healthcare provider, IDI

Regular visits and examination of the TB patients are an integral part of physician's daily responsibilities in the ambulatory setting. The acute patients are assessed and taken care of more frequently. The departments have specific journals for acute patients, where all information is recorded and transferred from shift to shift.

For the drug resistant cases, does not matter if they have complaints or not, we carry out a full examination every month, including sonography, sputum test, and electrocardiogram.

Healthcare provider, IDI

Weaknesses. During the medial record review, the research team found that almost half of the facilities visited did not contain consistent manner and location of assessment findings throughout all of the patients' records. The policy document review revealed absence of defined writings related to the scope and content of reassessments administered by each clinical discipline.

Opportunities. Development of guidelines and methodology assuring assessment finding documentation consistency throughout all patient records should be ensured. Development and formalization of defined writings regarding scope and content of reassessments conducted by each clinical discipline will be achieved through enhancement of policies and procedures.
Threats. Not identified.

4.3 AOP. The time frame for initial assessments and, as appropriate, reassessment is consistent with each patient's needs, organizational policy, and accepted professional guidelines.

Time frames are established for completing histories, physical and psychosocial examinations, discipline-specific assessments, and, when appropriate, reassessments. Time frames for initial assessments and reassessments may differ according to setting, unit, service (such as ambulatory surgery, dental, among others), and patient acuity. Definitions of time frames are based on the care needs and anticipated length of care for each patient population.

Measurable elements	Max. score	Obtained score
1. Time frames for performing assessments are established for all clinical disciplines and services	**2.0**	**2.0**
2. Time frames for performing reassessments are established for all clinical disciplines and services	**2.0**	**2.0**
3. Patients are assessed within a time frame consistent with their needs and as established by organization policy and accepted professional guidelines	**2.0**	**2.0**
4. Patients are reassessed within a time frame consistent with their needs and as established by organization policy and accepted professional guidelines	**2.0**	**2.0**
5. Patients are assessed for follow-up when required by the patient's needs	**2.0**	**2.0**
Total score	**10.0**	**10.0**

Strengths. Timelines for TB ambulatory care assessments and reassessments are established within National Guidelines and the WHO. Depending on the TB patient category (DR or DS, sputum negative or sputum positive, intensive or continuous phase of the treatment), assessments and reassessments are established for all clinical disciplines and services, within a time frame consistent with their needs and are asked to drop in for follow-up when required by the patient's needs.
Weaknesses. Not identified.

Opportunities. Not identified.

Threats. Not identified.

4.4 AOP. Laboratory services are available to meet patient needs, and all such services meet applicable local and national standards, laws, and regulations.

The laboratory services are available to meet patients' needs based on local and national standards, laws, and regulations. The laboratory results are available in a timely manner to the patient's practitioner, as defined by the organization.

Measurable elements	Max. score	Obtained score
1. Laboratory services are readily available to meet patients' needs	**4.0**	**4.0**
2. Laboratory services on site meet applicable local and national standards, laws, and regulations	**4.0**	**2.6**
3. Laboratory results are available in a timely manner to the patient's practitioner, as defined by the organization	**2.0**	**2.0**
Total score	**10.0**	**8.6**

Strengths. The IDIs with the laboratory physicians report high quality of laboratory services provided to the TB patients. There are established timeframes to guide the reporting of test results in the laboratory.

Weaknesses. The location and conditions of the laboratory department in a few ambulatories do not comply with local and national standards of proper laboratory state. The laboratories are located far away from the TB cabinets and do not have proper waiting areas for the number of patients using the services. In some cases the laboratory rooms' capacity do not meet the needs of the laboratory practitioners and their patients.

Opportunities. The laboratories need to be relocated and renovated to satisfy requirements and to provide adequate services.

Threats. Having laboratory services present in all of the outpatient TB facilities require huge financial resources. The lack of financial resources will hinder improvements in laboratory services.

4.5 AOP. Laboratory services provided within the ambulatory care organization are directed and staffed by qualified individuals; are organized with adequate supplies; and provide proper specimen management.

Laboratory services are under the direction of qualified team. The supervisory staff and all laboratory staff have the required education, training, qualifications, and experience. The laboratory develops and implements procedures for collecting and identifying specimens, transporting, storing, and preserving specimens. For obtaining accurate results the laboratory reagents and supplies are consistently available.

Measurable elements	Max. score	Obtained score
1. Laboratory services on site are under the direction of one or more qualified individuals	**1.0**	**1.0**
2. Laboratory supervisory staff and all staff performing laboratory tests and interpreting results on site have the required education, training, qualifications, and experience	**1.8**	**1.8**
3. The laboratory develops and implements procedures for ordering tests	**1.8**	**1.7**
4. The laboratory develops and implements procedures for collecting and identifying specimens	**1.8**	**1.3**
5. The laboratory develops and implements procedures for transporting, storing, and preserving specimens	**1.8**	**1.7**
6. Laboratory reagents and supplies are consistently available, evaluated for accuracy of results, and accurately labeled	**1.8**	**1.8**
Total score	**10.0**	**9.3**

Strengths. The staff qualification observation showed that all laboratory staff who supervise laboratory services, administer laboratory tests have proper qualification and experience. The order or result of laboratory tests is confirmed by the laboratory technician.

Weaknesses. Even though the laboratory is mainly supervised by the TB doctor, a technician with a nursing qualification but no specific TB specialization carries out the daily laboratory work. The laboratory workers do not label the collected specimens with the time of collection as they perceive it as a non-requirement.

Opportunities. Establishment of procedures for specimen collection and identification.

Threats. Not identified.

4.6 AOP. Laboratory quality, safety, and infection control programs are in place, followed, and documented and comply with the facility management and infection control programs.

The laboratory has a documented quality control program that demonstrates quality control procedures. Laboratory safety program addresses potential safety risks in the laboratory and other areas outside the laboratory. Safety program is part of the organization's facility management and infection control programs and includes the biosafety rules, rules prohibiting eating, drinking, smoking, applying cosmetics, manipulating contact lenses, and mouth pipetting. Corrective actions are taken, documented, and reviewed when problems occur.

Measurable elements	Max. score	Obtained score
1. There is a documented quality control program that demonstrates quality control checks on each test performed and on each piece of testing equipment as identified by the organization and recommended by the manufacturer	**1.0**	**0.6**
2. For laboratory services on site, a laboratory safety program addresses potential safety risks in the laboratory and other areas outside the laboratory where laboratory services are provided	**1.0**	**0.7**
3. The laboratory safety program is part of the organization's facility management and infection control programs and reports to the organization's safety structure at least annually and when any safety events occur	**1.0**	**0.6**
4. The laboratory safety program includes biosafety rules for the use of laboratory coats, gowns, or uniforms to protect street clothes and prevent contamination	**1.8**	**1.5**
5. The laboratory implements procedures that govern management of laboratory exposure to infectious agents such as accidental cuts, needle stick injuries, ingestion, and contact with mucous membranes	**1.7**	**1.5**
6. The laboratory safety program includes rules prohibiting eating, drinking, smoking, applying cosmetics, manipulating contact lenses, and mouth pipetting	**1.8**	**1.8**
7. When problems with practice are identified, or accidents occur, corrective actions are taken, documented, and reviewed	**1.7**	**1.8**
Total score	**10.0**	**8.5**

Strengths. The biosafety rules of the laboratory are compliant with the national and international standards. The use of lab coats, gowns or uniforms to protect street cloths and contamination prevention are appropriately implemented. Most of the observed laboratories had a quality control programs in place carrying out evaluations every three months of the quality of the laboratory procedures.

I have a specific gown that I wear underneath the surgical gown. I also put on a surgical hat, mask and gloves… At the end I sterilize the area with chloramine.

Healthcare provider, IDI

Weaknesses. Laboratory technicians had poor knowledge about the organization's safety management program and how it relates to the laboratory safety program. Even though they would report to the national tuberculosis center regarding the safety program of the laboratory, not frequent reports were made to the leadership of the organization itself.

Opportunities. A safety control program for laboratory services that directly relates to the overall safety control program of the organization will guarantee continuous safety improvement and will eventually result in establishing high-quality laboratory services.

Threats. Not identified

4.7 AOP. Laboratory access

Laboratory should follow important existing rules including availability of the biohazard warning symbol, biosafety level showed on the laboratory door. The name and telephone number of the lab manager should be available near the entrance of the laboratory. Only the authorized people must be allowed to enter the laboratory.

Measurable elements	Max. score	Obtained score
1. The international biohazard warning symbol, sign and biosafety level are displayed on the laboratory door.	**2.0**	**0.2**
2. Only authorized persons are allowed to enter the laboratory's working areas.	**2.0**	**0.9**
3. Children are not authorized or allowed to enter the laboratory's working areas.	**2.0**	**2.0**
4. The name, telephone number of the laboratory manager are placed at the entrance to the laboratory.	**2.0**	**0.2**
5. The rules of entering and exiting the laboratory are placed at the entrance to the laboratory	**2.0**	**0.1**
Total score	**10.0**	**3.4**

Strengths. It was clear from the observations and interviews with the laboratory technicians that biosafety and biohazard rules are strictly kept in accordance at most of the ambulatories visited.

Patients and visitors cannot access the general and working areas of the laboratories. The entrance area of the laboratory department restricts the entry of children.

Weaknesses. The international biohazard warning symbol, sign and biosafety level are not displayed on the laboratory door. The laboratory department is not visually protected from unauthorized entries to the area.

The laboratories director and managers' telephone numbers were not placed at the entrance. The rule for entering and exiting the laboratory department are not available at the entrance.

Opportunities. Developing policies and restrictions that are evident to all staff, patients and visitors will control the laboratory entrance area and unauthorized accesses. The laboratory department administration telephone numbers should be placed at the entrance, along with the rules for entering and exiting the laboratory.

Threats. Not identified.

4.8 AOP. Laboratory personal protective equipment

The laboratory workers must follow common rules of the laboratory. The personal protective equipment including gowns, gloves, hand washing procedures should follow biosafety standards. Eating, drinking, smoking, using mobile telephones in the laboratory should be prohibited.

Measurable elements	Max. score	Obtained score
1. Protective laboratory clothing (gown, gloves) and closed-toed footwear are worn at all times while working in the laboratory.	**1.5**	**1.5**
2. Protective clothing is worn and laundered appropriately as according to the biosafety standards	**1.5**	**1.5**
3. Personnel wash hands after any overt contamination, after completing work and leaving the laboratory.	**1.5**	**1.5**
4. Hand washing stations with automated taps, soap, paper towels and dispensers are located at the entrance to laboratory working areas.	**1.5**	**1.3**
5. Laboratory personnel do not eat, drink, smoke, apply cosmetics and handle contact lenses in the laboratory.	**1.5**	**1.5**
6. Food and drink are not stored in the laboratory working areas.	**1.5**	**1.3**

7. Mobile telephones are not used in the laboratory	**1.0**	**1.0**
Total score	**10.0**	**9.6**

Strengths. In both laboratories observed, staff wore laboratory clothing while performing the laboratory manipulations. The laboratory staff wore gloves whenever working with sputum, and always removed them aseptically. At the point of observation the staff was wearing special closed-toed footwear.

Staff had separate clothing for working areas and for clean zones in the department. The laboratory clothing was kept apart from the personal clothing in both observed laboratories, while clean laboratory clothing was kept separately from the used ones. Personal clothing was kept outside of the laboratories' working areas.

Laboratory staff washed their hands after performing manipulations and any contamination. Hand washing sinks with non- automated taps were placed at the laboratories' entrances with paper towels next to them. During the observation no one from staff ate, drank, smoked, applied cosmetics and/or handle contact lenses in the working areas. Food and drinks were mainly not stored in the working areas. The technicians might carry their phones with themselves while working in the laboratory, but the observation showed that those were not used at any point while in the laboratory.

Weaknesses. Laboratories did not have automated taps for hand washing. Some of the laboratories were using cloth towels instead of paper towels, and some interviews indiated that the staff personaly paid for and purchaseed paper towels, soap and hand sanitizers.

Opportunities. The laboratory director should continuously monitor the laboratory workers' compliance to the appropriate use of personal protective equipment as consistent with the bio-safety standards. The staff should be provided with adequate personal protection resources at all times and should be educated on safety practices and adequate personal protection.

Threats. Installation of hand-washing stations requires financial resources.

4.9 AOP. Laboratory procedures

Appropriate procedures should be done in a way to minimize risks of formation of aerosol and droplets. Standard procedures should be developed and followed for all processes. Proper actions should be taken to avoid placing materials into the mouth.

Measurable elements	Max. score	Obtained score
1. All procedures are performed in a way to minimize or prevent formation of aerosol and droplets	**2.0**	**2.0**
2. Mouth pipetting is not done and needles and syringes are not used as substitute for pipetting	**2.0**	**1.8**
3. No materials are placed in the mouth, and labels are self-adhesive	**2.0**	**1.1**
4. Written documentation that may be removed from the laboratory is protected from contamination	**2.0**	**1.8**
5. Standard operating procedures for all processes are developed and used	**2.0**	**0.5**
Total score	**10.0**	**7.2**

Strengths. The laboratory works in a way to avoid generation of aerosols and droplets. Staff never uses mouth pipettes and never place materials in mouths. They also never use needles and syringes as substitutes for pipettes. Labeling and notes on the flasks are done by only using markers. Written documents are entered and removed from the laboratory in special covering to prevent them from contamination.

Weaknesses. The labels are not self-adhesive; staff mainly uses markers and pencils to write on containers as they describe those to be more practical. In the laboratory, the standard operating procedures are mainly not developed and the National Standards are not available.

Opportunities. The PHC facilities should develop standard operating procedures for all processes and provide necessary equipment for implementing manipulations without triggering infections risks.

Threats. Not identified.

4.10 AOP. Laboratory work areas and design

The laboratory area is divided into two parts including clean and contaminated areas. The laboratory manager should control the access to the clean and contaminated areas. Appropriate actions must be taken to keep the area well-ordered and clean. The laboratory must have proper ventilation, reliable electricity supply glass window and fire rating.

Measurable elements	Max. score	Obtained score

1. The laboratory should be divided into "functionally clean" and "potentially contaminated" areas, with the clean areas reserved for administrative and preparatory work.	**1.5**	**1.0**
2. Access to the clean areas and the contaminated areas must be controlled and enforced by the laboratory's manager.	**1.0**	**1.0**
3. The laboratory work areas should be kept neat, clean and free of materials and equipment not used or not working.	**1.5**	**1.5**
4. Work surfaces are decontaminated after any spill of potentially infectious material and at the end of each work session.	**1.5**	**1.5**
5. Adequate ventilation and directional airflow is assured	**1.5**	**1.3**
6. Laboratory doors have a glass window and fire rating.	**1.5**	**0.5**
7. Laboratory has reliable and adequate electricity supply	**1.5**	**1.2**
Total score	**10.0**	**8.0**

Strengths. The laboratories in most of the facilities were designed in a way to have a conventional division of work areas that were clean, neat and free of unused equipment and materials. Whenever a spill occurs, it is immediately decontaminated. Ventilation was assured primarily through open windows. The laboratory technician was the only worker who had access to the clean and the contaminated areas. Electricity supply blockage was a rare event in the laboratories.

Weaknesses. The laboratories had no directional airflow, as no equipment was available to maintain proper environmental controls, including local and general ventilation systems with High-efficiency particulate air (HEPA) filtration in the rooms. The sole barrier to the "potentially contaminated" area in the microbiological laboratory was the door, which was predominantly open. Though the laboratory department manager was informally assigned to regulate protective access to functionally clean and potentially contaminated areas, the department regulation does not describe how. The doors of both laboratories failed to have appropriate fire ratings and glass windows.

Opportunities. The laboratory department should be thoroughly reconstructed to apply all required environmental measures, including clear division of functionally clean and potentially contaminated areas, functional general and local ventilation systems with HEPA filtration.

Threats. Reconstruction of the laboratory department for making it compliant to all bio-safety standards requires large financial resources.

4.11 AOP. Radiology and diagnostic imaging services are available to meet patient needs, and all such services meet applicable local and national standards, laws, and regulations.

The ambulatory care organization has a system for providing radiology and diagnostic imaging services required by its patient population, clinical services offered, and health care practitioner needs on site meet applicable local and national standards, laws, and regulations. The organization defines a timely manner for receiving the results of radiology and diagnostic imaging. Radiology and diagnostic imaging services have a specific schedule for patients with infectious TB and TB suspects. Adequate ventilation is assured for the X-Ray rooms. In the waiting are of the X-ray cabinet there is a UV light operating 24 hours a day.

Measurable elements	Max. score	Obtained score
1. Radiology and diagnostic imaging services are readily available to meet patients' needs	**2.0**	**2.0**
2. Radiology and diagnostic imaging services on site meet applicable local and national standards, laws, and regulations	**1.0**	**1.0**
3. Radiology and diagnostic imaging results are available in a timely manner to the patient's practitioner, as defined by the organization	**2.0**	**2.0**
4. Radiology and diagnostic imaging services have a specific schedule: patients with infectious TB and TB suspects have different admission time period (usually during the second half of the day to minimize contact with other patients in the primary healthcare facility).	**2.0**	**2.0**
5. X-ray examination room has a proper ventilation system: 6-12 air/hour, and in X-ray department – 20 full air change per hour in negative pressure conditions.	**2.0**	**1.5**
6. There is a UV light operating 24 hours a day in the waiting are of the X-ray cabinet of the ambulatory care organization.	**1.0**	**0.5**
Total score	**10.0**	**9.0**

Strengths. During the IDIs radiology physicians claimed that the radiology and diagnostic imaging department meets local and national standards, laws and regulations on practices to address the radiation safety risks. The department reports the undertaken measures to the safety program once a year. The department specialists reported that the department staff is working in a way to provide the results of examinations as soon as possible in order to not keep patients waiting. The TB patients have a priority while assisting the populations in the radiology department. The X-ray examination rooms are provided with powerful ventilation systems or an exhaust pipe. Most of the x-ray rooms have a functioning UV lamp that works at least for several hours a day.

Weaknesses. The Radiology and Diagnostic imaging department activities implemented to address the safety risks are not integrated in the overall safety program of the PHC facility.

Opportunities. A formal radiation safety program will summarize existing practices and will add up new activities targeted to addressing the radiation safety risks. The department staff should be oriented to the safety practices and be continuously educated on new practices.

Threats. Not identified.

4.12 AOP. Radiology and diagnostic imaging services provided within the ambulatory care organization are directed and staffed by qualified individuals and organized with adequate supplies.

Qualified individuals are in charge of radiology and diagnostic imaging services. Proper education, training, experience and qualification of the staff should be guaranteed. Interpretations and summaries must be performed and reported in a timely manner. The availability of the diagnostic imaging x-ray film and supplies should be assured.

Measurable elements	Max. score	Obtained score
1. Radiology and diagnostic imaging services on site are under the direction of one or more qualified individuals	**2.0**	**2.0**
2. Supervisory staff and all staff performing laboratory tests and interpreting results on site have the required education, training, qualifications, and experience	**2.0**	**2.0**
3. Interpretations and summary reports are performed in a timely manner	**2.0**	**2.0**

4. Authenticated, dated reports of all examinations are included in the patient's clinical record	**2.0**	**2.0**
5. Diagnostic imaging x-ray film and supplies are consistently available	**2.0**	**2.0**
Total score	**10.0**	**10.0**

Strengths. Assessment of the radiology and diagnostic imaging department staff members' data showed that the personnel and their supervisors have an adequate education, qualification, and work experience to perform and interpret the imaging studies and report the results in a timely manner. Patients' clinical record observation showed authenticated, dated reports of all examinations. Diagnostic imaging x-ray film and supplies were consistently available.

Weaknesses. Not identified.

Opportunities. N/A

Threats. N/A

4.13 AOP. Radiology and diagnostic imaging quality and safety programs are in place, followed, and documented and comply with the facility management and infection control programs.

The documented quality control program for the radiology and diagnostic imaging including quality control checks, instrument calibration equipment performance and evaluation should be performed. The radiation safety management program, which ensures the availability of safety protective devices appropriate to the practices and hazards, is based on standards, laws and regulations, compliant with the facility management and infection control programs.

Measurable elements	Max. score	Obtained score
1. For radiology and diagnostic imaging services on site, there is a documented quality control program that demonstrates quality control checks on each type of imaging service performed	**2.0**	**0**
2. The quality control program includes instrument calibration, equipment performance and evaluation, and test performance	**2.0**	**1.8**
3. There is a radiation safety management program is in place, which is compliant with applicable standards, laws, and regulations	**2.0**	**0**

4. The radiation safety program is compliant with the facility management and infection control programs, including reporting to the organization's safety structure at least annually and when any safety events occur	**2.0**	**0**
5. The radiation safety program ensures availability of safety protective devices appropriate to the practices and hazards encountered	**2.0**	**2.0**
Total score	**10.0**	**3.8**

Strengths. Despite the absence of a formal radiation safety and quality control program, the relevancy of described safety insurance of availability of safety protective devices appropriate to the practice and the encountered hazards were quiet appropriate. A private organization, which is responsible for equipment maintenance, performs annual check-ups and rapid corrections whenever identified.

Weaknesses. The department does not have a formal set of quality control guidlines or policies a radiation safety program protocol was not identified in any of the facilities.

Opportunities. A quality control program will continuously support and promote the quality of services provided in the radiology and diagnostic imaging department and will serve as a mean for continuous quality improvement.

Threats. The program will operate successfully only if staff of the department is oriented to the safety and quality control activities, share a common understanding of quality improvement and are trained to pass the safety practice knowledge to their patients accordingly.

5. Care of Patients (COP)

5.1 COP. Uniform care is provided to all patients and follows applicable laws and regulations.

The uniform care reflecting local and regional laws and regulation provided by the organization leaders. Patients' abilities to pay for the treatment should not be a barrier in receiving appropriate care. The day of the week or time should not be a limitation for patient in receiving care. The allocated resources of the care should match with the patients' needs.

Measurable elements	Max. score	Obtained score
1. The organization's leaders collaborate to provide uniform care processes	**2.0**	**2.0**
2. The provision of uniform care reflects local and regional laws and regulations	**2.0**	**2.0**
3. Access to and appropriateness of care and treatment do not depend on the patient's ability to pay or the source of payment	**2.0**	**2.0**
4. Acuity of the patient's condition determines the resources allocated to meet the patient's needs	**2.0**	**2.0**
5. The level of care provided to patients is the same throughout the organization	**2.0**	**2.0**
Total score	**10.0**	**10.0**

Strengths. Almost all interviewed managerial leaders agreed that within their facilities care provided to TB patients is uniform. Some of them explained this by the presence of a National Guideline and the National Standard for TB diagnosis and treatment. Others were attributing the uniformity of care to the fact that in their outpatient TB facilities there is only one TB physician working. The data collection suggests that care provided to TB patients is uniform across assessed outpatient TB facilities, and that care reflects the National Guideline. In particular, TB patients receive similar care regardless of their ability to pay as TB diagnosis and treatment come free of charge. By the virtue of the structure of TB care, the acuity of patient condition does not determine provision of TB diagnostics and treatment procedures, as all patients undergo similar procedures and receive similar level of treatment respective to their needs. The majority of leaders were stating that TB care is similar to other ones provided in their PHCs, yet because of contagiousness, it is provided with higher sense of responsibility.

The care is consistent with the standards and is not based on their [TB healthcare providers] *assumptions or wishes. That ensures uniformity of care*

Administration 1, IDI

There is no difference [between TB and other diseases]. *Contrary, TB patients are guaranted with medications, provided by the NTCC. They come, take a one-time dosage, and juice. We ensure all of these, what else should we do?*

Administration 2, IDI

There is no difference [in care provided to various patients]. *Moreover, TB patients are served quicker. The faster the care is organized the better. This is the only difference. But in terms of attitude, they* [TB patients] *are approached, it is similar to others.*

Administration 3, IDI

Weaknesses. Not identified.

Opportunities. N/A

Threats. N/A

5.2 COP. The care and procedures provided to each patient is planned and written in the patients' record.

The planning of the patient's care should be provided and documented in the patient record. The family of the patient can be involved in a planning of the care if needed. Changes in patient's conditions can lead to revisions in the care plan.

Measurable elements	Max. score	Obtained score
1. The care for each patient is planned	**2.0**	**2.0**
2. The patient and, when appropriate, the family are involved in the planned care	**2.0**	**2.0**
3. The planned care is revised when indicated by a change in the patient's condition	**2.0**	**2.0**
4. The planned care is provided	**2.0**	**2.0**
5. The planned care is documented in the patient record	**2.0**	**2.0**
Total score	**10.0**	**10.0**

Strengths. TB healthcare providers universally described that care for TB patients is agreed, developed and documented based on the National Guideline. Since family members are sought for contact investigation, their involvement in care process is strongly encouraged. Furthermore, family members are key for keeping patients adherent to TB treatment. Based on patients' health condition, presence of side effects or other complications, the treatment plan is subjected to

revisions. The revisions are based on the analysis results and x-ray examinations. As a result of revision, the medications or duration of treatment can be modified. The medical record review showed that patients planned and revised care are documented in the medical records.

The treatment is planned according to the National Guideline and Standard. We are not allowed to deviate. **Healthcare provider 1, IDI** *For the DR patients, the presence of side effects might become a reason for revision of the treatment. Issues related to treatment interruption or the scheme modification are discussed with the DR committee.* **Healthcare provider 2, IDI** *We do blood tests, sputum examination, x-ray examination. This might result on the treatment modification or update, depending on the presence of side effects or possible complications. In this case the treatment is revised and in case of a need the medications are changed.* **Healthcare provider 3, IDI**

Weaknesses. Not identified

Opportunities. N/A

Threats. N/A

5.3 COP.3 Policies and procedures guide the care of high-risk patients and the provision of high-risk services

High risk patients are identified by the ambulatory care organization and followed by relevant policies and procedures. The appropriate policies and procedures are defined for the care of immune-suppressed patients, patients on dialysis, patients receiving chemotherapy, dependent elderly people and children. Staff members should be trained on proper policies and procedures.

Measurable elements	Max. score	Obtained score
1. Ambulatory care organization leadership identifies high-risk patients and services and develops relevant policies and procedures of care	**2.0**	**2.0**
2. The care of immune-suppressed patients is guided by appropriate policies and procedures	**1.0**	**1.0**
3. The care of patients on dialysis is guided by appropriate policies and procedures	**1.0**	**1.0**
4. The care of frail, dependent elderly patients is guided by appropriate policies and procedures	**1.0**	**1.0**

5. The care of young, dependent children is guided by appropriate policies and procedures	**1.0**	**1.0**
6. The care of patients receiving chemotherapy or other high-risk medications is guided by appropriate policies and procedures	**1.0**	**0.5**
7. Staff have been trained and use the guidelines and procedures for care	**3.0**	**3.0**
Total score	**10.0**	**9.5**

Strengths. According to the policy review, high-risk patients are defined, and their care is included in the National Guideline. The definition of high-risk patients includes those with substance abuse and prisoners. Moreover, the Guideline lists those conditions that lead to weakened immune system and increase the risk of getting TB, including patients with immunosuppression, those with renal failure, elderly and children and patients that receive chemotherapy. In addition to the definitions, separate chapters and treatment schemes are developed and adapted for high-risk patients.

Weaknesses. The Guideline touches upon only chemotherapy for TB treatment, missing cases when patients receive other high-risk medications.

Opportunities. Care of patients who received beside chemotherapy other high-risk medications, should be incorporated in the National Guideline.

Threats. Not identified.

6. Medication Management and Use (MMU)

6.1 MMU. The ambulatory care organization develops and implements a program for the management and use of medications.

The ambulatory care organization develops and implements a program to guide medication management and use that meets applicable laws and regulations what medications are available within the ambulatory care organization;

a) what medications are available within the ambulatory care organization;

b) the procurement process;

c) the proper and safe storage and labeling of medications;

d) how medications will be prescribed and dispensed; (*Also see* MOI.9)

e) the safety and sanitation of medication preparation and dispensing areas;

f) the qualifications of those who can prescribe, dispense, and administer medications;

g) medication administration and medication monitoring;

h) the management of sample medications;

i) what emergency medications are available within the ambulatory care organization and how they are

securely stored; (*Also see* FMS.3)

j) the storage, distribution, handling, and dispensing of radioactive, investigational, and other medications;

k) the medication recall process, including patient notification and the inadvertent use of medications

known to be expired;

l) medication safety practices such as medication error reporting and adverse drug reaction reporting;

and

m) sources of contemporary drug information.

Measurable elements	Max. score	Obtained score
1. The ambulatory care organization develops and implements a program to guide medication management and use that meets applicable laws and regulations	**2.5**	**2.0**

2. Health care practitioners involved in ordering, dispensing, administering, and patient-monitoring processes are involved in the development and ongoing evaluation of the medication management and use program	**2.5**	**0**
3. The program addresses elements a) through m) in the intent as appropriate to the organization	**2.5**	**1.5**
4. One or more individuals are responsible for medication management and use processes and medication safety	**2.5**	**1.5**
Total score	**10.0**	**5.5**

Strengths. The processes of medication management and use are described in the National Guideline. The policy review confirmed that the list of anti-TB medications and medications for side-effects management, along with their forms, dosages, routes of administration, contraindications, side effects, and cautions are provided in the National Guideline. The specialists of the NTCC calculate and maintain the necessary stock of anti-TB medications in each outpatient TB facility, based on approved treatment schemes and an additional reserve stock of 20%. The procurement of medications is organized based on a special request system. In case if additional amounts of medications are needed (out of the general procurement process), healthcare providers should request through a separate request form. The conditions of proper and safe storage of all medications are also included in the National Guideline. The flow of anti-TB medications in each outpatient TB facility is reflected in the TB-12 form, i.e. medication distribution register. In addition, a process is in place for handling medications with close expiry date. In fact, in outpatient TB facilities, medication with close expiry date are administer first. Healthcare providers of outpatient TB facility should notify the NTCC six months prior to the expiry date, in order to redistribute them to other healthcare facilities with higher demand of a certain medication. The medication management and use process are organized and conducted by the healthcare providers of outpatient TB facilities in collaboration with the NTCC.

Weaknesses. The PHCs do not have a separate medication management and use program, local policies and procedures and, thus TB facilities are guided only by the National Guideline. The information on emergency medications, samples of medications, and contemporary sources about medications were missing in the Guideline. Due to the absence of formal medication management and use program, no guidance is provided on how and who is responsible for the implemented processes. The healthcare providers of outpatient TB facilities are de facto

responsible for medication management. In addition, there are no any responsibilities defined and placed on healthcare providers for developing and monitoring the medication management and use program. The National Guideline missed information on proper labeling of medications.

Opportunities. In PHC level, formal medication use and management programs should be developed for outpatient TB facilities. The program should outline key persons and define their responsibilities in medication management and use processes. The program should address points from a) to m) to comply with the international recommendations.

Threats. Not idenitified

6.2 MMU. Medication administration within the ambulatory care organization follows standardized processes to ensure patient safety.

Medication administration within the ambulatory care organization is a standardized process which includes:

- a uniform dispensing system that, when feasible, makes medications available in the most ready-to-administer form possible;
- medications administered by qualified individuals as identified and permitted by the organization and relevant licensure, laws, and regulations;
- verification that the medication, dosage amount, and route of administration are correct based on the prescription or order;

In addition, the ambulatory care organization standardizes the process to oversee the medications for an individual patient through the use of a medication summary list in the patient's record.

Measurable elements	Max. score	Obtained score
1. There is a uniform medication dispensing and distribution system	**2.5**	**2.5**
2. Medications are administered by qualified individuals as identified and permitted by the organization and relevant licensure, laws, and regulations	**2.5**	**2.5**
3. The medication, dosage amount, and route of administration are verified with the prescription or order	**2.5**	**2.5**
4. Medications prescribed and/or administered within the ambulatory care organization are noted in the patient's record	**2.5**	**2.5**

Total score	**10.0**	**10.0**

Strengths. Medication dispensing and distribution in outpatient TB centers are organized by the NTCC. All anti-TB medications are distributed according to the treatment schemes implemented in each outpatient TB facility. The process is uniform throughout all facilities observed. Medication administration in outpatient TB facilities is organized by physicians and nurses. The staff qualification review revealed that those healthcare providers who are in charge for medication administration have appropriate qualifications (higher medical education). The medication administration process is guided by the National Guideline. TB physicians indicated that patients who receive the first category treatment are administered with fixed-dose combinations of anti-TB medications. Those who receive the second category of treatment, additionally receive an injectable drug. According to physicians, in all cases the administered medications are verified with the treatment scheme. Some physicians further described that medication dosages are determined based on the patients' weight and therefore the treatment scheme can be modified.

Our medications are fixed-dose capsules. We provide those medications according to the treatment scheme.

Healthcare provider 1, IDI

The dosage is determined based on the weight. Nurses distribute one-time dose for each patient. The patient takes the medication and leaves. Each dose administered is mentioned in the medical record. We also have patient who receive injections. The latter's' dose is also determined by patients' weight.

Healthcare provider 2, IDI

Weaknesses. Not identified.

Opportunities. N/A

Threats. N/A

6.3 MMU. Medications are monitored for patient adherence, effectiveness, and adverse medication effects.

The patient and his or her physician, nurse, and other health care practitioners work together to monitor patients on medications. Monitoring medication effects includes observing and documenting any adverse effects. The ambulatory care organization identifies all adverse effects that are to be recorded when observed and those that must be reported. Adverse effects can to be reported as required.

Measurable elements	Max. score	Obtained score
1. Patient adherence in taking medications, medication effectiveness, and adverse medication effects on patients are monitored	**4.0**	**2.0**
2. The ambulatory care organization identifies the adverse effects that are to be documented in the patient's clinical record and those that are to be reported	**3.0**	**3.0**
3. Adverse effects are documented in the patient's record and reported as required	**3.0**	**1.5**
Total score	**10.0**	**6.5**

Strengths. All TB patients' adherence to treatment is ensured through DOT scheme and if necessary through home visits. Various healthcare providers continuously mentioned that the process of patients' drug administration is monitored in outpatient TB facilities by physicians or nurses. The National Guideline includes the list of most common side effects that should be monitored among TB patients. TB physicians mentioned that they monitor side effects and take different measures (e.g., laboratory examinations, prescription of medications against side effects, etc) to minimize or prevent themundertaking different actions. However, only side effects that occur among DR patients are rigorously monitored, recorded and reported.

We necessarily report about all side effects to the NTCC, we have special forms, furthermore I report to the DR committee about the side effects in a written form.

Healthcare provider, IDI

Weaknesses. Monitoring and recording of side effects is systematically implemented only among DR patients, as forms, registers, and procedures are developed for those patients only. No special procedures are developed for methodically monitoring the side effects in DS patients.

Opportunities. Side effects occurring among DS and other TB patients should be also systematically tracked and collected. Processes and procedures should be developed to assure that patients' adverse effects of medications and treatment are monitored.

Threats. Not identified.

6.4 MMU. The ambulatory care organization establishes and implements a program for reporting and acting on medication errors and near misses.

The ambulatory care organization has a process to identify and to report medication errors and near misses. The process includes defining a medication error and near miss which have to be reported. The reports are directed to one or more individuals who are accountable for taking action. Improvements in medication processes and staff training are used to prevent errors in the future.

Measurable elements	Max. score	Obtained score
1. The ambulatory care organization establishes a definition for a medication error and near miss	**2.5**	**0**
2. The ambulatory care organization establishes and implements a process for reporting and acting on medication errors and near misses	**2.5**	**0**
3. Those accountable for taking action on the reports are identified	**2.5**	**0**
4. The ambulatory care organization uses medication errors and near misses reporting information to improve medication use processes	**2.5**	**0**
Total score	**10.0**	**0**

Strengths. Not identified

Weaknesses. None of the assessed outpatient TB facilities had definitions of medication errors or near misses. In all outpatient TB facilities formal processes for reporting and acting on medication errors or near misses were lacking. The PHCs did not identify accountable persons responsible for taking actions on the reports. Therefore, the information on medication errors and near misses are not analyzed and used for improvements of medication use processes.
When asking the healthcare providers about the processes that are developed for identifying and reporting on medication errors or near misses, the majority of them did not understand the concepts of those event, instead, they were talking about the failure of TB treatment or side effects of medications.

> *We do that* [reporting of errors] *by reporting forms, as sometimes bad TB treatment outcomes also occur. We try to find solutions.*
>
> **Healthcare provider, IDI**

Opportunities. PHC facilities should develop their own, uniform definitions of medication errors and near misses and then make them available to outpatient TB facilities. Furthermore, a

culture should be developed within PHCs and between the NTCC, so that the healthcare providers would not fear and will be open to share any events of medication errors or near misses. Acknowledgement of errors will lead to the improvements in processes.

Threats. Not identified

7. Patient and Family Education (PFE)

7.1 PFE. The ambulatory care organization provides education that supports patient and family participation in care decisions and care processes.

The ambulatory care organization integrates education into care processes based on its mission, services provided, and patient population. The ambulatory care organization chooses the ways to organize education based on its educational resources in an efficient and effective manner.

Measurable elements	Max. score	Obtained score
1. The organization plans education consistent with its mission, services, and patient population	**3.0**	**0**
2. There is an established structure or mechanism for education	**4.0**	**4.0**
3. The education structure and resources are organized in an effective manner	**3.0**	**0**
Total score	**10.0**	**4.0**

Strengths. TB healthcare providers shared their practice on the established mechanism of TB patients and their family members education. The majority of TB physicians initiate the first educational discussion with their patients, in a separate room. In addition to physicians, other organizations such as Red Cross and MSF also organize patient education.

> *… educational activities are important as many of patients are not aware of the disease.*
>
> **Healthcare provider 1, IDI**
>
> *When we identify the patient, we call him/her, family and start discussion. We tell and explain them everything.*
>
> **Healthcare provider 2, IDI**

Weaknesses. Though some mechanisms of educational processes are established in the outpatient TB facilities, the majority of TB healthcare providers stated that TB patients are not provided with structured and uniform education. The process of patient education is not systematized on the organization level, rather individual healthcare providers do based on their own initiative and their own understanding of patient education. Therefore, any information provided to patients with the purpose of education, does not necessarily reflect the PHC facilities' and outpatient TB facilities' mission, provided services and patient population. Considering the inconsistenties in conducting patient education, the effectiveness of the latter is

uncertain. Moreover, educating patients on similar topics by different organizations compromises the its effectiveness.

> *Beside us* [TB facility healthcare provider], *the Red Cross also…come, talk and educate patients. At times patients hear the same information so many times, they refuse to listen it again.*
>
> **Healthcare provider, IDI**

Opportunities. The leadership of PHC facilities should embark on establishment of formal patient education program, consistent with the mission, services and patient population of outpatient TB facilities. The program should be designed the way to achieve higher level of effectiveness and efficiency within the given educational resources.

Threats. Designing an educational program requires intellectual resources and significant time. Shortage of any of these two may hinder its enforcement.

7.2 PFE. Each patient's educational needs are assessed and recorded in his or her record

For the purpose of to understand the educational needs of each patient and his or her family, there is an assessment process. The finding from the assessment is recorded as a uniform recording in patients' record by the staff.

Measurable elements	Max. score	Obtained score
1. The educational needs of the patient and family are assessed	**4.0**	**1.1**
2. Educational needs assessment findings are recorded in the patient's record	**2.0**	**0**
3. There is uniform recording of patient education by all staff	**2.0**	**0**
Total score	**10.0**	**1.1**

Strengths. The majority of TB physicians told that they learn about patients' educational needs by talking and getting to know them. The only method for assessing such needs is a healthcare providers' intuition.

> *When you talk to patients, it is* [educational needs] *immediately becomes clear to you.*
>
> **Healthcare provider 1, IDI**
>
> *When patient enters the TB health center we see what type of patient we are dealing with; does s/he have education, is s/he conscious or s/he does not care for treatment or infecting others.*
>
> **Healthcare provider 2, IDI**

Weaknesses. According to TB healthcare providers, they do not have specific criteria for evaluating patients' and families' education needs and, thus, no formal assessment is conducted.

Therefore, no information is recorded in patients' medical records concerning their educational needs.

We don't have special assessment tool; we understand their needs by talking and in case if they have questions, they come and ask. **Healthcare provider 1, IDI** *We don't have a specific criteria* [for assessing educational needs]. **Healthcare provider 2, IDI**

Opportunities. In outpatient TB facilities, healthcare provider should initiate assessment of patients' and families' educational needs, to ensure that information provided to them is more targeted and corresponds to patients' and families' level and needs. This would help healthcare providers to improve the effectiveness of patient and family education processes and achieve higher comprehension of the topic being told.

Threats. Introduction of educational needs assessment

7.3 PFE. The patient's and family's ability to learn and willingness to learn are assessed

Before planning the education, the ambulatory care organization must assess and document

- The patient's and family's literacy, including health care literacy, educational level, and language
- Emotional barriers and motivations; and
- Physical and cognitive limitations.
- Patients' willingness to receive information

Measurable elements	Max. score	Obtained score
1. The patient and family are assessed on: • Beliefs and values • Literacy, educational level and language • Emotional barriers and motivations • Physical and cognitive limitations • The patient's willingness to receive information	**4.0**	**0.2**
2. The assessment findings are used to plan the education	**2.0**	**0**
3. The assessment findings are documented in the patient's record	**2.0**	**0**
Total score	**10.0**	**0.2**

Strengths. TB physicians reported that they ask patients about their educational level and document that information in a dedicated area of the medical records.

Weaknesses. All TB healthcare providers stated that they do not assess patients' beliefs and values, their emotional and psycho-social state and not even patients' willingness to learn.

Opportunities. Assessment and documentation of patients' beliefs and values, their emotional and psycho-social state, as well as their educational level and literacy can help in planning of effective educational programs in the outpatient TB centers.

Threats. Healthcare providers might be reluctant to implement these new assessments which can threaten its implementation.

7.4 PFE. Patient and family education includes the following topics, related to the patient's care: the safe use of medications and potential interactions between medications. Patients and families receive adequate information about the illness, proposed treatment(s), and health care practitioners so that they can make care decisions.

Patients need to be informed on several points related to their condition, proposed treatment process and possible benefits and problems that may occur during the treatment process. Patients should be familiar to the people who are in charge of their care. Proper information related to the nutrition, side effects, transmission of the disease should be delivered to the patient.

Measurable elements	Max. score	Obtained score
1. Patients are informed of these points, as relevant to their condition and planned treatment • The patient's condition • The proposed treatments • The name of the person providing the treatment • Potential benefits and drawbacks • The likelihood of success • Possible problems related to recovery • Possible results of non-treatment	**2.5**	**2.5**
2. Patients know the identities of the physicians or other practitioners responsible for their care	**2.5**	**2.5**

3. As related to the care provided, patients and families are educated about the safe and effective use of all medications, potential side effects of educations, and prevention of potential interactions with over-the-counter medications and/or food	**2.5**	**2.5**
4. As related to TB care provided, patients and families are educated on following topics: transmission of TB difference between latent TB Infection (LTBI) and active TB disease, progression of LTBI to active TB, signs and symptoms of disease, importance of HIV testing, respiratory isolation and use of masks infectious periods, importance of chemotherapy as prescribed, side effects and adverse medication reactions, importance of regular medical assessment, importance of contact investigation, importance of treatment adherence	**2.5**	**2.5**
Total score	**10.0**	**10.0**

Strengths. Across all data collection methods and study population categories, it was reported that TB physicians cover all the topics listed in the standard. TB healthcare providers perceived the role of educating patients as prevention of treatment discontinuation. All interviewed TB patients and family members confirmed that they know well the TB health practitioners who are responsible for their care and who at the time when they were informed about the disease, explained what was their health condition, talked about the importance of taking medications on a daily basis, the disease outcomes and consequences if left untreated. Patients also indicated that by the MSF, especial focus was given to the use of medications.

… We start with explaining what is TB, how it is transmitted, the treatment and etc. If we don't talk to them, don't explain everything, after two months they will stop the treatment, as in general, after one month of treatment the patients start feeling well. At that moment we need to explain that if they abandon the treatment, the disease will progress again and will become more complicated. It is very important to convince them.

Healthcare provider, IDI

Yes, we have been informed about the disease, outcomes, treatment and consequences if not treating it.

Patient/FM 1, IDI

I got to know about my disease by asking questions, reading and almost understood it, but then MSF came and in more details explained what TB is and told everything about it… They covered all topics listed above... I was mostly told about the infection. I was also informed about the medications, their effects. They talked about the medications a lot.

Patient/FM 2, IDI

Of course I was told about my disease, everything about the treatment. I was also told that if I don't take care of myself... the disease can repeat and in that case it will be worse. Also, I was told that treatment success significantly depends on me.

Patient/FM 3, IDI

Weaknesses. Not identified.

Opportunities. N/A

Threats. N/A

7.5 PFE. Education methods include the patient's and family's values and preference and allow sufficient interaction among the patient, family, and staff for learning to occur

The provided education should be assessed to understand how much the information was understood by the patients and their families. Educators should encourage patients and their families to ask questions. The ambulatory care organization decides when and how verbal education is reinforced with written materials to enhance understanding and to provide a future educational reference.

Measurable elements	Max. score	Obtained score
1. There is a process to verify that patients and families received and understood the education provided	**3.4**	**2.3**
2. Those who provide education encourage patients and their families to ask questions and to speak up as active participants	**3.3**	**1.0**
3. Verbal information is reinforced with written material that is related to the patient's needs and consistent with the patient's and family's learning preferences	**3.3**	**2.0**
Total score	**10.0**	**5.3**

Strengths. Almost all TB physicians stated that the only way for verifying if patients understood provided information is to track what type of questions they ask and how adherent they are. Most of TB physicians told that in order to engage patients in the treatment process they provide them various educational materials such as brochures and special literature.

Well, in the beginning we educate, then the treatment starts. During the treatment from their adherence, attitude it becomes evident how much information they have perceived. If the situation is unsatisfactory, we need to work with them again.

Healthcare provider 1, IDI

I necessarily provide brochures to all patents. We try to make them reading those materials, in order to get engaged in the process and not throw them away.

Healthcare provider 2, IDI

Weaknesses. The process of verification if patients understood the provided information is somehow neutral. Indeed, some physicians told that they do not implement specific actions to verify how their patients understood the provided information. Moreover, some physicians stated that there are no specific actions for engaging patients and their family members in education processes. According to TB physicians' and most of patients' responses, the patient education can be characterized as information provision in case if patients ask questions. There were also physicians, who did not indicate that they provide written materials as an aid to verbal information.

Opportunities. After each educational session physicians should implement specific actions, to check how their patients comprehended the information. Those healthcare professionals involved in the patient education processes should be proactive in encouraging patient to participate.

Threats. The provided education without assessment on how much the information was understood by the patients and their families might cause non-adherence to treatment among shy patients and those with lower education.

7.6 PFE. Health professionals caring for the patient collaborate to provide education

Collaboration between health care practitioners is very important, in helps ensure that the information patients and families receive is enough comprehensive, consistent, and as effective as possible. Knowledge of the subject matter, available adequate time, and ability to communicate effectively are important considerations in effective education.

Measurable elements	Max. score	Obtained score
1. Patient and family education is provided collaboratively when indicated	**2.5**	**2.5**
2. Those who provide education have the subject knowledge to do so	**2.5**	**2.5**
3. Those who provide education have adequate time to do so	**2.5**	**2.5**
4. Those who provide education have the communication skills to do so	**2.5**	**2.5**
Total score	**10.0**	**10.0**

Strengths. Consistently all TB healthcare providers mentioned that patients are educated collaboratively by physicians and nurses of the TB outpatient centers. In addition, some of them indicated other international organizations that are also involved in these processes, such as MSF and Red Cross. Most of TB physicians considered their time, knowledge and communication skills to be satisfactory for provision of education to patients. This was confirmed by their personal records and the trainings they have passed.

Physician and nurse… and MSF always organize educational sessions for TB patients. **Patient/FM, IDI**
The time for patient education is enough. I have participated in a seminar regarding patient education. **Healthcare provider, IDI**

Weaknesses. Not identified.

Opportunities. N/A

Threats. N/A

8. Quality Improvement and Patient Safety (QPS)

8.1 QPS. The ambulatory care organization's program for quality and patient safety includes both patient and staff safety and includes the organization's risk management and quality control activities.

All parts of the ambulatory care organization and all staff are involved in the quality and patient safety program. A comprehensive program includes the safety of patients and their families, staff, and visitors.

Measurable elements	Max. score	Obtained score
1. The quality and patient safety program is organization wide	**3.3**	**0.5**
2. The quality and patient safety program includes all patients, staff, and visitors	**3.4**	**0**
3. The quality and patient safety program unites all quality and safety activities of the ambulatory care organization	**3.3**	**0**
Total score	**10.0**	**0.5**

Strengths. From all assessed PHC facilities, a few had an organization wide quality and patient safety programs.

Weaknesses. Since there is no quality improvement and patient safety program in most of the PHC organizations, none of the listed above requirements represented by the measurable elements are met. Moreover, the understandings of quality and patient safety in the ambulatories are very limited.

> *"We have never had any complaints or problems…"*
>
> **Administration, IDI**

Opportunities. Despite the absence of quality improvement and patient safety program in the ambulatories, there was willingness towards work related to the quality improvement given the already existing non-systematic components of patient safety and quality control.

Threats. Lack of risk management and quality control activities in the PHC facilities might threat patients and staff safety.

8.2 QPS. The quality and patient safety program includes the aggregation and analysis of data to support patient care, organization management, and the quality management program and participation in external databases.

The process of aggregating data is part of the patient quality and safety program. The aggregated data should support the overall quality and safety program. When required, the needed data is provided to the agencies outside of the organization.

Measurable elements	Max. score	Obtained score
1. The quality and patient safety program has a process to aggregate data	**3.3**	**0.5**
2. Aggregate data and information support patient care, organization management, professional practice review, and the overall quality and patient safety program	**3.3**	**0.5**
3. Aggregate data and information are provided to agencies outside the ambulatory care organization when required by laws or regulations	**3.3**	**3.0**
Total score	**10.0**	**4.0**

Strengths. The ambulatories develop different reports for the monitoring bodies when required by laws or regulations. Those are usually developed by the administration of the facility or the TB doctor depending on who these reports need to be provided to.

"During the outbreaks we get in contact with the local epidemiology center. We have a nurse who collects data and reports it to the epidemiology center at the end of each day. We have an infectious disease doctor who also handles these processes, if there is an infection."

Administration, IDI

Weaknesses. Data gathering or assessments are not conducted by the ambulatory staff. The development of reports and presentations for the TB situation in Armenia are solely the responsibility of the NTCC. However, they do not deal with ambulatory-level quality and patient safety related issues.

"We do not have someone in particular who handles statistics and reports…"

Administration, IDI

Opportunities. Considering the fact that there is an operating infrastructure dealing with continuous data analysis, it would be feasible to expand the duties and responsibilities of the data

management unit to include specific ambulatory or TB cabinet-related quality and safety measures in their daily activities.

Threats. Newly added job duties demand more time commitment. The latter might threaten the expansion of functions of the data management unit.

8.3 QPS. Individuals with appropriate experience, knowledge, and skills systematically aggregate and analyze data in the organization.

Data must be aggregated, analyzed, and transformed into useful information. Data analysis involves individuals who understand information management, have skills in data aggregation methods, and know how to use various statistical tools. Results of data analysis need to be reported to those individuals responsible for the process or outcome being measured and who can take action based on the results.

Measurable elements	Max. score	Obtained score
1. Data are aggregated, analyzed, and transformed into useful information	**2.5**	**0**
2. Individuals with appropriate clinical or managerial experience, knowledge, and skills participate in the process	**2.5**	**1.9**
3. Statistical tools and techniques are used in the analysis process when suitable	**2.5**	**1.9**
4. Results of analysis are reported to those accountable for taking action	**2.5**	**0.6**
Total score	**10.0**	**4.4**

Strengths. The staff in the ambulatories that have a data monitoring team, have an appropriate experience, qualification, knowledge and skills of using statistical tools and techniques for the mentioned activities whenever appropriate. In the few organizations that have proper data management activities, the data is used for future improvements inside of the ambulatories. Some of the organizations share data on infection control with local epidemiological centers.

Weaknesses. In the few organizations that data collection and analysis took place, the data was hardly ever used for improvements or taking actions upon the results of the analyzed data.

Opportunities. Individuals working with the data could have an extra responsibility for developing list of recommendations for the appropriate bodies in charge of the specific unit that needs improvement.

Threats. Newly added job duties demand more time commitment. It might result in resistance or require financial incentives for the employees.

8.4 QPS. The ambulatory care organization uses a defined process for identifying and managing sentinel events.

A *sentinel event* is an unanticipated occurrence involving death or serious physical or psychological injury, serious physical injury specifically includes loss of limb or function. Such events are called sentinel because they signal the need for immediate investigation and response. The PHC facilities leaders establish a definition of a sentinel event that includes at least an unanticipated death, including, but not limited to

a)death that is unrelated to the natural course of the patient's illness or underlying condition (for example, death from a postoperative infection or a health care–associated infection); death of a full-term infant; and suicide;

b) major permanent loss of function unrelated to the patient's natural course of illness or underlying condition;

c) wrong-site, wrong-procedure, wrong-patient surgery;

d) transmission of a chronic or fatal disease or illness as a result of infusing blood or blood products or transplanting contaminated organs or tissues;

e) infant abduction or an infant sent home with the wrong parents; and

f) rape, workplace violence such as assault (leading to death or permanent loss of function), or homicide (willful killing) of a patient, staff member, practitioner, medical student, trainee, visitor, or vendor while on organization property.

Measurable elements	Max. score	Obtained score
1. The PHC facilities leaders have established a definition of a sentinel event that at least includes a) through f) found in the intent statement	**3.3**	**0**
2. The organization conducts a root cause analysis on all sentinel events in a time period specified by the PHC facilitie's leaders	**3.4**	**0**
3. Organization leadership takes action on the results of the root cause analysis	**3.3**	**0**
Total score	**10.0**	**0**

Strengths. Not identified.

Weaknesses. There is no operational definition of a sentinel event at the ambulatories. Correspondingly no root cause analysis is done, thus rare actions are taken afterwards.

Opportunities. Though there is no definition of sentinel events and respectfully no root cause analysis is done, there is a potential basis to initiate the development of definition for such events. There is a so called central medical commission, consisting of managerial leaders, and heads of departments, which deals with difficult cases, provides consultations to the patients for the sake of quality improvement. This commission could have a key role in developing an operational definition of sentinel events, as well as in conducting root-cause analysis when such events occur.

Threats. The inherited culture of the organization does not support open discussions of problems. There is a blaming approach towards any possible errors. In such situation it would be difficult to introduce a new approach, where learning from failures is more valued.
Besides, the members of the mentioned above commission have very busy schedules, and the newly added functions will increase their workload, which, in turn, might result in resistance to change. Another threat could be the lack of corresponding knowledge and skills to conduct root-cause analysis of sentinel events.

8.5 QPS. Data are always analyzed when undesirable trends and variation are evident from the data.

The analysis of the data should indicate adverse levels, patterns and trends. Ambulatory care organization should analyze and define adverse medication effects when needed.

Measurable elements	Max. score	Obtained score
1. Intense analysis of data takes place when adverse levels, patterns, or trends occur	**2.5**	**0**
2. All serious adverse drug events, if applicable and as defined by the ambulatory care organization, are analyzed.	**2.5**	**0.2**
3. All significant medication errors, if applicable and as defined by the ambulatory care organization, are analyzed	**2.5**	**0**

4. Other adverse events defined by the ambulatory care organization are analyzed	**2.5**	**0**
Total score	**10.0**	**0.2**

Strengths. One of the ambulatory directors claimed to analyze adverse drug events.

Weaknesses. The ambulatory neither has developed definitions of adverse events including medication errors, nor it has processes to analyze and respond to the occurred errors. That is to say, the adverse events and medication errors are not defined or reported in the ambulatories and no data is used to improve these processes.

Opportunities. The ambulatory organization should introduce a system which will take actions to monitor the adverse events and medication errors, including recording and reporting. This system should include all settings of the organization and share the common understanding of importance of acknowledging the adverse events and medication errors for improving the overall quality level.

Threats. The adverse event handling process will not be improved, unless the whole ambulatory staff perceive the importance of acknowledging the errors, recording and reporting them.

8.6 QPS. The ambulatory care organization uses a defined process for the identification and analysis of near-miss events.

The ambulatory care organization establishes the definition of the near misses and type of the events that should be reported. The process for reporting near misses is defined. For the purpose to reduce near misses the data should be analyzed and appropriate actions must be taken.

Measurable elements	Max. score	Obtained score
1. The ambulatory care organization establishes a definition of a near miss	**2.5**	**0**
2. The ambulatory care organization defines the type of events to be reported	**2.5**	**0**
3. The ambulatory care organization establishes the process for the reporting of near misses	**2.5**	**0**
4. The data are analyzed and actions taken to reduce near-miss events	**2.5**	**0**
Total score	**10.0**	**0**

Strengths. Not identified.

Weaknesses. The ambulatory neither has developed definitions of near misses, nor does it have processes to analyze and respond to these. No data is used to improve the near misses.

Opportunities. The ambulatory organization should introduce a system which will take actions to assess the near misses, including recording and reporting. This system should include all settings of the organization and share the common understanding of importance of acknowledging the near misses for improving the overall quality level.

Threats. The near misses will not be handled appropriately and learnt from, unless the whole ambulatory staff perceive the importance of acknowledging these, recording and reporting them.

9. Prevention and Control of Infection (PCI)

9.1 PCI. The ambulatory care organization designs and implements a comprehensive program to reduce the risks of healthcare–associated infections in patients and staff. There is a designated coordination mechanism for all infection prevention and control activities that involves physicians, nurses, and others based on the size and complexity of the organization.

The ambulatory care organizations should have a comprehensive infection prevention and control program, which will guide and coordinate all the infection prevention activities throughout the organization. The infection prevention and control program should include both – patient care and staff health. According to JCI the program should be multidisciplinary, and implemented all over the organization- in patient, staff, and visitor areas. The staff should be educated about the program, including their role in the program.

Measurable elements	Max. score	Obtained score
1. The ambulatory care organization designs and implements an infection prevention and control program to reduce the risk of health care–associated infections in patients and staff that is based on the organization's size, geographic location, services, patients, and staff	**1.25**	**1.25**
2. The program is multidisciplinary and supported by necessary human and technical resources	**1.25**	**1.25**
3. The program is implemented throughout all patient, staff, and visitor areas of the ambulatory care organization	**1.25**	**1.25**
4. All staff are educated regarding their role in the program	**1.25**	**1.25**
5. One or more individuals oversee the infection prevention and control program	**1.25**	**1.25**
6. There is a designated mechanism for the coordination of the infection prevention and control program	**1.25**	**1.25**
7. The infection prevention and control program involves physicians, nurses, and others based on the size and complexity of the ambulatory care organization.	**1.25**	**1.25**
8. Program coordination includes the communication of important infection risk and prevention information to all staff.	**1.25**	**1.25**

Total Score	**10.0**	**10.0**

Strengths: All the facilities included in the assessment had infection prevention and control program based on the requirements of the Minister's order of N 1853-A of July 03.2013 of the Ministry of Health of the RA. In most of the cases the program comprised of the epidemiologist, infectionist, TB physician/nurse, and administration representative. The staff of the outpatient TB centers was well aware of the infection prevention measures and was trained about their roles and responsibilities in the program.

The information about infection prevention and control program was collected via document review and face-to-face interviews with key informants. The document review showed that the program was described in the methodological guide for TB management in Armenia. The detailed program activities and procedures were also described. The interviews with healthcare providers showed that the described activities are carried out by the trained staff.

We have a specially developed infection control program. Our infectionist along with some other specialists from other structural units, is responsible for the program. We have a special journal where the activities of TB infection control are listed. The director, vice director, laboratory physician,and nurses are included in that program. We know how to carry out each of the activities.

Healthcare provider 1, IDI

We have an epidemiologist and an infectionist, I have an infection control plan, which we implement. We do it in collaboration with family physicians.

Healthcare provider 2, IDI

The healthcare providers and administration representatives indicated that they are equipped with necessary resources, including personal protection kits and disinfectants to carry out infection prevention activities.

The IDIs with healthcare providers showed that they are well aware of the infection control activities and have undergone special trainings. Those trainings were mainly organized by the National TB Control Center. Besides, the TB physicians update their knowledge on infection control activities every trimester when attending NTCC meetings. During those meetings they also get familiar with the results of the infection prevention and control measurements that NTCC conducts in the TB cabinets.

There has been a training on infection control. We know how to use the UV lamps, how frequently those should be cleaned, we have a special journal, were we track everything.

Healthcare provider 1, IDI

We visit NTCC once per trimester, and they show us the results of their monitoring and spot check on a huge screen. We get familiar with the results of their monitoring, and if they tell us that we have certain drawbacks, we try to overcome those.

Healthcare provider 2, IDI

Weaknesses: Not identified.

Opportunities: Not identified.

Threats: Not identified.

9.2 PCI. The infection prevention and control program is based on current scientific knowledge, accepted practice guidelines, applicable laws and regulations, and standards for sanitation and cleanliness.

It is very important to have a solid base for the infection prevention and control programs. With this regards JCI recommends that the ambulatory care organizations consider current scientific knowledge, accepted practice guidelines, as well as applicable laws and regulations in their infection prevention and control activities.

Measurable elements	Max. score	Obtained score
1. The infection prevention and control program is based on current scientific knowledge, accepted practice guidelines, and local laws and regulations	**2.5**	**2.5**
2. The infection prevention and control program is based on standards from national or local agencies and publications and professional organizations that address environmental sanitation and cleanliness	**2.5**	**2.5**
3. Infection prevention and control program results are reported to public health agencies as required	**2.5**	**2.5**
4. The ambulatory care organization takes appropriate action on reports from relevant public health agencies	**2.5**	**2.5**
Total score	**10.0**	**10.0**

Strengths: The infection prevention and control programs in the TB ambulatory care facilities included in the assessment were based on the Minister's order N 1853-Ա of 03.07.2013 of the MoH of the RA. The latter includes an exemplary infection prevention and control program for

the TB outpatient facilities, which consists of various components. Those components are grouped into three main categories. The first category includes details about establishment of infection control committees, monitoring of infection control, separation of risky/dangerous zones, facility conditions, improvement of process of early detection and treatment of TB cases, respiratory protection, sanitary-hygienic activities, including organization of proper waste disposal, staff health monitoring, and staff trainings. The second category is about monitoring of environmental conditions, including ventilation of the building (natural, mechanical), assessment of ventilation, purchasing of engineering control devices, usage of UV lamps, training on engineering control, and implementation of engineering control activities. The third category covers personal protection, including assessment of personal protection activities implementation, safe and proper use of respirators, and staff and patient education. The document indicated above is based on the current recommendations of the WHO and is consistent with recent scientific evidence.

In parallel with the PHC facilities' internal programs, the infection control is a part of NTCC responsibilities toward outpatient TB centers in a frame of TB program coordination and monitoring in the country. These responsibilities include periodic checking of infection prevention and control activities and sharing the results with TB ambulatory facilities for improvement.

NTCC conducts monitoring every three months, and they inform us on the results both orally and in written form.

Healthcare provider 1, IDI

The monitoring results are presented to the director, and s/he reacts on the situation based on those results. Of course, s/he controls continuously, this is our discipline.

Healthcare provider 2, IDI

Monitoring is conducted quite often, multiple times per year…When they point out drawbacks, we discuss and try to overcome.

Healthcare provider 3, IDI

Additionally, epidemiologists in the PHC facility report results of all infection prevention and control program to the Health and Labor Inspection body of the Republic of Armenia for taking appropriate actions based on the public health agency feedback.

Weaknesses: Not identified.

Opportunities: Not identified.

Threats: Not identified.

9.3 PCI. The organization identifies the procedures and processes associated with the risk of infection and implements strategies to reduce infection risk.

Ambulatory care organizations assess and care for patients using many simple and complex processes, each associated with a level of infection risk to patients and staff. It is important for an organization to measure and review those processes and, as appropriate, implement needed strategies, such as policies, procedures, education, and evidence-based activities designed to reduce the risk of infection. The ambulatory care organization implements strategies that are in compliance with applicable laws and regulations to reduce the risk of infection by ensuring:

a) adequate equipment cleaning and sterilization
b) a process to manage reuse of single use devices
c) availability and proper use of gloves, protective eyewear, masks, and gowns
d) safe storage and disposal of clinical waste and potentially infectious waste that require special disposal such as sharps/needles and other disposable equipment that may have come in contact with body fluids

Measurable elements	Max. score	Obtained score
1. The organization has identified those processes associated with infection risk	**3.3**	**0**
2. The organization identifies which processes require policies, procedures, staff education, practice changes, evidence-based activities, and other strategies to support risk reduction	**3.3**	**0**
3. The organization implements strategies to reduce the risk of infection by ensuring:	**3.4**	**3.4**
a) adequate equipment cleaning and sterilization;		
b) a process to manage reuse of single use devices;		
c) availability and proper use of gloves, protective eyewear, masks, and gowns;		
d) safe storage and disposal of clinical waste and potentially infectious waste that require special disposal such as sharps/needles and other disposable equipment that may have come in contact with body fluids		
Total score	**10.0**	**3.4**

Strengths: All the ambulatory TB facilities have infection control programs, which contain certain activities to reduce risk of infection, fulfilling the standard's third measurable element requirements from a) to d). Those activities target equipment cleaning and sterilization, management of single use devices, personal protective equipment, as well as waste management. The IDIs showed that healthcare providers were well aware of the infection prevention and control program, as well as the activities carried out in frames of the program. The observations showed that single use devices, medical waste disposal boxes, as well as personal protective equipment were available in the TB facilities at PHC level. For the purposes of waste management the ambulatory TB facilities contract special agencies responsible for proper disposal of hazardous medical waste. Contagious waste is kept in a special room, which is later transported to the outsource agency. The glassware is not sterilized in the facility, since it is single use, and is later on transported to the agency.

Weaknesses: The weaknesses are connected with overall lack/absence of organization-wide policies. It is recommended that the facilities identify those processes, which are associated with infection risk, as well as those processes, which require policies, procedures, staff education, practice changes, evidence-based activities, and other strategies to support risk reduction.

Opportunities: To fully meet the infection prevention and control standards', the TB ambulatory care facilities should identify those processes associated with infection risk, as well as processes requiring policies, procedures, staff education, practice changes, evidence-based activities, and other strategies to support risk reduction.

Threats: Lack of human resources to develop all the indicated above processes might hinder the fulfillment of the standard.

10. Governance, Leadership and Direction (GLD)

Effective leadership is essential in the provision of high-quality healthcare services. The leaders of the healthcare organization should identify the mission of the organization and allocate the existing resource to fulfill the mission. Effective leadership plays an important role in the integration of all quality improvement activities in the organization.

10.1GLD. Governance responsibilities and accountabilities are described in bylaws, policies and procedures, or similar documents that guide how they are to be carried out.

The ambulatory care organization has a governance structure. The responsibilities, accountabilities, annual evaluation of the governance are described in the documents.

Measurable elements	Max. score	Obtained score
1. The organization's governance structure is described in written documents, and those responsible for governance and managing are identified by title or name	**3.4**	**0**
2. Governance responsibilities and accountabilities are described in the documents	**3.3**	**0**
3. There is an annual documented performance evaluation of governance	**3.3**	**0**
Total score	**10.0**	**0**

Strengths. Not identified.

Weaknesses. There are no documents describing organization's governance structure, governance responsibilities and accountabilities in written documents. It is not mentioned how the performance of the governing body will be evaluated, and no performance evaluation of the governance is documented.

Opportunities. Documents should be developed outlining organization's governance structure. A special document could be developed describing how the performance of the governing entity will be evaluated. Based on that document the NTCC can perform evaluation of the governance annually.

Threats. Not identified.

10.2GLD. A chief executive/managing director(s) is responsible for operating the ambulatory care organization and complying with applicable laws and regulations.

Effective leadership is essential for an ambulatory care organization to be able to operate efficiently and to fulfill its mission. The chief executive/managing director(s) is responsible for the organization's overall day-to-day operations, recommending policies and strategic plans compliant with the laws and regulations. The chief executive/managing director(s) should respond to any reports from inspecting and regulatory agencies.

Measurable elements	Max. score	Obtained score
1. The education and experience of the chief executive/managing director(s) match the requirements in the position description	**2.0**	**2.0**
2. The chief executive/managing director(s) manages the ambulatory care organization's day-to-day operations, including those responsibilities described in the position description	**2.0**	**1.5**
3. The chief executive/managing director(s) recommends policies, strategic plans, and budgets to the governing body	**2.0**	**1.5**
4. The chief executive/managing director(s) ensures compliance with approved policies	**2.0**	**1.5**
5. The chief executive/managing director(s) ensures compliance with applicable laws and regulations	**2.0**	**1.5**
Total score	**10.0**	**8.0**

Strengths. The medical staff qualification review showed that persons in charge of the management of the ambulatories have adequate education and qualifications to carry out their responsibilities in their assigned positions. In more than half of the ambulatories the director of the facility supervises the everyday functions of the outpatient TB centers.

Mainly, the director manages the organization. The director's medical assistant is responsible for the supervision, management of the outpatient TB centers. If there are any problems, the TB physician comes here [to the director's office] and we solve the problem, we try to have everything organized and appropriate.

Administration, IDI

In most of the clinics the director oversees the compliance of policies, applicable laws and regulations, strategic plans and the budget and makes recommendations to the according governing bodies.

Weaknesses. The IDIs with some of the supervisors of the clinics showed that the facility manager does not assume full supervision over the outpatient TB centers' daily work. NTCC director manages daily operations of the outpatient TB centers and is the one, who serves as a linkage between the governing body and the ambulatory itself. Other managers make the director informed about the situation in the outpatient TB centers through regular reports.

Opportunities. Having supervision and providing support by both the NTCC and the ambulatory management with the outpatient TB centers daily work could strengthen the quality and safety of the services provided.

Threats. Not identified.

10.3GLD. Ambulatory care organization leadership is identified and collectively responsible for defining the organization's mission and creating the programs and policies needed to fulfill the mission.

The chief executive/managing director(s) and ambulatory care organization leadership are identified by title and name, and their collective accountabilities are described in written documents. The leadership defines the ambulatory care organization's mission and responsible to follow the policies and procedures to support the defined mission.

Measurable elements	Max. score	Obtained score
1. The chief executive/managing director(s) and ambulatory care organization leadership are identified by title and name, and their collective accountabilities are described in written documents	**2.5**	**2.5**
2. Ambulatory care organization leadership is responsible for defining the organization's mission	**2.5**	**0**
3. Ambulatory care organization leadership is responsible for creating the policies and procedures necessary to carry out the mission	**2.5**	**0**
4. Ambulatory care organization leadership ensures that policies and procedures are followed	**2.5**	**2.5**
Total score	**10.0**	**5.0**

Strengths. Written documents clearly identify the names and titles of the leadership of the ambulatory organizations. The observations of staff qualification revealed that the directors ensure of the practice correspondence to the approved policies and procedures.

Weaknesses. According to the policy review, the supervisor does not have any role or responsibility for defining organization's mission, creating policies and procedures to implement the mission.

Opportunities. Policies and processes related to the supervision of the ambulatory should be developed. Clear and distinct mission should be outlined for the organization that is under the direct oversight of the ambulatory management team. It would be feasible to include the organization mission statement in its organizational charter. After having a formally defined mission it could be made available to public through official website, as well as social and mass media.

Threats. Lack of commitment and understanding the importance of policy development and adherence by the leadership might potentially hinder development of such policies.

10.4GLD. Organization leaders ensure that there are uniform programs for the recruitment, retention, development, and continuing education of all staff.

The recruitment and retention of the staff should be according to the planning process of recruitment and retention. Continuing education for the staff should be included in a collaborative planning process.

Measurable elements	Max. score	Obtained score
1. There is a planned process for staff recruitment	**2.5**	**0**
2. There is a planned process for staff retention	**2.5**	**0**
3. There is a planned process for staff personal development and continuing education	**2.5**	**0**
4. The planning is collaborative and includes all departments and services in the organization	**2.5**	**0**
Total score	**10.0**	**0**

Strengths. Not identified.

Weaknesses. There is no planned comprehensive staff recruitment processin the NTCC or the ambulatories. There are no specific domains on planning staff recruitment activities for outpatient TB centers across the PHC organizations. NTCC also has no staff retention plan. The personal development and continuing education issues of the staff are not well systematized and standardized either. Despite the fact that the medical and administrative personnel periodically participate in different educational programs outside the PHC facilities, in which nurses do not even participate. There is no systematic organization of periodic training programs for staff. The planning of the educational activities is not collaborative and does not include all the services.

There is no such standard or legal document…They just undergo 3 months probation period during which we try to asses the relevance of their qualifications to their practice. **Administration, IDI**

Opportunities. On the basis of the existing infrastructures, particularly the human resource department and the advisor of the director on scientific and educational affairs, it will be feasible to come up with comprehensive recruitment and retention plans for the staff. While developing those plans, all the services of the outpatient TB centers should be considered. Morreover, since there is recognition and political will to improve the situation regarding continuing education of nurses, the development of the plan could be done easily.

Threats. Lack of commitment and understanding the importance of comprehensive staff recruitment and retention plans might interfere with the development of such plans.

10.5GLD. Ambulatory care organization leadership plans and oversees a quality improvement and patient safety program and sets measurement priorities and priorities for improvement.

The leadership of the ambulatory care organization plans the organization's quality improvement and patient safety program. Ambulatory care organization leadership identifies priority performance measures to monitor the clinical and managerial structures, processes, and outcomes. The leadership of the organization confirms that staff training in quality and patient safety should be provided.

Measurable elements	Max. score	Obtained score

1. Ambulatory care organization leadership plans and oversees the organization's quality improvement and patient safety program	**2.0**	**0**
2. The quality improvement and patient safety program is described in a plan or other written document	**2.0**	**0**
3. Ambulatory care organization leadership identifies priority performance measures to monitor the clinical and managerial structures, processes, and outcomes	**2.0**	**2.0**
4. Ambulatory care organization leadership identifies priority improvement activities to be carried out	**2.0**	**0.6**
5. Ambulatory care organization leadership ensures that staff training in quality and patient safety is provided and that adequate resources are allocated to the quality and patient safety program	**2.0**	**0**
Total score	**10.0**	**2.6**

Strengths. The directors were well aware of the priority performance measures and some could identify needed improvements related to those measures inside of their organizations.

Weaknesses. Both the policy review and the IDIs with the administration have confirmed that even though the ambulatories address at least a basic level of patient safety and quality improvements issues, they all lack official written plan on both. The administration does not hold responsibility for overseeing or developing quality improvement and patient safety plans, staff was not trained on the topic, appropriate resource allocation was not carried out.

Although the physicians working within the outpatient TB centers showed priority performance based on the difference and severity of the clinical case and its related outcome, these processes weren't monitored by the administration.

Opportunities. Conducting periodic trainings with the administration as well as health care providers of the ambulatory organizations on the quality improvement and patient safety topics, introducing structure and processes of quality improvement would support the oversight of the quality of services.

Threats. Lack of commitment to quality all over the ambulatory might potentially threaten the development of quality improvement infrastructure and processes.

10.6GLD. Ambulatory care organization leadership makes decisions related to the purchase or use of resources—human and technical—with an understanding of the quality and safety implications of those decisions.

The leadership of the ambulatory care organization uses data and information on the quality and safety implications of medical technology choices, quality and safety implications of staffing choices, the recommendations of professional organizations and other authoritative sources in making resource decisions.

Measurable elements	Max. score	Obtained score
1. Ambulatory care organization leadership uses data and information on the quality and safety implications of medical technology choices	**3.3**	**0**
2. Ambulatory care organization leadership uses data and information on the quality and safety implications of staffing choices	**3.3**	**0**
3. The ambulatory care organization uses the recommendations of professional organizations and other authoritative sources in making resource decisions	**3.4**	**0**
Total score	**10.0**	**0**

Strengths. Not identified.

Weaknesses. Directors of the PHC facilities do not obtain data and information on the quality and safety implications of medical technology choices or staffing choices. Moreover, there is no criterion about those issues at all. Resource decisions are made within the organizations. Everything is based on so called “common sense”.

Opportunities. The ambulatory organizations’ staff, especially the leadership, should undergo a comprehensive training on the importance of data collection, management and analysis for further quality improvement and effective resource management purposes.

Threats. The above-indicated processes require time and efforts. It will increase the workload of the people involved in the process, which might, in turn, cause resistance to change.

10.7GLD. Ambulatory care organization leadership seeks and uses data and information on the safety of the supply chain for drugs, medical technology, and supplies to protect patients and staff from contaminated, fake, and diverted products.

The leadership of the ambulatory care organization identifies the supply chain of critical supplies and medical technology, evaluates the integrity of each supplier in that chain, makes resource decisions based on their understanding of the risks in the supply chain, tracks critical supplies to prevent diversion or substitution.

Measurable elements	Max. score	Obtained score
1. Ambulatory care organization leadership identifies the supply chain of critical supplies and medical technology	**2.5**	**0.5**
2. Ambulatory care organization leadership evaluates the integrity of each supplier in that chain	**2.5**	**0.4**
3. Ambulatory care organization leadership makes resource decisions based on their understanding of the risks in the supply chain	**2.5**	**0**
4. Ambulatory care organization leadership tracks critical supplies to prevent diversion or substitution	**2.5**	**0.4**
Total score	**10.0**	**1.3**

Strengths. The law requires the supply of medical technologies to be organized with tenders and some of the organizations make the best of this opportunity to identify appropriate suppliers and assess their integrity. Diversion of critical supplies and need for substitutions is a rare event in some of the ambulatories.

All the medical supplies are purchased through tenders based on last year's consumption plus 5-10%.
Administration, IDI

Weaknesses. The supply chain of medical technologies being organized through tenders limits some of the administrations in their decision-making processes of the supply chain and assessing the integrity of each supplier. In most of the organizations visited, the ambulatory administration provides the outpatient TB centers with the basic medical supplies while the main responsibility of TB related critical supply provision is organized through the NTCC.

During the competition [tenders] *the lowest price offerings win.*
Administration, IDI

Opportunities. Having the administration take responsibility in providing the critical supplies to the outpatient TB centers would introduce a more structured process of supply management and maintaining. It would also lift the weight off of NTCC in organizing and providing supply for all of the outpatient TB centers, which would lead to a more equal distribution of supply, improved efficiency and quality of supply management in the overall system.

Threats. The above-indicated processes require time and efforts. It will increase the workload of the people involved in the administration, which might, in turn, cause resistance to change.

10.8GLD. Ambulatory care organization leadership creates and supports a culture of safety program throughout the organization.

The leadership of the ambulatory care organization establishes and supports an organizational culture that promotes accountability and transparency, develops and documents a code of conduct, provides resources to promote and support the culture of safety, implements a process to provide a system for reporting issues, identifies and manages systems issues that lead health care practitioners to engage in unsafe behaviors.

Measurable elements	Max. score	Obtained score
1. Ambulatory care organization leadership establishes and supports an organizational culture that promotes accountability and transparency	**2.0**	**0**
2. Ambulatory care organization leadership develops and documents a code of conduct and identifies and corrects behaviors that are unacceptable	**2.0**	**0**
3. Ambulatory care organization leadership provides resources to promote and support the culture of safety within the organization	**2.0**	**0**
4. Ambulatory care organization leadership implements a process to provide a simple, accessible, and confidential system for reporting issues relevant to a culture of safety in the organization and prevents retribution against individuals who report issues	**2.0**	**0**
5. The ambulatory care organization identifies and manages systems issues that lead health care practitioners to engage in unsafe behaviors	**2.0**	**0**
Total score	**10.0**	**0**

Strengths. Not identified.

Weaknesses. The leadership of the ambulatory organization claimed to have accountability and transparency as part of the organizational culture but when asked about details of how exactly these processes are maintained and supported; the interviewers weren't able to obtain any details on the matter from any of the directors of the clinics visited. The same is true for the rest of the functions of the above-mentioned standard. The interviews showed that the administration does not have an accurate understanding of what is meant by "culture of safety". The answers of how safety is promoted within the organization most of the time included concepts about basic sanitation rules and did not take any other directions. The leadership of the ambulatories does not have any functions related to developing a process for unsafe behavior engagement issue identification within the staff of the organization. The inherited culture of the ambulatories is a blaming and hiding one, where talking about the drawbacks, weaknesses and areas for improvement is not an accepted practice.

Opportunities. Despite all of the reported problems, the willingness of the leadership of the organizations towards improvement and already existing non-systematic elements of patient safety may serve as a ground to establish a safety system in the organization. The establishment patient safety program will enable the leadership to design new clinical and managerial processes, to be able to measure how those processes work, to analyze the obtained data, and to implement changes that will lead to improvement.

Threats. Resistance to change is one of the major threats to the implementation of patient safety program. It becomes more obvious when considering that there is no universal understanding and commitment to safety accepted all over there organizations, at least by the majority of the staff. Another threat to develop and establish a safety program is the lack of appropriately trained staff sharing a mutual vision towards quality and patient safety.

11. Staff Qualification and Education (SQE)

11.1 SQE. The ambulatory care organization uses a defined process to ensure that clinical and nonclinical staff knowledge and skills are consistent with the requirements of the position.

The ambulatory care organization establishes the process to match clinical and nonclinical staff knowledge, skills, and competency with patient needs. The staff members are evaluated at the time they begin their work responsibilities. There is at least one documented evaluation of each clinical and nonclinical staff. There is a staff record that contains the individual's qualifications, results of evaluations, and work history.

Measurable elements	Max. score	Obtained score
1. The ambulatory care organization uses a defined process to match clinical and nonclinical staff knowledge, skills, and competency with patient needs	**2.0**	**0**
2. New clinical and nonclinical staff members are evaluated at the time they begin their work responsibilities by the department or service to which they are assigned	**2.0**	**0**
3. There is at least one documented evaluation of each clinical and nonclinical staff member working under a job description each year or more frequently as defined by the ambulatory care organization	**2.0**	**0.8**
4. There is at least one documented evaluation of each staff member working under a job description each year or more frequently as defined by the organization	**2.0**	**0**
5. There is a staff record that contains the individual's qualifications, results of evaluations, and work history	**2.0**	**1.5**
Total score	**10.0**	**2.3**

Strengths. The staff qualification review showed that staff working under specificjob descriptions have at least one documented assessment of their work.. The majority of the organizations held a staff record documenting their qualifications and work history.

Weaknesses. There is no process of matching clinical staff knowledge with patient needs. No formal evaluations are conducted for the clinical staff members. The departments do not evaluate newly hired staff members at the beginning of their work.

Opportunities. A process of clinical staff's evaluation needs to be designed. The process should focus both – initial evaluation, and on-service evaluation in order to detect the educational needs and provide appropriate on-service trainings when necessary.

Threats. Since there is no experience of conducting staff evaluations, it will be difficult to initiate one. Lack of recognition of the importance of those evaluations, as well as lack of commitment might serve as potential obstacles in establishing an evaluation process.

11.2 SQE. Department and service leaders of the ambulatory care organization define the desired education, skills, knowledge, and other requirements of all staff members

The ambulatory care organization defines requirements of staff including desired education, skills, and knowledge based on mission, volume and mix of patients, services, and medical technology. Appropriate laws and regulations are incorporated into the requirements of staff.

Measurable elements	Max. score	Obtained score
1. The ambulatory care organization's mission, volume and mix of patients, services, and medical technology are used in defining requirements of staff	**3.3**	**0**
2. The desired education, skills, and knowledge are defined for staff	**3.3**	**2.5**
3. Applicable laws and regulations are incorporated into the requirements of staff	**3.3**	**0**
Total score	**10.0**	**2.5**

Strengths. There are some job descriptions developed for some of the positions containing educational and experience requirements. This was both confirmed by the staff education and qualification review observation and the interviews with the administration of the ambulatories. The human resource management units of the ambulatories maintain personal files for all the staff members. Those personal folders capture information about qualifications of the staff member, job description, work history, records about trainings. Those files are standard, and are regularly updated whenever necessary.

Weaknesses. Defining the requirements for staff does not use the organization's mission, which is something that is not defined for any of the ambulatories. It also does not take into consideration the volume, the mix of patients, services and technology. Laws and regulations do not take part in defining the requirements for staff.

Opportunities. Since there are already developed job descriptions for some of the positions, it will be feasible to use that experience to develop job descriptions for the rest of the positions. The outdated regulations for organizational units need to be updated. New regulations need to be developed for those organizations, which do not have any regulations. After establishing regulations, those need to be incorporated into the requirements for staff.

Threats. Increased workload might hinder the development of the processes indicated above.

11.3 SQE. Each staff member receives ongoing in-service and other education and training to maintain or to advance his or her skills and knowledge

The ambulatory care organization uses various sources to identify staff educational needs and provide training opportunities. Ambulatory care organization staff are provided ongoing in-service education and training. The education is appropriate to each staff member's ability to meet patient needs and/or continuing education requirements.

Measurable elements	Max. score	Obtained score
1. The ambulatory care organization uses various sources of data and information, including the results of quality and safety measurement activities, to identify staff education needs	**2.5**	**0**
2. Education programs are planned based on these data and information	**2.5**	**0**
3. Ambulatory care organization staff are provided ongoing outsource education and training	**2.5**	**2.5**
4. The education is relevant to each staff member's ability to meet patient needs and/or continuing education requirements	**2.5**	**2.3**
Total score	**10.0**	**4.8**

Strengths. Many of the staff members at the ambulatories, both administrative, and clinical, participate in different trainings. Most of physicians have participated in such trainings. The administration of the PHC facilities tries to engage as many physicians in trainings as possible.

Weaknesses. Though the staff of ambulatories participates in various training programs, no formal assessments using systematic approach are carried out to identify the educational needs of the staff. The training programs described above are mainly organized by external organizations, and the ambulatories link their staff to those trainings. There is no systematic formalized on-service educational program for the staff.

Opportunities. The administration plans to organize on-service examinations to test the education and skills of the staff, and later to use that information to design the continuing educational program for staff. For the educational program to succeed, it should have a comprehensive plan based on the real needs of the staff. The plan should include detailed information on how the educational needs will be assessed, what kind of activities will be carried out to address those needs, how the impact of those activities will be measured, etc.

Threats. Lack of experience, knowledge and skills to develop a comprehensive plan for continuing education of the staff might hinder those processes.

11.4 SQE. The ambulatory care organization provides a staff health and safety program.

Staff health and safety program responsive to urgent and non-urgent staff needs through direct treatment and referral is provided by the ambulatory care organization. The ambulatory care organization identifies areas for potential workplace violence and implements measures to reduce the risk.

Measurable elements	Max. score	Obtained score
1. The ambulatory care organization provides, and incorporates into the ambulatory care organization quality and safety program, a staff health and safety program that is responsive to urgent and non-urgent staff needs through direct treatment and referral	**3.3**	**3.3**
2. The ambulatory care organization identifies epidemiologically significant infections, as well as staff that are at high risk for exposure to and transmission of infections, and implements a staff vaccination and immunization program	**3.3**	**0**
3. The ambulatory care organization provides evaluation, counseling, and follow-up for staff exposed to infectious diseases that are coordinated with the infection prevention and control program	**3.3**	**0**

Total score	**10.0**	**3.3**

Strengths. There is a special program for staff health and safety in the ambulatories. The program is based on several documents, including governmental decrees and internal ambulatory-wide regulations.

Weaknesses. According to the interviews with the administrations of the ambulatories, not all organizations had a special program for staff health and safety. There is lack of defined process at the outpatient facilities for identifying staff for high- risk exposures and organizing vaccinations and immunizations for these persons. No processes are carried out for providing evaluation, counseling and follow up for the exposed staff within the infection prevention and control program.

Opportunities. The infection prevention and control program should define a process for treating the staff working with high-risk exposure patients and train the staff accordingly.

Threats. The above-mentioned processes might require financial resources and increased workload.

11.5 SQE. The organization has an effective process for gathering, verifying, and evaluating the credentials (licensure, education, training, competence, and experience) of the medical, nursing, and other staff.

Essential credentials are gathered and maintained in the personnel folders. All the credentials are verified with the source that issues the credential before the individual begins providing services to or for patients. The credentials should be current and updated.

Measurable elements	Max. score	Obtained score
1. Required credentials (education, licensure, registration) are gathered and maintained in the personnel folders for each medical, nursing, and other staff members	**3.3**	**3.3**
2. All the credentials are verified with the source that issues the credential before the individual begins providing services to or for patients	**3.3**	**0**
3. All credentials are current and updated	**3.3**	**3.3**
Total score	**10.0**	**6.6**

Strengths. All the required documents capturing the education and licensure of staff members are gathered and kept in the personnel folders of the staff members. Those folders are updated whenever there is any new information to add to the credentials.

Weaknesses. Though the credentials are gathered and kept in up-to-date personnel folders, there is no mechanism of verification of those credentials. In other words, there is no process to ensure that the documents provided by the staff members are not false/fake:

Opportunities. A process of verification of staff credentials should be developed, in order to ensure that the staff members providing care to or for patients are in fact qualified to do so.

Threats. Verifying credentials of the staff members requires time and resources. It will also increase the workload of the specialists involved in the process of verification, causing resistance to change the already established practice.

11.6 SQE. A staffing strategy for the ambulatory care organization, developed by the department/service leaders of the ambulatory care organization, identifies the number and types of staff needed to provide adequate and safe patient care.

The written strategy for staffing (revised and updated when necessary) the ambulatory care organization that complies with local laws and regulations is developed by the department/service leaders. The staffing strategy addresses the assignment and reassignment of staff.

Measurable elements	Max. score	Obtained score
1. The ambulatory care organization's department/service leaders develop a written strategy for staffing the ambulatory care organization in a manner that complies with local laws and regulations	**2.5**	**0**
2. The number and types of staff are identified in the strategy using a recognized staffing method	**2.5**	**0**
3. The strategy addresses the assignment and reassignment of staff	**2.5**	**0**
4. The strategy is revised and updated when necessary	**2.5**	**0**
Total score	**10.0**	**0**

Strengths. Not identified.

Weaknesses. The whole process of developing a staffing strategy and reviewing the medical staff members' files is missing. Accordingly, there are no designated individuals to make an official recommendation about staffing decision.

Opportunities. Since there is a human resource management infrastructure in the organization, in collaboration with the leadership of the PHC facility, they could initiate developing a process to develop a staffing strategy and reviewing the files of the medical staff. While establishing this process the individuals who make official decision about staffing should be also defined.

Threats. The development and implementation of the above mentioned process of developing a staffing strategy and reviewing the credential files of the medical staff members will require time and efforts. It will, in turn, increase the workload of the staff involved in the process, causing resistance to change.

12. Management of Information (MOI)

12.1MOI. Confidentiality, security, and accuracy of data are maintained. Records and information are protected against loss, destruction, tampering, and unauthorized access or use.

Maintaining confidentiality and security of data are of high priority for the organization, particularly in case of sensitive data and information. The ambulatory care organization should ensure the accuracy, consistency, and completeness of data and information. In order to fulfill this requirement, the organization should develop effective processes specifying

- who has access to information;
- the maintaining information to which an individual has access;
- the user's obligation to keep information confidential;
- the process for data accuracy, consistency, and completeness;
- the process followed when confidentiality and security are violated.

The ambulatory care organizations should protect patients' data and information. **For example**, active patient records should be kept in areas where only authorized health care providers have access.

Measurable elements	Max. score	Obtained score
1. The ambulatory care organization develops and implements processes to ensure the confidentiality of data and information	**2.0**	**1.0**
2. The ambulatory care organization develops and implements processes to ensure the security of data and information	**2.0**	**1.0**
3. The ambulatory care organization develops and implements processes to ensure the accuracy, consistency, and completeness of data and information	**2.0**	**0**
4. Records and information are protected from loss or destruction	**2.0**	**2.0**
5. Records and information are protected from tampering and unauthorized access or use	**2.0**	**2.0**
Total score	**10.0**	**6.0**

Strengths. The vast majority of healthcare providers understand the importance of respecting confidentiality and security of patient data. They emphasized that they put certain efforts to

prevent information leak in their daily practice. As a means to ensure confidentiality they mention that they do not provide any patient related information to other parties without patients' permission. As a way to keep the patient data secure, the healthcare providers indicated that they keep the medical records in special shelves, or in lockers, and only the respective physicians have access to those records. These efforts serve as ways to protect the records from loss, destruction, tampering and unauthorized access.

> *I keep my patients' medical records in the locker only. I had an experience* [in the past] *when some people from inspection bodies came and took all my journals, where patient data is captured, and I couldn't get those back. I could not work, because all my reports are based on that data. After that incident I bought lockers and installed on the shelves so that I can keep the data secure.*
>
> **Healthcare provider, IDI**

The healthcare providers also mentioned that they are very cautious towards their patients' TB related information.

> *We open separate treatment cards for the TB patients, in order not to circulate their TB related information along with general information. Whenever our* [TB] *patients need general check-ups not related to their disease, we tell them to take their medical records from the general practitioners. They use their TB related medical records only when they undergo TB-related check-ups and consultations.*
>
> **Healthcare provider 1, IDI**
>
> *I do not trust the clinical records to anyone. Even if the patient undergoes other medical check-up, we organize it either through me or through the nurse; we don't let the cards remain with them [the patients, and other healthcare providers].*
>
> **Healthcare provider 2, IDI**

Weaknesses. Though the healthcare providers outline the importance of confidentiality and security of patient data, there are no formal processes to ensure that the confidentiality and security are maintained. All the activities carried out with this regard are based merely on healthcare providers' individual initiatives. The ambulatory organizations providing outpatient TB treatment services do not have any policies and procedures to keep the data and information confidential and secure. Moreover, there are no processes in place to ensure that the data in the patients' medical records are consistent, accurate, and complete.

Opportunities. The outpatient TB facilities should develop a policy addressing data security and confidentiality, along with a special monitoring mechanism to track the implementation of the policy, as well as to monitor the accuracy, consistency and completeness of the data and information.

Threats. Lack of political will from the facility administration might be a potential threat. Lack of capacity to develop organization-wide policies might also hinder the establishment of the formal process.

12.2MOI. The ambulatory care organization uses standardized diagnosis codes, procedure codes, symbols, abbreviations, and definitions.

It is recommended for the ambulatory care organizations to use standardized terminology, definitions, vocabulary, and nomenclature to make the comparison of data and information effective within and among ambulatory care organizations. Standardization also prevents miscommunication and potential errors. Data aggregation and analysis benefit from uniform diagnosis and procedure codes, too. According to JCI the ambulatory care organizations should standardize abbreviations and symbols, including do-not-use list consistent with local and national standards.

Measurable elements	Max. score	Obtained score
1. Standardized diagnosis codes are used and their use is monitored	**2.5**	**1.25**
2. Standardized procedure codes are used and their use is monitored	**2.5**	**1.25**
3. Standardized definitions are used	**2.5**	**1.25**
4. Standardized symbols are used, and those not to be used are identified and monitored	**2.5**	**1.25**
Total score	**10.0**	**5.0**

Strengths. The medical records review showed that TB healthcare providers use standarddiagnosis and procedure codes, as well as symbols, and those are captured in the medical records. Moreover, the national guideline on TB management in Armenia has a special chapter dedicated to the TB patients' data registry and exchange, which outlines the specific codes, definitions, and symbols. Our medical records review showed that the healthcare providers follow the mentioned above guideline in terms of using specific codes and symbols.

Weaknesses. Despite the fact that there are special requirements for using standard codes, symbols, and definitions, there is lack of ambulatory organization-wide monitoring mechanism

to track whether or not those are used appropriately. In this context monitoring is conducted by the National TB Control Center, however it is not considered as an organization-wide effort.

Opportunities. Developing a monitoring mechanism in the outpatient facility level will monitor and supervise the process of data registry and exchange in the facility, including in the TB cabinet.

Threats. Lack of understanding of the importance of data registry and exchange by the higher administration might be a potential obstacle in establishing the proposed mechanism.

12.3 MOI. Written documents, including policies, procedures, and programs, are managed in a consistent and uniform manner.

Organization-wide policies and procedures are very important in terms of providing uniform knowledge on organizational functions. According to JCI the ambulatory care organizations should have special written document on how the policies, procedures and programs are developed and controlled in the organization. It should serve as a guidance document, and have the following components.

a) Review and approval of all documents by an authorized person before issue
b) The process and frequency of review and continued approval of documents
c) The controls for ensuring that only current, relevant versions of documents are available
d) How changes in a document can be identified
e) The maintenance of document identity and legibility
f) A process for managing documents that originated outside the ambulatory care organization
g) Retention of obsolete documents for at least the time required by laws and regulations, while ensuring that they will not be mistakenly used
h) Identification and tracking of all documents in circulation

These processes for developing and maintaining policies, procedures, and programs are implemented.

Measurable elements	Max. score	Obtained score

1. There is a written guidance document that defines the requirements for developing and maintaining policies, procedures, and programs, including at least items a) through h) in the intent	**5.0**	**0**
2. There are standardized formats for all similar documents; **for example**, all policies	**2.5**	**0**
3. The requirements of the guidance document are implemented and evident in the policies, procedures	**2.5**	**0**
Total score	**10.0**	**0**

Strengths. Not identified.

Weaknesses. All the requirements of the standard are completely absent. One of the weakest aspects of all the ambulatory care organizations included in the assessment is lack of internal organization-wide policies and procedures. Even those internal documents (e.g. the organizational charters) and policies that are present in some of the organizations, are very vague and too general, usually simply copy-pasted from the corresponding national laws and regulations.

Opportunities. Developing guidance documents for ambulatory care organizations internal use, specifying how the policies, procedures and programs are developed and controlled in the organization. Considering the lack of appropriate organization-wide policies, the development of the mentioned above document would serve as a potential ground to further develop the policies of the organization.

Threats. Lack of recognition of the importance of organization-wide policies and procedures might serve as a potential challenge. During the in-depth interviews with administration representatives and healthcare providers, whenever there was a discussion on organization-wide policies and procedures, they were referring to the national guidelines and TB treatment standards, transferring the responsibilities from themselves to the higher authorities. Besides, during the in-depth interviews the lack of organization-wide policies was never mentioned by the healthcare providers and administration representatives, which might indicate that the importance of the internal regulations is not well recognized.

12.4MOI. The organization initiates and maintains a clinical record for every patient assessed or treated. The clinical record contains sufficient information to identify the patient, to support the diagnosis, to justify the treatment, to document the course and results of treatment, and to promote continuity of care among health care practitioners.

All the patients, who receive treatment in the ambulatory care organization should have a clinical record, which is unique to the patient. The clinical records should be available for the healthcare providers involved in the treatment process. The clinical records should contain sufficient information to support the diagnosis, justify the treatment, as well as track the process of treatment along with the results.

Measurable elements	Max. score	Obtained score
1. A clinical record is initiated for every patient assessed or treated by the organization	**2.0**	**2.0**
2. The specific content, format, and location of entries for patient clinical records are standardized and determined by the ambulatory care organization	**2.0**	**2.0**
3. Patient clinical records contain adequate information to identify the patient	**2.0**	**2.0**
4. Patient clinical records contain adequate information to support any diagnosis, care, and treatment	**2.0**	**2.0**
5. Patient clinical records contain adequate information to document the course and results of care and treatment	**2.0**	**2.0**
Total score	**10.0**	**10.0**

Strengths. In all the assessed ambulatory care TB centers , a clinical record was initiated for every patient undergoing TB treatment in those facilities. The medical records review showed that the format and specific contents of the entries are standard and based on the Minister's Decree. All the facilities were using the similar formatting of the medical records. The medical record review also showed that those records contain sufficient information to identify the patient. Information on the diagnosis, course of treatment, as well as progress and results are also included in the medical records.

I open separate medical record for each patient, where I write all the details regarding him/her. We also have special TB treatment forms, which are updated very frequently. I write cursus mainly once a month, or when giving a referral form, or in case if the patient has health complaints. There is no need to do it more frequently.

Healthcare provider 1, IDI

The results of assessments of other relevant healthcare providers are also included in the medical records.

The entries in the medical records of the patient are made by me. If s/he [the patient] *needs another assessment by another specialist, s/he takes the records along with the referral form to the other specialist, who makes her/his entries, and then s/he brings the records back to me.*

Healthcare provider, IDI

Weaknesses. Not identified.

Opportunities. N/A

Threats. N/A

12.5 MOI. The ambulatory care organization identifies those authorized to have access to and make entries in patient clinical records.

As a means to maintain security of patient information JCI recommends the ambulatory care organizations to determine who is authorized to obtain a patient clinical record and who can make entries in the patient clinical record. There should be separate policy to authorize such individuals. Besides the policy, there should also be a process to make sure that only authorizes individuals make entries in patient clinical records and that each entry identifies the author and date. The policy should also specify how the patient record are corrected or overwritten.

According to JCI an effective process should define:

- who has access to patient clinical records;
- who is authorized to make entries in patient clinical records;
- the information in the patient clinical record to which an individual has access;
- the user's obligation to keep information confidential; and
- the process followed when confidentiality and security are violated.

Measurable elements	Max. score	Obtained score

1. Those authorized to have access to the patient clinical record are identified in ambulatory care organization policy	**2.0**	**0**
2. There is a process to ensure that only authorized individuals have access to the patient clinical record	**2.0**	**2.0**
3. Those authorized to make entries in the patient clinical record are identified in ambulatory care organization policy	**2.0**	**0**
4. There is a process to ensure that only authorized individuals make entries in the patient clinical record	**1.0**	**1.0**
5. The author and date of each entry can be identified	**2.0**	**2.0**
6. There is a process that addresses how entries in the patient clinical record are corrected or overwritten	**1.0**	**1.0**
Total score	**10.0**	**6.0**

Strengths. The in-depth interviews with TB physicians and nurses showed that only they have access to the medical records, and only physicians make entries in the clinical records of the patients.

Only I make entries in the patient's records. No one else has the right to.

Healthcare provider 1, IDI

Only we [the physician and nurse] *can "touch" the cards. The cards are stored here and no one can take those cards. … We* [the nurses] *do not have the right to make entries in the patients' records. Only the physician is authorized to make entries.*

Healthcare provider 2, IDI

They [the nurses] *don't make entries in the clinical records, only if I am on vacation, my nurse does the writing; we trust each other. Once, when I was on vacation, and she was not available, we selected the most trusted nurse, trained her about confidentiality, and since she was highly qualified, she could do that job.*

Healthcare provider 3, IDI

The medical records review showed that the author and the date of each entry was mentioned, and this practice was the same in all the assessed facilities.

Weaknesses. Although the healthcare providers respect the standard's requirements of access and making entries in the patients' clinical records, there is no formal policy document regulating who has access and who can make entries in the records. This can potentially be a basis for violations.

Opportunities. The ambulatory healthcare facilities should develop internal policies that are comprehensive enough to address all the challenges regarding information communication across the organization, including defining those who have access and right to make entries in the patients' clinical records.

Threats. Lack of recognition of the importance of internal policies might be a potential obstacle for the mentioned above initiative. Besides, since the healthcare providers respect the rule in their practice, the necessity of such policies might be underestimated.

13. TB and Tobacco (TBTC)

13.1TBTC. Availability of "No smoking" signs.

According to the national law of the RA on the limitation of tobacco distribution, consumption and use, smoking is prohibited in the healthcare organizations. Moreover, according to the same law the healthcare organizations should have "No Smoking" signs placed in visible areas.

Measurable elements	Max. score	Obtained score
1. There are "No Smoking" signs visible from outside of the building	**2.0**	**1.4**
2. There are "No Smoking" signs visible on the entrance door	**2.0**	**1.3**
3. There is "No Smoking" sign inside the building	**2.0**	**1.8**
4. There are warning signs of financial (and other) penalties	**2.0**	**0.6**
5. In general, the existing "No Smoking" signs are clearly visible	**2.0**	**1.6**
Total score	**10.0**	**6.7**

Strengths. In the overwhelming majority of outpatient TB facilities, the "No smoking" signs were posted outside of the building, on the entrance door and inside the building. The majority of displayed "No smoking" signs were characterized as clearly visible.

Weaknesses. Only in one outpatient TB facility the research team observed posted warning sign on financial penalty of 1000 dram in case of smoking, however even this single post did not reflect the current Nation Law which levies 5000 dram in case of smoking. There were facilities that missed "No Smoking" signs in places recommended by the international standards.

Opportunities. The leaders of PHC facilities should further enforce the law and post clearly visible "No smoking" inside the building, at the entrance door and outside the building. Furthermore, the up-to-date financial penalties should be displayed in all PHC facilities.

Threats. Not identified

13.2 TBTC. Presence of proofs related to tobacco-free environment, smoking related functional items and policies in the areas where smoking is prohibited.

The WHO FTCC Article 8 discusses second-hand smoking and requires undertaking measures to protect people from second-hand smoke in several places, including healthcare organizations. To go in line with the mentioned requirement, there should be no tobacco smoke, no tobacco leftovers, as well as no smokers in the areas where smoking is prohibited. Besides, ashtrays and

lighter containing tobacco logotypes should be eliminated from the PHC facility, since those items might advertise and provoke smoking. According to the WHO Framework Convention on Tobacco Control (FCTC), functional items related to tobacco smoking (such as ashtrays) should be eliminated in the healthcare organizations.

Measurable elements	Max. score	Obtained score
1. There is no tobacco smoke in no-smoking-areas	**2.5**	**2.4**
2. There are no ashtrays in the no-smoking-areas	**2.5**	**2.3**
3. There are no cigarette vendors or vending machines inside the building	**2.5**	**2.5**
4. There are no ashtrays and lighters with tobacco logotypes in the PHC facility.	**2.5**	**2.5**
Total score	**10.0**	**9.7**

Strengths. In none of the facilities there were cigarette vendors, vending machines, or smoking related items with tobacco logotypes. In the overwhelming majority of observed outpatient TB facilities, ashtrays and tobacco smoke were absent.

Weaknesses. In one of the observed outpatient TB facility, the research team has felt tobacco smoke in an area where the smoking is prohibited and in two outpatient TB cabinets there were ashtrays on the table.

Opportunities. The leaders and healthcare professionals of PHC facilities should further enforce the National Law and prevent smoking in prohibited areas and the use of smoking-related functional items.

Threats. Not identified

13.3TBTC. Presence of policies guiding elimination and/or limitation of smoking

Internal policies and/or procedures describe strategies of elimination of smoke from facilities. Policies and/or procedures apply to patients, families, visitors and staff.

Measurable elements	Max. score	Obtained score
1. Policy and/or procedure guides elimination or limitation of smoking	**6.0**	**0**
2. Smoking limitation policy and/or procedure applies to patients	**1.0**	**0.5**
3. Smoking limitation policy and/or procedure applies to families	**1.0**	**0.5**

4. Smoking limitation policy and/or procedure applies to visitors	**1.0**	**0.5**
5. Smoking limitation policy and/or procedure applies to staff	**1.0**	**0.5**
Total score	**10.0**	**2.0**

Strengths. The National Law that prohibits smoking in healthcare facilities applies to patients, staff, families and visitors.

Weaknesses. The PHC facilities failed to develop local policies that would guide the elimination or limitation of smoking from their healthcare facilities.

Opportunities. The leaders of PHC facilities should initiate development of internal policies and procedures based on the National Law that will describe the actions and guide the processes of elimination/limitation of smoking.

Threats. Not identified

CONCLUSIONS

1. INTERNATIONAL PATIENT SAFETY GOALS (IPSG)					
Standards and Scores met	**Not** (0)	**Minimally** (0.1 - 3.3)	**Partially** (3.4 – 6.6)	**Satisfactory** (6.7 - 9.9)	**Fully** (10)
1.1 Identify patients correctly. The ambulatory care organization develops and implements a process to improve accuracy of patient identifications.					10
1.2 Improve effective communication.					10
1.3 The ambulatory care organization adopts and implements evidence-based hand-hygiene guidelines to reduce the risk of health care–associated infections.			4.0		
Function mean score	**8.0**				

In all assessed outpatient TB facilities, patient identification is carried out properly, by the use of several identifiers and excluding the room numbers or location. Communication between different healthcare providers during ordering and receiving laboratory tests and results is organized in a way to rule out mistakes.

Introduction of formal hand-hygiene program will advance the organizations' efforts in fighting health care–associated infections.

The ambulatory TB care organizations achieved 80% performance for IPSG function by meeting specific standards, eitherfully or partially. The overall function was graded as **satisfactorily performed**. On the level of assessed standards for this function the PHC facilities required some improvements.

2. ACCESS AND CONTINUITY OF CARE (ACC)					
Standards and Scores met	**Not** (0)	**Minimally** (0.1 - 3.3)	**Partially** (3.4 – 6.6)	**Satisfactory** (6.7 - 9.9)	**Fully** (10)
2.1 Patient flow in the ambulatory care organization is designed to provide efficient care and uniform access based on the needs of the patient.				7.2	
2.2 The ambulatory care organization designs and carries out processes to provide continuity of patient care services in the ambulatory care organization and coordination among health care practitioners.					10
2.3 The ambulatory care organization develops and implements a process to refer patients to other health care practitioners, other health care settings, or other organizations to meet their continuing care needs.					10
2.4 The ambulatory care organization develops and implements a process to transfer patients to another organization to meet their continuing care needs.			5.0		
2.5 Information about the care and services that the patient will need when he or she is referred by the ambulatory care organization is communicated to the patient, family, and continuing care practitioner and/or setting.					10
2.6 Patient follow-up instructions are given in a form and language the patient can understand.	0				
2.7 The process for referring or transferring the patient evaluates the need for transportation.	0				
Function mean score	**6.0**				

In visited PHC facilities care of TB patients is organized in a way to ensure the continuity and coordination between various services and healthcare providers. Based on patients' health condition, TB healthcare providers organize patients' transfers to other organizations to meet patients' continuing health needs. During transfers/referrals patients, families and continuing care practitioners are provided with information about needed care.

PHC facilities should reorganize and formalize patient prioritization processes in order to improve patients' access to and uniformity of healthcare services. When referring/transferring patients to other healthcare organizations, TB healthcare providers should provide follow-up instructions in a writing form with instructions for follow-up or urgent care.

The ambulatory TB care organizations achieved 60% performance for ACC function by meeting specific standards fully, satisfactory, partially or not meeting at all. The overall function was graded as **partially performed**. On the level of assessed standards for this function the PHC facilities required several improvements.

3. PATIENT AND FAMILY RIGHTS (PFR)					
Standards and Scores met	**Not** (0)	**Minimally** (0.1 - 3.3)	**Partially** (3.4 – 6.6)	**Satisfactory** (6.7 - 9.9)	**Fully** (10)
3.1 The ambulatory care organization is responsible for providing processes that support patient and family rights during care				9.4	
3.2 The patient's rights to privacy and confidentiality of care and information are respected.			4.8		
3.3 Vulnerable populations are identified and protected from additional risks.			6.5		
3.4 The ambulatory care organization provides care that is respectful of patients' and families' personal values and beliefs and supports their rights to participate in the care process.				7.3	
3.5 The ambulatory care organization identifies patient and family responsibilities in the care process.	0				
3.6 All patients are informed about their rights and responsibilities in a manner and language they can understand.		3.1			
3.7 Patient informed consent is obtained through a process defined by the organization and carried out by trained staff in a language the patient can understand.			3.9		
3.8 The organization establishes a process, within the context of existing law and culture, for when others can grant consent.			3.5		
3.9 Patients and families receive adequate information about the illness, proposed treatment(s), and health care practitioners so that they can make care decisions.				7.0	
Function mean score	**5.1**				

In general, TB healthcare providers correctly identify patients' right to make decisions regarding their care and act in a way to protect patients' privacy and confidentiality. Yet there are TB physicians who are skeptical if such prerogative should be given to patients. Policies and procedures defining and guiding privacy and confidentiality of patient information are absent in all outpatient TB facilities.

The National Standard that applies to all TB healthcare providers outlines socially vulnerable patient groups that need extra efforts in their rights' protection. PHC facilities should adapt the National Standard into internal policies and procedures and educate staff members to recognize the needs of vulnerable patients.

Care that is provided in outpatient TB facilities is respectful of patients and families values and beliefs. However, trainings are missing to formalize TB healthcare providers' capacities in identifying those values and beliefs apart from their own perceptions.

TB patients and families receive complete information about proposed treatment and procedures. However, PHC facilities have failed to identify patients' responsibilities during provision of care. TB healthcare providers apply their own initiative and their understanding while informing patients about their rights and responsibilities. Only DR TB patients are being informed about their rights and responsibilities by virtue of the contract that they sign before treatment start.

The structured informed consent process is only implemented among DR TB patients in scope of their treatment contracts. The small portion of TB healthcare providers reported practicing informed consent with people other than patients.

No formal processes are established for informing other TB patients about their rights and responsibilities and for implementing the informed consent process. The biggest share of information is provided to patients during the inpatient treatment phase, therefore outpatient TB facilities should take the initiative to introduce an informed consent process for outpatient treatment phase as well.

The ambulatory TB care organizations achieved 51% performance for PFR function by meeting specific standards satisfactory, partially, minimally, or not meeting at all. The overall function was graded as **partially performed**. On the level of assessed standards for this function the PHC facilities required several improvements.

4. ASSESSMENT OF PATIENTS (AOP)					
Standards and Scores met	**Not** (0)	**Minimally** (0.1 - 3.3)	**Partially** (3.4 – 6.6)	**Satisfactory** (6.7 - 9.9)	**Fully** (10)
4.1 An initial assessment process is used to identify the health care needs of all patients and the scope and content of that assessments is defined in writing and based on applicable laws and regulations.				8.9	
4.2 Assessment findings are integrated and documented in the patient's record and readily available to those responsible for the patient's care. There is an established reassessment process for patients requiring additional services or ongoing care.				8.2	
4.3 The time frame for initial assessments and, as appropriate, reassessment is consistent with each patient's needs, organizational policy, and accepted professional guidelines.					10
4.4 Laboratory services are available to meet patient needs, and all such services meet applicable local and national standards, laws, and regulations.				8.6	
4.5 Laboratory services provided within the ambulatory care organization are directed and staffed by qualified individuals; are organized with adequate supplies; and provide proper specimen management.				9.3	
4.6 Laboratory quality, safety, and infection control programs are in place, followed, and documented and comply with the facility management and infection control programs.				8.5	
4.7 Laboratory access.			3.4		
4.8 Laboratory personal protective equipment.				9.6	
4.9 Laboratory procedures.				7.2	
4.10 Laboratory work areas and design.				8.0	
4.11 Radiology and diagnostic imaging services are available to meet patient needs, and all such services meet applicable local and national standards, laws, and regulations.				9.0	
4.12 Radiology and diagnostic imaging services provided within the ambulatory care organization are directed and staffed					10

by qualified individuals and organized with adequate supplies.					
4.13 Radiology and diagnostic imaging quality and safety programs are in place, followed, and documented and comply with the facility management and infection control programs.			3.8		
Function mean score	**8.0**				

All practicing physicians have qualification to perform the appropriate procedures to diagnose TB, including the licensure and certifications. All patients admitted to the TB cabinets undergo a defined set of examinations. The patients' records are accessible to all of the health care providers working with the TB patients. All practicing physicians have qualification to perform the appropriate reassessments during the TB treatment, including the licensure and certifications. Planned reassessments are conducted continuously in PHC facilities. On the other hand, there is absence of defined writings related to the scope and content of reassessments administered by each clinical discipline. Timelines for TB ambulatory care assessments and reassessments are established within National Guidelines and the WHO. Assessments and reassessments are established for all clinical disciplines and services, within a time frame consistent with their needs.

High quality of laboratory services are provided to the TB patients. There are established timeframes to guide the reporting of test results in the laboratory. All laboratory and radiology services staff have proper qualification and experience. The biosafety rules, including the radiation safety risks, of laboratories and the radiology and diagnostic imaging department are compliant with the national and international standards.

However, the location and conditions of the laboratory department do not always comply with the local and national standards of proper laboratory state. The laboratories have no directional airflow, as no equipment available to maintain proper environmental controls, including local and general ventilation systems. Laboratory technicians have little knowledge of the organization's safety management program and how it relates to the laboratory safety program. The Radiology and diagnostic imaging department activities implemented to address the safety risks are not integrated in the overall safety program of the PHC facilities. The department does not have a formal quality control program regulated by documents or policies; a radiation safety program protocol is not identified in any of the facilities.

The ambulatory TB care organizations achieved 80% performance for AOP function by meeting specific standards fully, satisfactory, and partially. The overall function was graded as **satisfactorily performed**. On the level of assessed standards for this function the PHC facilities required some improvements.

5. CARE OF PATIENTS (COP)					
Standards and Scores met	**Not** (0)	**Minimally** (0.1 - 3.3)	**Partially** (3.4 – 6.6)	**Satisfactory** (6.7 - 9.9)	**Fully** (10)
5.1 Uniform care is provided to all patients and follows applicable laws and regulations.					10
5.2 The care and procedures provided to each patient is planned and written in the patients' record.					10
5.3 Policies and procedures guide the care of high-risk patients and the provision of high-risk services				9.5	
Function mean score	**9.8**				

Care provided in all outpatient TB facilities is uniform for all TB patients. All patients receive a similar level of care corresponding to their needs, including the diagnostic procedures and the treatment. The uniformity is ensured by the National Guideline and the National Standard that TB healthcare providers are following to while planning care for patients. The National Guideline defines care of various groups of high-risk patients, thus ensuring that needs of patients that require alertness are met.

The ambulatory TB care organizations achieved 98% performance for COP function by meeting specific standards fully and satisfactory. The overall function was graded as **satisfactorily performed**. On the level of assessed standards for this function the PHC facilities required little improvements.

6. MEDICATION MANAGEMENT AND USE (MMU)					
Standards and Scores met	**Not** (0)	**Minimally** (0.1 - 3.3)	**Partially** (3.4 – 6.6)	**Satisfactory** (6.7 - 9.9)	**Fully** (10)
6.1 The ambulatory care organization develops and implements a program for the management and use of medications.			5.5		
6.2 Medication administration within the ambulatory care organization follows standardized processes to ensure patient safety.					10
6.3 Medications are monitored for patient adherence, effectiveness, and adverse medication effects.			6.5		
6.4 The ambulatory care organization establishes and implements a program for reporting and acting on medication errors and near misses.	0				
Function mean score	**5.5**				

Outpatient TB facilities manage TB medications in accordance with the National Guideline, that describes the procurement, storage, prescription and dispensing, medication use and monitoring, management of expired medications and other processes for all TB facilities. Outpatient TB facilities perform well for providing patients with uniform dispensing and distribution of TB medications by qualified individuals.

However, on the facility level, the medication management and use processes are not shaped with a formal management program and some processes indicated by the standards are missing. Moreover, in outpatient TB facilities the processes for tracking patients' adverse medication effects are formally established only for DR patients.

The ambulatory TB care organizations achieved 55% performance for MMU function by meeting specific standards fully, partially, or not meeting at all. The overall function was graded as **partially performed**. On the level of assessed standards for this function the PHC facilities required several improvements.

7. PATIENT AND FAMILY EDUCATION (PFE)					
Standards and Scores met	**Not** (0)	**Minimally** (0.1 - 3.3)	**Partially** (3.4 – 6.6)	**Satisfactory** (6.7 - 9.9)	**Fully** (10)
7.1 The ambulatory care organization provides education that supports patient and family participation in care decision and care processes			4.0		
7.2 Each patient's educational needs are assessed and recorded in his or her record		1.1			
7.3 The patient's and family's ability to learn and willingness to learn are assessed		0.2			
7.4 Patient and family education includes the following topics, related to the patient's care: the safe use of medications, potential interactions between medications. Patients and families receive adequate information about the illness, proposed treatment(s), and health care practitioners so that they can make care decisions.					10
7.5 Education methods include the patient's and family's values and preference and allow sufficient interaction among the patient, family, and staff for learning to occur.			5.3		
7.6 Health professionals caring for the patient collaborate to provide education					10
Function mean score	**5.1**				

TB healthcare providers and other external organizations initiate patient education when they start the treatment. During educational counseling sessions, TB healthcare providers discuss various topics including patients' condition, proposed treatment, consequences if not treating TB, and other details related to transmission and development of disease.

However, information provided to patients is not framed by a structured program. All outpatient TB facilities reported not having educational programs developed in their TB cabinets. In fact, information TB healthcare providers share with patients reflect neither patients' educational needs, nor their willingness and ability to learn. Finally, TB physicians do not verify how

patients understood the provided information, rather they wait to see the impact on treatment adherence and questions patients ask.

The ambulatory TB care organizations achieved 51% performance for PFE function by meeting specific standards fully, partially, minimally, or not meeting at all. The overall function was graded as **partially performed**. On the level of assessed standards for this function the PHC facilities required several improvements.

8. QUALITY IMPROVEMENT AND PATIENT SAFETY (QPS)					
Standards and Scores met	**Not** (0)	**Minimally** (0.1 - 3.3)	**Partially** (3.4 – 6.6)	**Satisfactory** (6.7 - 9.9)	**Fully** (10)
8.1 The ambulatory care organization's program for quality and patient safety includes both patient and staff safety and includes the organization's risk management and quality control activities.		0.5			
8.2 The quality and patient safety program includes the aggregation and analysis of data to support patient care, organization management, and the quality management program and participation in external databases.			4.0		
8.3 Individuals with appropriate experience, knowledge, and skills systematically aggregate and analyze data in the organization.			4.4		
8.4 The ambulatory care organization uses a defined process for identifying and managing sentinel events.	0				
8.5 Data are always analyzed when undesirable trends and variation are evident from the data.		0.2			
8.6 The ambulatory care organization uses a defined process for the identification and analysis of near-miss events.	0				
Function mean score	**1.5**				

The ambulatory TB centers develop different reports for the monitoring bodies when required by laws or regulations. Those are usually developed by the administration of the facility or the TB doctor depending on who these reports need to be provided to.

However, there is no quality improvement and patient safety program in the assessed facilities with very narrow understandings of what is quality and patient safety. The inherited culture of the organization does not support open discussions of problems. There is a blaming approach towards any possible errors.

The ambulatory TB care organizations achieved 15% performance for QPS function by meeting specific standards minimally and partially, or not meeting at all. The overall function was graded as **minimally performed**. On the level of assessed standards for this function the PHC facilities required major improvements.

9. PREVENTION AND CONTROL OF INFECTION (PCI)					
Standards and Scores met	**Not** (0)	**Minimally** (0.1 - 3.3)	**Partially** (3.4 – 6.6)	**Satisfactory** (6.7 - 9.9)	**Fully** (10)
9.1 PCI. The ambulatory care organization designs and implements a comprehensive program to reduce the risks of healthcare–associated infections in patients and staff. There is a designated coordination mechanism for all infection prevention and control activities that involves physicians, nurses, and others based on the size and complexity of the organization.					10
9.2 The infection prevention and control program is based on current scientific knowledge, accepted practice guidelines, applicable laws and regulations, and standards for sanitation and cleanliness.					10
9.3 The organization identifies the procedures and processes associated with the risk of infection and implements strategies to reduce infection risk.		3.4			
Function mean score	**7.8**				

All the facilities included in the assessment had infection prevention and control program based on the requirements of the Minister's order of N 1853-A of July 03.2013 of the Ministry of Health of the RA. In most of the cases the program was multidisciplinary consisting of the epidemiologist, infectionist, TB physician/nurse, and administration representative. The staff of the TB outpatient centers was well aware of the infection prevention measures, and trained about their roles and responsibilities in the program. The ambulatory TB facilities were equipped with

necessary resources, including personal protection equipment, needed disinfectants to carry out infection prevention activities.

However, despite the presence of infection control program, the ambulatory TB facilities did not formally identify those processes, which are associated with infection risk, as well as those processes, which require policies, procedures, staff education, practice changes, evidence-based activities, and other strategies to support risk reduction.

The ambulatory TB care organizations achieved 78% performance for PCI function by meeting specific standards fully or minimally. The overall function was graded as **satisfactorily performed**. On the level of assessed standards for this function the PHC facilities required some improvements.

10. GOVERNANCE, LEADERSHIP, AND DIRECTION (GLD)					
Standards and Scores met	**Not** (0)	**Minimally** (0.1 - 3.3)	**Partially** (3.4 – 6.6)	**Satisfactory** (6.7 - 9.9)	**Fully** (10)
10.1 Governance responsibilities and accountabilities are described in bylaws, policies and procedures, or similar documents that guide how they are to be carried out.	0				
10.2 A chief executive/managing director(s) is responsible for operating the ambulatory care organization and complying with applicable laws and regulations.				8.0	
10.3 Ambulatory care organization leadership is identified and collectively responsible for defining the organization's mission and creating the programs and policies needed to fulfill the mission.			5.0		
10.4 Organization leaders ensure that there are uniform programs for the recruitment, retention, development, and continuing education of all staff.	0				
10.5 Ambulatory care organization leadership plans and oversees a quality improvement and patient safety program and sets measurement priorities and priorities for improvement.		2.6			
10.6 Ambulatory care organization leadership makes decisions related to the purchase or use of resources—human and technical—with an understanding of the quality and safety implications of those decisions.	0				

10.7 Ambulatory care organization leadership seeks and uses data and information on the safety of the supply chain for drugs, medical technology, and supplies to protect patients and staff from contaminated, fake, and diverted products.		1.3			
10.8 Ambulatory care organization leadership creates and supports a culture of safety program throughout the organization.	0				
Function mean score	**2.1**				

The persons in charge for management activities in the ambulatory facility (in most of the facilities the director) have the required education and qualifications to carry out the assigned position, oversee the compliance of policies, applicable laws and regulations, strategic plans and the budget, making recommendations to the according governing bodies.

However, ambulatory organizations, in majority, failed to meet the required standards. There are no written documents describing organization's governance structure, responsibilities and accountabilities. The administration does not hold roles or responsibilities for defining organization's mission, creating policies and procedures to implement the mission, overseeing or developing quality improvement and patient safety plans. There is no planned comprehensive staff recruitment process either in the NTCC or the ambulatories themselves. Directors of the PHC facilities do not obtain data and information on the quality and safety implications of medical technology or staffing choices. Accountability, transparency and culture of safety are not clear concepts for the administrations of the ambulatory organizations.

The ambulatory TB care organizations achieved 21% performance for GLD function by meeting specific standards satisfactorily, partially, minimally, or not meeting at all. The overall function was graded as **minimally performed**. On the level of assessed standards for this function the PHC facilities required major improvements.

11. STAFF QUALIFICATIONS AND EDUCATION (SQE)					
Standards and Scores met	**Not** (0)	**Minimally** (0.1 - 3.3)	**Partially** (3.4 – 6.6)	**Satisfactory** (6.7 - 9.9)	**Fully** (10)
11.1 The ambulatory care organization uses a defined process to ensure that clinical and nonclinical staff knowledge and skills are consistent with the requirements of the position.		2.3			
11.2 Department and service leaders of the ambulatory care organization define the desired education, skills, knowledge, and other requirements of all staff members		2.5			
11.3 Each staff member receives ongoing in-service and other education and training to maintain or to advance his or her skills and knowledge			4.8		
11.4 The ambulatory care organization provides a staff health and safety program.		3.3			
11.5 The organization has an effective process for gathering, verifying, and evaluating the credentials (licensure, education, training, competence, and experience) of the medical, nursing, and other staff.			6.6		
11.6 A staffing strategy for the ambulatory care organization, developed by the department/service leaders of the ambulatory care organization, identifies the number and types of staff needed to provide adequate and safe patient care.	0				
Function mean score	**3.3**				

Though all the required documents capturing the education, licensure, and training of staff members are gathered and kept in the personnel folders of the staff members, there is no process to ensure that the documents provided by the staff members are not false/fake. The whole process of developing a staffing strategy and reviewing the medical staff members' files is missing.

There is no process of matching clinical staff knowledge with patient needs. No evaluations are conducted for the clinical staff members. The outpatient TB centers do not evaluate newly hired staff members at the beginning of their work. Laws and regulations do not take part in defining the requirements for staff. No formal assessments using systematic approach are carried out to identify the educational needs of the staff. There is no defined process at the outpatient facilities

for identifying staff for high- risk exposures and organizing vaccinations and immunizations for these persons.

The ambulatory TB care organizations achieved 33% performance for SQE function by meeting specific standards partially and minimally, or not meeting at all. The overall function was graded as **minimally performed**. On the level of assessed standards for this function the PHC facilities required major improvements.

12. MANAGEMENT OF INFORMATION (MOI)					
Standards and Scores met	**Not** (0)	**Minimally** (0.1 - 3.3)	**Partially** (3.4 – 6.6)	**Satisfactory** (6.7 - 9.9)	**Fully** (10)
12.1 Confidentiality, security, and accuracy of data are maintained. Records and information are protected against loss, destruction, tampering, and unauthorized access or use.			6.0		
12.2 The ambulatory care organization uses standardized diagnosis codes, procedure codes, symbols, abbreviations, and definitions.			5.0		
12.3 Written documents, including policies, procedures, and programs, are managed in a consistent and uniform manner.	0				
12.4 The organization initiates and maintains a clinical record for every patient assessed or treated. The clinical record contains sufficient information to identify the patient, to support the diagnosis, to justify the treatment, to document the course and results of treatment, and to promote continuity of care among health care practitioners.					10.0
12.5 The ambulatory care organization identifies those authorized to have access to and make entries in patient clinical records.			6.0		
Function mean score	**5.4**				

In all the ambulatory care TB facilities included in the assessment for every patient a clinical record was initiated, containing sufficient information to identify the patient, as well as to justify the diagnosis, track course of treatment, progress and results. Only the corresponding healthcare providers have access to the medical records, and only physicians make entries in the clinical records of the patients.

The majority of healthcare providers understand the importance of respecting confidentiality and security of patient data. They put certain efforts to prevent information leak in their daily practice: they do not provide any patient related information to other parties without patients' permission. However, there are no formal processes to ensure that the confidentiality and security are maintained. All the activities carried out with this regard are based merely on healthcare providers' individual initiatives. The ambulatory organizations providing outpatient TB treatment services do not have any policies and procedures to keep the data and information confidential and secure.

One of the weakest aspects of all the ambulatory care organizations included in the assessment is lack of internal organization-wide policies and procedures. And even those internal documents (e.g. the organizational charters) and policies that are present in some of the organizations, are very vague and too general, usually simply copy-pasted from the corresponding national laws and regulations.

The ambulatory TB care organizations achieved 54% performance for MOI function by meeting majority of specific standards partially, one fully and another not met at all. The overall function was graded as **partially performed**. On the level of assessed standards for this function the PHC facilities required several improvements.

13. TB-TOBACCO CONTROL (TBTC)					
Standards and Scores met	**Not** (0)	**Minimally** (0.1 - 3.3)	**Partially** (3.4 – 6.6)	**Satisfactory** (6.7 - 9.9)	**Fully** (10)
13.1 Availability of "No Smoking" signs				6.7	
13.2 Presence of proofs related to tobacco-free environment, smoking related functional items and policies in the areas where smoking is prohibited.				9.7	
13.3 Presence of policies guiding elimination and/or limitation of smoking		2.0			
Function mean score	**6.1**				

The "No Smoking" signs were posted in the majority of outpatient TB cabinets, in the recommended locations. The majority of visited TB facilities were smoke-free, since no tobacco smoke, ashtrays or items with tobacco logotypes were observed.

However, in few TB facilities, the enforcement of the National Law was insufficient as tobacco smoke, ashtrays were noticed, and the facilities missed up-to-date financial penalties and "No Smoking" signs in proper places

The ambulatory TB care organizations achieved 61% performance for TBTC function by meeting specific standards satisfactory and minimally. The overall function was graded as **partially performed**. On the level of assessed standards for this function the PHC facilities required several improvements.

RECOMMENDATIONS

The main recommendations that derived from the quality assessment of TB diagnostic and treatment services delivery at the PHC level target interventions on two levels of the organization's operation:

- recommendations for structure-related improvements that include actions to improve the structures, conditions and environment of patient care delivery and establishment of modern infrastructures

and

- recommendations for process-related improvements that include actions towards improving the patient care processes.

Based on the quality assessment findings the CHSR/AUA research team recommends:

- Establish hand-hygiene programs in PHC facilities along with outpatient TB centers. As part of this program develop hand-hygiene guidelines and adapt them as a measure against PHC facility acquired infections. Educate staff on correct hand-washing and hand-disinfection practices.
- In policies and procedures, define decision criteria for patient prioritization both in low-patient load and high-patient load outpatient TB facilities to ensure that urgent needs of acute patients are always met.
- Identify healthcare providers that bear the responsibility for those patients who are being transferred. Determine situations when transfers are impossible.
- In a writing form provide patients with TB treatment follow-up instructions on how to obtain urgent care and information on return for follow-up care, guided by existing protocols.
- Consider the transportation needs of patients who are being transferred or referred to improve the patient-centeredness of services.
- Adapt policies and procedures from the national law that will guide the minimum content of assessment and define the assessment information that is to be collected and documented. Establish a uniform psychological assessment for all patients.
- Reconstruct and renovate laboratories that failed to meet applicable local and national standards, laws and regulations. Establish laboratory equipment management, quality control and laboratory safety programs in the ambulatories. Develop policies and procedures that

will outline the requirements and responsibilities for laboratory staff and quality control procedures with respect to environmental control, equipment inspection, maintenance, calibration or validation of test results.

- Establish radiology and diagnostic equipment management, quality control and radiation safety programs in PHC facilities; organize continuous staff orientation programs related to safety practices.
- Develop medication management and use programs specific to outpatient TB facilities in PHC level to cover all aspects of medication management and use, not limited to procurement, storage, and recall. Define and place the responsibilities of healthcare providers in implementing monitoring and evaluation of the program.
- Uniformly implement monitoring, recording and reporting of medication side effects in all outpatient TB facilities, both among DR and DS patients.
- Develop definitions and implement practice of medication errors and near misses reporting in all outpatient TB centers of PHC facilities. Assign the leadership of PHC facilities to identify persons responsible for taking actions on the reports and use that information for improvements in medication use processes.
- Develop and implement formal patient education programs in all outpatient TB centers of PHC facilities reflecting specific needs of TB patients.
- Conduct formal assessment for patients' and families' actual educational needs, their values and beliefs to implement targeted and effective patient and family education programs. The assessment findings should be documented in a consistent manner and healthcare providers should verify that participants have understood the information provided in the scope of the education program.
- Develop policies describing the medication adverse effects that should be documented, tracked, reported, monitored and analyzed. The respective policies should be enforced in all outpatient TB centers of PHC facilities.
- Establish a formal comprehensive quality improvement program, which will incorporate specific measures, standards, and goals to be achieved. The program should have its own staff with clearly defined roles and responsibilities.
- Along with establishment of the quality improvement program, organize special trainings for the whole staff of PHC facilities to expand their understandings on quality and patient safety,

as well as to share the same vision and dedication to quality improvement. In this context the ambulatory-wide organizational culture should undergo several changes to go in-line with the notion of healthcare quality and patient safety.

- Ensure that the proposed quality improvement program closely collaborates with the monitoring and evaluation unit of the NTCC. The latter should be involved in conducting outpatient-level evaluations along with their other functions. This should include comparing outpatient-level data with similar data from other organizations, as well as with acceptable practices.
- Develop clear operational definitions of "sentinel events" and "near misses" relevant to their practice areas. Root cause analysis and other techniques of analyzing such events should be incorporated into the daily practice.
- Identify processes associated with infection risk in TB ambulatory care facilities to support risk reduction, the PHC facilities should also identify processes requiring policies, procedures, staff education, practice changes, evidence-based activities, and other strategies.
- Define clearly and share with the public the mission of outpatient TB centers and PHC facilities.
- Come up with a comprehensive program for staff recruitment, retention, and development. The senior management should be involved in the development of the proposed program. The program should incorporate criteria related to the needed education, skills, knowledge and experience of the professional staff. The program should involve staff evaluation, appointment, as well as the matching of clinical staff knowledge with patient needs. The program should involve processes for verifying the credentials of the staff, as well as periodically reviewing and giving official recommendations about renewal decision of the clinical staff to continue providing patient care services.
- Establish policies and procedures related to data collection, management and analysis for further quality improvement and effective resource management purposes
- Organize procedures leading to a centralized medical supply management process throughout all ambulatories.
- Identify clear accountability and transparency practices for the organizations and train the staff on the matter.

- Establish formal processes to evaluate the educational needs of the staff. Based on that evaluation, develop a formal on-service educational program.
- Introduce a formal orientation program for the staff consistent throughout the organization.
- Develop processes for staff credentials verification.
- Develop clear policies for staff health and safety and specific ones for the treatment of the high-risk exposure staff. Make it mandatory for all outpatient TB facilities.
- Develop policies and procedures on staffing strategies of the ambulatory organizations.
- Develop a policy addressing data security and confidentiality, along with a special monitoring mechanism to track the implementation of the policy, as well as to monitor the accuracy, consistency and completeness of the data and information. The ambulatory healthcare facilities should develop internal policies, defining those who have access and right to make entries in the patients' clinical records.
- Develop and implement a monitoring mechanism to supervise the process of data registry and exchange within the PHC facility, including the outpatient TB center.
- Develop guidance documents for the PHC facilities internal use. These documents should specify how the policies, procedures and programs are developed and controlled in the organization.
- Post clearly visible "No Smoking" signs outside of PHC facilities, at the entrance area and inside of the building. Warnings of financial (and other) penalties should also be displayed in PHC facilities. According to the National Law, smoking and the use of functional items related to smoking should be strictly prohibited in PHC facilities, to promote the healthy image of healthcare facilities.
- Develop internal policies to describe actions towards elimination/ limitation of tobacco use in PHC facilities and establishment of smoke-free environments.

STRATEGIC PLAN

To comprehensively address the identified gaps in TB services at PHC level in Armenia and develop an outpatient services improvement strategy aligned with best international practices, the research team conducted a literature review on the existing approaches applyed in health services globaly.[34–50] The relevance and the appropriateness of this knowledge was assessed in the

context of countries social, cultural, and economic profile and was considered while developing a Continuous Quality Improvement system for TB care at PHC level.

Core Quality Indicators for Establishing a Continuous Quality Improvement System in Outpatient TB Centers at the PHC Level in Armenia

	Indicator	**Corresponding JCI function** (Performance %)	**Responsible parties**	**Measurement**
1	Continuous Quality Improvement (QI) program	QPS (15%), GLD (21%), MMU (55%)	Organization leadership, healthcare providers, quality specialist	• Continuous QI plan developed, along with quality improvement priorities • QI principles are implemented in practice (safety culture, open discussions of adverse events and near misses), data aggregation and analysis conducted • The leadership takes appropriate actions based on those results.
2	Continuous Professional Development (PD) program	SQE (33%)	Organization leadership, HR department, healthcare providers	• Staff continuous PD plan developed, focusing on on-service education of staff • Annual performance assessment of staff conducted and results captured in the personnel folders
3	Patient and Family Rights (PFR) program	PFR (51%)	Organization leadership, healthcare providers	• A document summarizing patient and family rights developed • Rights and responsibilities posted in a visible place within the facility • Informed written consent obtained for treatment, which is documented in the patients' medical records
4	Patient Education (PE) program	PFE (51%)	Organization leadership, healthcare providers	• PE plan developed, which includes assessment of patients' educational needs and topics covered by the plan • The results documented in the patients' medical records
5	Data Management (DM) program	MOI (54%)	Organization leadership, healthcare providers, epidemiologist/data specialist/statistician	• DM program developed • Data aggregation and analysis conducted • Patients data protected from loss, destruction, and unauthorized use

6	Hand Hygiene (HH) program	PCI (78%), IPSG (80%)	Organization leadership, epidemiologist, healthcare providers	• HH program developed, including corresponding guidelines • Main hand hygiene rules posted in visible places and material resources (sanitizers, paper towels, …) available throughout the organization
7	Laboratory and Radiation Safety (LRS) program	AOP (80%)	Organization leadership, representatives of laboratory and radiology department	• A document on LRS developed • Annual performance evaluation of radiology and laboratory services conducted • All activities documented

REFERENCES

1. WHO. *Global Tuberculosis Report 2018*.; 2018. http://apps.who.int/bookorders.
2. WHO. TB comorbidities and risk factors. https://www.who.int/tb/areas-of-work/treatment/risk-factors/en/. Published 2018. Accessed November 27, 2018.
3. WHO. Drug-resistant tuberculosis. WHO. https://www.who.int/tb/areas-of-work/drug-resistant-tb/en/. Published 2018. Accessed November 28, 2018.
4. WHO. *Global Tuberculosis Report*.; 2019. http://apps.who.int/bookorders. Accessed December 16, 2019.
5. WHO. endTB in Armenia. http://www.endtb.org/armenia.
6. CDC. Drug-Resistant TB | TB |CDC. https://www.cdc.gov/tb/topic/drtb/default.htm. Accessed November 28, 2018.
7. Ministry of Health RA. Տուբերկուլոզի վարման կլինիկական ուղեցույց. 2019.
8. Truzyan N, Lusine Musheghyan M, Zaruhi Grigoryan M, Varduhi Petrosyan M, Hayrapetyan A. *In-Patient Tuberculosis (TB) Treatment in Armenia: Establishment of a Continuous Quality Improvement System: A Needs Assessment Prepared for the Armenian Medical Fund*.; 2016. http://chsr.aua.am/files/2016/02/NTCC-Inpatient-Services-Assessment-Report_Dec-2016-reporting.pdf.
9. Ahamed N, Yurasova Y, Zaleskis R, Reichman LB, Mangura BT. *Brief Guide on Tuberculosis Control for Primary Health Care Providers for Countries in the WHO European Region with a High and Intermediate Burden of Tuberculosis*. http://www.euro.who.int/__data/assets/pdf_file/0015/123162/E82858.pdf.
10. Elmira Berikova C, Golubchikov P, Federation Alexander Golubkov R, et al. *Stemming the Tide of Drug-Resistant Tuberculosis: Handbook on Best Practices for Clinical and Program Management of Drug-Resistant Tuberculosis: Lessons Learned from Global Fund to Fight AIDS, Tuberculosis, and Malaria*. https://www.giz.de/expertise/html/7192.html.
11. Szigeti S. *Improving Payment Mechanisms to Support a New Delivery Model of TB Care in Romania*.; 2017. http://who.int/tb/country/data/download/en/,. Accessed November 19, 2018.
12. RCGP learning. Summary of Tuberculosis in General Practice. http://elearning.rcgp.org.uk/course/info.php?id=107. Accessed November 19, 2018.

13. Curatio International Foundation. *Integrating Tuberculosis Services in Primary Health Care: Evidence Summary*.; 2017. https://goo.gl/K9V4NS.
14. WHO. *Joint ECDC/WHO Regional Office for Europe Tuberculosis Country Visit*. https://www.regjeringen.no/globalassets/upload/hod/dokumenter20fha/fos/tb_final_report_ecdc_who_country_visit_norway.pdf?id=2215750.
15. Amaratunga K, Alvarez G. Primary care pearls to help eliminate tuberculosis in Canada. 2016;3(3). http://www.tstin3d.com/.
16. NICE. Tuberculosis | Guidance and guidelines. https://www.nice.org.uk/guidance/ng33. Accessed November 19, 2018.
17. Pealing L, Moore D, Zenner D. The resurgence of tuberculosis and the implications for primary care. *Br J Gen Pract*. 2013;63(612):344-345. doi:10.3399/bjgp13X669077
18. WHO. *Health System Response to TB: Learning from the Armenian Experience*. World Health Organization; 2018. http://www.euro.who.int/en/health-topics/communicable-diseases/tuberculosis/news/news/2018/2/health-system-response-to-tb-learning-from-the-armenian-experience.
19. Ministry of Health RA. Տուբերկուլյոզի Դեմ Պայքարի Կաբինետների Վարակի Հսկողության Միջոցառումների Օրինակելի Ծրագիր.; 2013.
20. Hopewell PC, Pai M, Maher D, Uplekar M, Raviglione MC. International standards for tuberculosis care. *Lancet Infect Dis*. 2006;6(11):710-725. doi:10.1016/S1473-3099(06)70628-4
21. Gebrekidan G, Tesfaye G, Hambisa MT, Deyessa N. Quality of tuberculosis care in private health facilities of Addis Ababa, Ethiopia. *Tuberc Res Treat*. 2014;2014:1-9. doi:10.1155/2014/720432
22. WHO. *Quality of Care*.; 2006.
23. USAID. *Halth Care Improvement Project*.; 2013.
24. Joint Comission International. *Joint Commission International Accreditation Standards for Ambulatory Care*.; 2002.
25. Raviglione M. *Global Strategy and Targets for Tuberculosis Prevention, Care and Control after 2015: Information Session for Permanent Missions, WHO Headquarters*.; 2013.
26. Truzyan N, Musheghyan L, Grigoryan Z, Crape B. *Comprehensive Mixed-Methods*

Assessment of Quality of Inpatient Tuberculosis Healthcare in High-Burden Resource-Limited Settings: Case Study from Armenia.; 2019. doi:10.2196/preprints.13903

27. Patton MQ. Qualitative evaluation and research methods, 2nd ed. https://psycnet.apa.org/record/1990-97369-000.
28. WHO. *Framework for Conducting Reviews of Tuberculosis Programmes*.; 2014. www.who.int/about/licensing/.
29. WHO. *Tuberculosis Laboratory Biosafety Manual*.; 2012. www.who.int.
30. Bradley EH, Curry LA, Devers KJ. Qualitative data analysis for health services research: Developing taxonomy, themes, and theory. *Health Serv Res*. 2007;42(4):1758-1772. doi:10.1111/j.1475-6773.2006.00684.x
31. Meyer J. Qualitative research in health care. Using qualitative methods in health related action research. *Pub-Med*. https://www.ncbi.nlm.nih.gov/pubmed/10634744.
32. Curry LA, Nembhard IM, Bradley EH. Qualitative and mixed methods provide unique contributions to outcomes research. https://www.ncbi.nlm.nih.gov/pubmed/19289649.
33. Van Wijngaarden JDH, Scholten GRM, Van Wijk KP. Strategic analysis for health care organizations: the suitability of the SWOT-analysis. https://www.ncbi.nlm.nih.gov/pubmed/20603842. Accessed December 16, 2019.
34. WHO. *A Patient Centered Approach to TB Care*. https://apps.who.int/iris/bitstream/handle/10665/272467/WHO-CDS-TB-2018.13-eng.pdf?ua=1. Accessed October 4, 2019.
35. WHO. *Good-Practices Strengthening-HS Prevention Care TBC and Drug-Resistant TBC*.
36. Zinatsa F, Engelbrecht M, van Rensburg AJ, Kigozi G. Voices from the frontline: barriers and strategies to improve tuberculosis infection control in primary health care facilities in South Africa. *BMC Health Serv Res*. 2018;18(1):269. doi:10.1186/s12913-018-3083-0
37. Laurie Garrett. The Challenge of Global Health | Foreign Affairs. https://www.foreignaffairs.com/articles/2007-01-01/challenge-global-health.
38. Wagenaar BH, Hirschhorn LR, Henley C, et al. Data-driven quality improvement in low- and middle-income country health systems: lessons from seven years of implementation experience across Mozambique, Rwanda, and Zambia. *BMC Health Serv Res*. 2017;17(S3):830. doi:10.1186/s12913-017-2661-x
39. Wysocki AD, Ponce MAZ, Brunello MEF, et al. Atenção Primária à Saúde e tuberculose:

avaliação dos serviços. *Rev Bras Epidemiol*. 2017;20(1):161-175. doi:10.1590/1980-5497201700010014

40. Nwankwo B, Sambo MN. Can training of health care workers improve data management practice in health management information systems: a case study of primary health care facilities in Kaduna State, Nigeria. *Pan Afr Med J*. 2018;30:289. doi:10.11604/pamj.2018.30.289.15802
41. Ade S, Trébucq A, Harries AD, et al. Follow-up and tracing of tuberculosis patients who fail to attend their scheduled appointments in Cotonou, Benin: a retrospective cohort study. *BMC Health Serv Res*. 2015;16(1):5. doi:10.1186/s12913-015-1219-z
42. Kumar SR, Pooranagangadevi N, Rajendran M, et al. Physician's advice on quitting smoking in HIV and TB patients in south India: a randomised clinical trial. *Public Heal action*. 2017;7(1):39-45. doi:10.5588/pha.16.0045
43. Sheikhtaheri A. Near misses and their importance for improving patient safety. *Iran J Public Health*. 2014;43(6):853-854. http://www.ncbi.nlm.nih.gov/pubmed/26110160.
44. Tuberculosis National Unit Disease. *Guidelines for TB Infection Prevention and Control for Health Care Workers in Keny*.
45. Aspden P, Corrigan JM, Wolcott J ES. Patient safety: achieving a new standard for care. 2004. doi:10.17226/10863
46. Ridderhof JC, van Deun A, Kam KM, Narayanan PR, Aziz MA. Roles of laboratories and laboratory systems in effective tuberculosis programmes. *Bull World Health Organ*. 2007;85(5):354-359. doi:10.2471/blt.06.039081
47. Le-Abuyen S, Ng J, Kim S, et al. Patient as observer approach: an alternative method for hand hygiene auditing in an ambulatory care setting. *Am J Infect Control*. 2014;42(4):439-442. doi:10.1016/j.ajic.2013.12.003
48. Jadgal KM, Nakhaei-Moghadam T, Alizadeh-Seiouki H, Zareban I, Sharifi-Rad J. Impact of educational intervention on patients behavior with smear-positive pulmonary tuberculosis: a study using the health belief model. *Mater Sociomed*. 2015;27(4):229-233. doi:10.5455/msm.2015.27.229-233
49. Larson E, Goldmann D, Pearson M, et al. Hygiene adherence: measuring hand hygiene adherence. 2009:234.
50. Lau L, Pérez M. World Health Organization global initiative on radiation safety in

healthcare settings: technical meeting report. 2008:1-100.

APPENDIX 1: Examples of the data collection tools

In-depth Interview/FGD guide for TB Physicians and Nurses (1)

Access and Continuity of Care (ACC)

1. Could you please describe the general process of providing TB treatment and care in your TB cabinet? What are the policies/guidelines you follow in providing TB treatment?

2. Let us discuss how you prioritize patients. ***Probe:*** If you have patients with urgent needs, or patients who have more serious conditions, how do you define who to treat/serve first? What is your decision based on? Are there any relevant guidelines you base your decision on? What about the patients who have an appointment, and who just walk in? Who do you serve first?

3. Sometimes your patients might have needs which are not directly related to your responsibilities, and in such cases you can provide follow-up instructions on how to seek continuing care. Let us discuss how you provide instructions, and how do you make sure that the patients understood your instructions. Do you provide those instructions in writing? How do you engage patients' families in the process?

Assessment of Patients (AOP)

4. What lab tests are conducted to diagnose patients suspected of having pulmonary TB and are capable of producing sputum? Is it done in your facility? If not where?

5. What procedures are used to establish the diagnosis of extra-pulmonary TB? Are histopathology tests commonly used? Is it done in your facility? If not where?

6. For suspected tuberculosis meningitis which test is used for rapid diagnosis? Is it done in your facility? If not where?

7. What is the procedure for managing a patient suspected of having drug-resistant TB?

8. Which patients are considered for drug susceptibility testing? What is the initial diagnostic test performed for patients at risk for drug resistance? Is it done in your facility? If not where?

9. If Rifampicin resistance is detected what are the procedures that follow?

10. In order to minimize the potential for transmission what are the actions to be taken for patients in whom Rifampicin resistance is detected?

11. How is the response to treatment monitored in patients with pulmonary drug sensitive TB? What about patients with drug-resistant TB?

12. What is the best method for assessing response to treatment among patients with extra-pulmonary TB in adults and children?

13. Based on what the plan for continued treatment is developed? Who does participate in the planning of continuation phase of the treatment? Is the plan documented? How?

14. What kind of reassessments are performed? Lab tests? X-ray examinations? What are the intervals between reassessments? How is that interval determined? What is the frequency of reassessments of your patients? How do you document the assessment/reassessment data?

15. How and who analyzes the patient assessment data? How is the analyzed data used?

16. What is the initial diagnostic test performed for patients at risk for HIV?

17. When is anti-tuberculosis treatment initiated among smear- and Gen Xpert negative persons with clinical evidence strongly suggestive of TB?

18. What is the general process of HIV testing and counseling for TB suspects and TB patients?

19. Who initiates and maintains antiretroviral therapy (ART) for HIV– positive TB patients?

Childhood TB

20. What standard operating procedures or guidelines do you use for childhood TB? How are they different from adults?

21. What Lab tests are conducted to diagnose children suspected of having pulmonary TB and are capable of producing sputum? Where it is done?

22. Which investigations are usually undertaken to confirm the diagnosis of TB in children who are not capable of producing sputum?

23. What types of diagnostic examinations are done for children suspected of having intrathoracic tuberculosis? Where it is done?

24. What is the mechanism of the contacts investigation of children with TB?

25. What is the best method for assessing response to treatment among children with TB?

Care of Patients (COP)

26. After registering in your TB cabinet when is care for each patient planned and by whom? How is the care plan different from patient to patient? What data do you use to plan care for patients?

27. How is the planned care *(doses, frequencies, duration of treatment)* for patients reviewed and verified? How do you monitor the provision of care?

28. Do you usually update or revise the process of treatment and care? Who and when (in which case) is this done?

29. How are the medications verified to ensure that the correct medication, correct dose is used? ***Probe:*** Is the dosage/amount of medication and the route of administration verified with prescription or order every time before administering?

30. How is the patients' adherence to the treatment regimen monitored? ***Probe:*** I know that in some cases TB physicians provide patients (during winter when roads are paralyzed or those leaving the country for work) with certain amount of medication to support treatment continuation. Is there any mechanism for monitoring od such cases?

31. If the treatment is interrupted or discontinued, how are the factors leading to it addressed?

32. What do you do to promote adherence to treatment, improve quality of life and relieve suffering?

33. How do you monitor the side effects to medications? How do you document those? How do you report those?

34. What treatment regimen is prescribed to patients who have not been treated previously and do not have other risk factors for drug resistance? Which drugs are used? What is the duration of treatment? Initial phase? Continuation phase? What about extra-pulmonary TB?

35. Which drugs are used for treating patients having or highly likely of having drug resistant TB? For how long is the treatment given after the culture conversion? Are MDR-TB treatment regimens aligned with national guidelines? What about extra-pulmonary TB?

36. Is Isoniazid preventive therapy (IPT) administered to those whose contact investigation did not identify anyone with active TB?

37. Are fixed-dose combinations (FDCs) of anti-TB medications used? Are patient kits used?

38. For patients with HIV and tuberculosis who have profound immunosuppression what is the first treatment of choice?

39. How are patients with HIV and tuberculosis, regardless of their CD4 count *(CD4 cells are a type of white blood cells that fight infection. The CD4 count helps tell how strong the immune system is, and indicates the stage of HIV disease)* treated? Which TB treatment regimens are used for HIV-positive patients with TB?

40. As a prophylaxis for other infections, do patients with TB and HIV receive other than HIV/TB drugs? If yes, what drugs do patients receive?

41. Patients with HIV infection who do not have active TB infection, how are they treated for presumed latent TB infection?

42. Is Isoniazid preventive therapy (IPT) offered to people living with HIV after active TB disease has been ruled out? Are people living with HIV screened for TB each time they visit a health facility?

In-Depth Interview/FGD guide for TB Physicians and Nurses (2)

Patients and Family Rights (PFR)

1. Let us discuss patients' rights and responsibilities. In your opinion, how knowledgeable are you about patients' right and responsibilities? How do you perceive your role in protecting those rights?

2. What do you think about patients' (*children*) needs for privacy during care and treatment? How do you identify patients' expectations and their need for privacy?

3. How is the privacy of a patient respected for all clinical interviews, examinations, procedures, and treatments? What policies are you aware of, which guide you in this process?

4. Your patient population is very diverse, and you deal with various people coming from different contexts. They might have certain values and beliefs which matter during treatment. How do you identify those values and beliefs?

5. How do you encourage patient and family participation in the care process? What processes do you develop to support patient and family participation in the treatment process?

6. How do you inform patients about their rights and responsibilities? Do you provide their rights and responsibilities in a written form to your every patient? How do you provide information to your patients on their rights and responsibilities when written communication is not effective or appropriate?

7. What do you think about confidentiality of the patient's health information?

8. Do you have policies and procedures for obtaining informed consent regarding the planned care from the patient (parent)? If yes, to what extent is the informed consent obtained from the patient (parent) consistent with the policies and procedures?

9. How were you trained to obtain patient informed consent? How do you ensure that the patient (parent) understands the consent?

10. In which situations do you obtain a separate informed consent other than the planned care consent form? What is the list of procedures that require separate consent? By whom was developed this list? When do you obtain a separate informed consent? ***Probe:*** Surgical or invasive procedures, anesthesia, before the use of blood and blood products, before other high-risk procedures and treatments.

11. Do you have a defined process for when others (e.g. family members, other relatives) can grant consent?

12. How is the vulnerable patient group defined by the organization? How do you perceive your responsibility in protecting these vulnerable patients (children, disabled individuals, the elderly and others)?

13. What do you think about the right of patients (children) and their family to choose what information regarding their care to be provided to family or others?

Patient and Family Education (PFE)

14. Let us discuss what structure/mechanism you have for patient education. How it is organized? Do you provide education to every patient?

15. How do you identify educational needs of the patients (children) and their families? What criteria are used to assess patients (children) and family education needs?
16. How do you assess patients' (children) and family's ability to learn? What does assessment include? ***Probe:*** beliefs and values, educational level, emotional barriers and motivations, physical and cognitive limitations, willingness to receive information)

17. How do you document educational assessment findings? Do you mention about it in the patient records?

18. What aspects of treatment you cover specifically? ***Probe:*** patients' conditions, proposed treatments, potential benefits and drawbacks, likelihood of success, possible problems related to recovery, possible results of non-treatment?

19. What topics are covered during education of patients (children) and families? What are the underlying goals of education and trainings?

- transmission of TB
- difference between Latent TB infection and active TB disease
- progression of LTBI to active TB
- signs and symptoms of disease
- importance of HIV testing
- respiratory isolation and use of masks
- infectious periods
- importance of chemotherapy as prescribed
- side effects and adverse medication reactions
- DOTs
- importance of regular medical assessment
- importance of contact investigation

20. How do you train your patients and families about the effective and safe use of medications, side effects?

21. What educational materials and sources do you use? Do you use a guideline on how to effectively educate patients and families? What kind of educational materials do you provide to your patients?

22. How do you reinforce patients and their families' participation in the education?

23. Who participates in provision of education to patients (children) and family? How many professionals caring for the patient participate in education? How do they participate? How do they collaborate? In what cases education is provided?

24. How do you verify whether or not the provided education has been understood by the patients and families? Are your patients interested in receiving education on their condition?

25. How would you evaluate your own communication skills and subject knowledge to provide appropriate patient education? How have you been trained to provide patient education? Do you have adequate time to allocate for patient education?

In-Depth Interview/FGD guide for TB Physicians and Nurses (3)

Quality Improvement and Patient Safety (QPS)

1. Do you have quality improvement and patient safety program in this clinical setting? How is the information on the quality improvement and patient safety program communicated to you? What are the channels of communication? How do you get informed about the activities carried out with the program?

2. How do you perceive your role in the organization-wide quality and safety program? What about your role in terms of providing high quality treatment to your patients?

3. In your opinion how should the organization be informed about the quality and patient safety issues across the facility? Are you aware of any types of events that should be reported? ***Probe:*** Sentinel events, near misses, adverse events, medication errors, etc.? How do you report on such events?

4. In your opinion what should be done if such events occur? Are you aware of any processes and procedures that follow after occurrence and reporting of such events? ***Probe:*** E.g. Root cause analysis?

Prevention and control of infection (PCI)

5. Let us now discuss infection prevention and control activities. Could you, please describe the infection prevention program? Who is in charge of the program? What about your role in the program?

6. How do you receive information on results of infection prevention and control measurements?

7. To what extent are you familiar with the policies, procedures, and practices of the infection prevention and control program?

8. How do you receive education on infection prevention and control? In what types of educational activities have you participated in response to significant trends in infection data?
9. What do you do as a physician to minimize the risk of infection in your daily activities? What about using personal protective equipment?

10. Let us discuss what hand hygiene guidelines you follow in this setting.

Staff qualification and education (SQE)

11. Let us now discuss some topics related to staff qualification and education. As a staff member how confident do you feel in this clinical setting and about your job responsibility?

12. What in-service education and trainings do you receive to maintain or to advance your skills and knowledge?

13. How relevant is the provided education to your ability to meet patient needs?

14. How often do you receive evaluation of the quality and safety of your services provided to patients?

15. Let us now talk about staff health and safety program. Is the program responsive to urgent and non-urgent needs of the staff? Does it offer direct treatment or referral when necessary?

Management of Information (MOI)

16. In your opinion, what are the processes through which this organization, and this TB cabinet more specifically, ensures confidentiality of data and information? How are the patients' clinical records and information protected from loss or destruction? What about unauthorized access or use?

17. What policies, procedures and programs do you use in your daily activities? Are those documents easily accessible for you? Are you trained on how to use those documents/policies/guidelines?

18. What is your opinion regarding the availability of the patients' records to the health care practitioners, needed for the care of patients?

19. Let us now talk about patients' clinical records. Do you initiate a clinical record for every patient assessed or treated? How up-to-date is the information in the patients' records?

20. How do you ensure that only authorized individuals have access/can make entries to patients' clinical records?

21. How are the entries in the patient's record corrected and overwritten?

Laboratory Observation Checklist

	Standards	***Yes***	***No***	***Comment***
1.	The international biohazard warning symbol and sign are displayed on the laboratory door.			
2.	The biosafety level is displayed on the laboratory door.			
3.	The supervisor's name is displayed on the laboratory door.			
4.	Telephone numbers are displayed on the laboratory door.			
5.	Required procedures for entering and exiting the laboratory are displayed on the laboratory door.			
6.	Laboratory access is restricted.			
7.	Laboratory employees use personal protective equipment.			
8.	Face protection is used when manipulating specimens inside or outside a biosafety cabinets:			
	a) Goggles/gown/gloves/close-toed footwear			
	b) Face shield			
	c) Other splatter guard *(specify)*			
9.	Masks are used as personal protective equipment in the laboratory			
10.	Protective laboratory clothing is worn at all times while staff is working in the laboratory.			
11.	Protective clothing is worn outside the laboratory area (For example, in canteens, coffee rooms, offices, libraries, staff rooms and toilets)			
12.	Laboratory coats and gowns are stored separately from personal clothing.			
13.	Clean gowns and used gowns are stored in different areas of the laboratory			
14.	Gloves are worn for all procedures that involve direct contact, or may involve accidental contact, with sputum, blood, body fluids and other potentially infectious materials.			
15.	After use, gloves are removed aseptically			
16.	After use, gloves are removed, hands are washed. *Personnel should thoroughly lather their hands with soap, using friction, for at least 15 seconds; rinse them in clean water; and dry them using a clean paper towel.*			
17.	Personnel wash their hands after any overt contamination.			
18.	Personnel wash their hands after completing work with infectious materials.			
19.	Personnel wash their hands before leaving the laboratory's working areas.			
20.	Is standard safety equipment available in the laboratory?			
	a) Hand-washing station near the exit (automated or hands-free taps are recommended)			
	b) A dispenser for paper towels is near the sink			

	c) First aid kits			
21.	Is standard safety equipment used in the laboratory?			
	a) Hand-washing station, hands-free taps, and dispenser for paper towels			
	b) Spill kits			
	c) First aid kits			
22.	Some people eat in the laboratory			
23.	Some people drink in the laboratory			
24.	Some people apply cosmetics in the laboratory			
25.	Some people handle contact lenses in the laboratory			
26.	Facilities for eating and drinking, and for rest, are provided outside work areas			
27.	Food or drink sometimes stored in the laboratory's working areas.			
28.	Some people wore open-toed footwear in the laboratory			
29.	Mobile telephones are used in the laboratory			
30.	All procedures are performed in a way as to minimize or prevent the formation of aerosols and droplets.			
31.	Mouth pipetting is done in the laboratory.			
32.	Sometimes materials are placed in the mouth.			
33.	All labels used in the laboratory are self-adhesive.			
34.	Written documentation that may be removed from the laboratory is protected from contamination			
35.	The laboratory is divided into "functionally clean" and "potentially contaminated" areas. (*The clean areas reserved for administrative and preparatory work*).			
36.	Laboratory doors have a glass window panel.			
37.	Laboratory doors have appropriate fire ratings			
38.	Laboratory doors are self-closing			
39.	The laboratory has a reliable and adequate electricity supply			
40.	Separate autoclaves are used to sterilize solutions or glassware (clean materials).			
41.	Infectious and non-infectious waste is separated			
42.	Autoclaves decontaminate infectious waste			
43.	Identified essential reagents are available.			
44.	*Check* how *the reagents are dispensed:*			
	a) All reagents are dispensed according to manufacturers' directives or packaging instructions.			
	b) All reagents and solution are completely and - accurately labeled with chemical name			
	c) All reagents and solutions are labeled with hazard marking (WHO-TB)			
45.	Is the airflow appropriately directed?			

	Directional airflow with 6–12 air exchanges per hour; Directional airflow refers to air flowing from clean areas towards areas where aerosols maybe generated			
46.	*Observe whether sputum is collected in*			
	a) Well ventilated areas in the building			
	b) Outside the building			
47.	Are sputum-collection containers:			
	a) Wide-mouthed			
	b) Sterile			
	c) Clear			
	d) Leak-proof			
	e) Have a screw lid			
48.	Are specimens labeled with patient information?			
49.	Are specimens labeled with test?			
50.	Are specimens labeled with date?			
51.	Are specimens labeled with time of collection?			
52.	Are specimens labeled with authorized requester?			
53.	Are national laboratory guidelines and standard operating procedures for sputum processing available and used? *Check availability*			
54.	Is a laboratory-specific biosafety manual prepared and adopted as policy, available and accessible? *Check availability*			
55.	Environmental controls are in place:			
	a) Through Local exhaust ventilation in <u>all</u> rooms			
	b) Through General ventilation in <u>all</u> rooms			
	c) Through High efficiency particulate air (HEPA) filtration			
	d) Through Ultraviolet germicidal irradiation (UVGI)			

Prevention and Control of Infection Observation Checklist

	Standards	***Yes***	***No***	***Comment***
1.	There is an Infection prevention and control program and the following are included in it. *Observe all areas included in **infection prevention and control program.** The waiting areas for patients, the treatment rooms and patients' rooms and the flow of patients. Note any overcrowding, small and narrow spaces, whether ventilation is adequate (If yes, specify in the comments section %)*			
	a) All patients' care areas			
	b) All staff care areas			
	c) All visitors' areas			
2.	Is there Local exhaust ventilation (enclosing devices and exterior devices)?			
3.	Is there General ventilation (e.g., single-pass system, recirculation system)?			
4.	Is there Natural ventilation (*for low-risk procedures it is sufficient)*			
5.	Is the ventilation available for all rooms?			
6.	Are there Air-cleaning methods (e.g., high efficiency particulate air [HEPA] filtration and ultraviolet germicidal irradiation [UVGI])?			
7.	Does the X-ray examination room have a proper ventilation?			
8.	Is there a UV light operating 24 hours a day in the waiting area of the X-ray cabinet?			
9.	Are the Air-cleaning methods available in high-risk areas?			
	a) Sputum-induction rooms			
	b) Bronchoscopy			
10.	Are surgical masks available in the facility?			
11.	Do the patients use surgical masks?			
12.	Do the health-care workers use surgical masks during contacts with patients? *(If yes, specify in the comments section % of use)*			
13.	Are respirators available in the facility? *(If yes, specify in the comments section the type of respirators)*			
14.	Do the visitors use the respirators? *(If yes, specify in the comments section % of use)*			
15.	Do the health-care workers use respirators during contacts with patients? *(If yes, specify in the comments section % of use)*			
	Preventing transmission of Infection			

16.	Sharps and needles are in dedicated, puncture-proof containers			
17.	Sharps and needles are not reused			
18.	Gloves, masks, eye protection are correctly used in defined situations *From the hospital guidelines define the situations in which masks, eye protection, gowns or gloves are required*			
19.	Hand washing procedures are performed correctly *From the hospital guidelines define hand washing and hand disinfection procedures.*			
20.	Soap, disinfectants, towel are located in the required areas *Observe the areas where hand washing and disinfecting procedures are required*			
	Access and Continuity of Care			
21.	Patients are identified before administering medication			
22.	Patients are identified before providing treatment and procedures.			
23.	Patients are identified before taking blood and other specimens for clinical testing.			
24.	Specimen taking hygiene guidelines that have been adapted are implemented.			
25.	The complete test results are written down by the receiver of the test result.			
26.	The order or test result is confirmed by the individual who gave the order or test result. *(**If no**, indicate in the comments section how the order or test result is confirmed)*			
27.	Is a statement of patients' rights and responsibilities posted or otherwise available from staff at all times?			
28.	Are the guidelines for establishing the diagnosis of TB available in the health facility?			
29.	Are the standard operating procedures or guidelines on childhood TB available at the health facility?			
30.	Are there any training materials (Prevention and Control of Infection) about implementing activities?			

Staff Qualifications Review Checklist

	Standard	***Yes***	***No***	***Comment***
1.	Personnel information is maintained for each staff member *(count the rate: number of staff members for whom personal file is maintained over total number of staff members)*			
2.	Personnel files are standardized and kept current			
3.	All credentials on file (education, licensure, registration, among others) are current and updated as required			
4.	TB laboratory supervisory staff and all staff performing laboratory tests and interpreting results on site have the required education, training, qualifications and experience *(Indicate in the 'Comments' if facility has no TB laboratory)*			
5.	Staffing of radiology and diagnostic imaging department have the required education, training, qualifications, and experience *(Indicate in the 'Comments if facility has no rad/imaging dep.)*			
6.	One or more individuals oversee the infection prevention and control program			
7.	The individual(s) is qualified in infection prevention and control practices			
8.	The individual(s) who oversee the planning and implementation of the program to manage the risks in the care environment is qualified by experience or training			
9.	TB physician has the required education, training, qualifications, and experience			
10.	TB nurse has the required education, training, qualifications, and experience			
11.	Job descriptions are current according to the ambulatory policy			
12.	There is at least one documented evaluation of each clinical staff member working under a job description each year or more frequently as defined by the organization			

13.	The desired education, skills, and knowledge are defined for staff			
14.	There is a staff record that contains the individual's qualifications, results of evaluations, and work history			

Smoke-free Environments Observation Checklist

1. Are there "No Smoking" signs visible from outside of the observed location?	1. ☐Yes	0.☐No
2. Are there "No Smoking" signs in the entrance area of the observed location?	1. ☐Yes	0. ☐ No
3. Are there "No Smoking" signs inside the observation site?	1. ☐Yes	0. ☐ No
4. "No smoking" signs are displayed (Check all that apply):	1. ☐ At the main entrances 2. ☐ At every entrance to a building 3. ☐ In all hallways 4. ☐ Toilets 5. ☐ Lifts 6. ☐ Stairwells 7. ☐ Other (*specify*) _____	
5. How would you describe the "No-smoking" signs?	1. ☐ Poorly visible signage 2. ☐ Clearly visible signage 3. ☐ Other (*specify*)_____ 4. ☐ No smoking signs	
6. Are there any warning signs of financial (and other) penalties?	1. ☐Yes(*specify*) _____ _	0. ☐ No
7. Are there any ashtrays inside the observation site?	2. ☐Yes(*specify*) _____ _	0. ☐ No
8. Are there any cigarette vendors or vending machines?	3. ☐Yes(*specify*) _____ _	0. ☐ No
9. Are there any functional objects with tobacco product's name or logo (ashtrays, lighters, umbrella, and watch)?	1. ☐Yes(*specify*) _____ _	0. ☐ No

10. Is there any tobacco advertising inside the observation site?	1. ☐Yes(*specify*) _____ _		0. ☐ No
11. Is there any area designated for smoking inside the observation site?	1. ☐Yes(*specify location*) _____ _		0. ☐ No
11.1 Is there any announcement *"Smoking is permitted only here"* near the entry area?	1. ☐Yes		0. ☐ No
11.2 Is it a closed area separated from the No smoking site?	1. ☐Yes		0. ☐ No
12. Are there smokers (TB patients, family members, visitors, or healthcare providers) in the following locations?	1. ☐Yes		0. ☐ No
1. Lobby *(specify who)* _____	1. ☐Yes	0. ☐ No	2.☐N/A
2. Corridors*(specify who)* _____	1. ☐Yes	0. ☐ No	2. ☐ N/A
3. Cafes*(specify who)* _____	1. ☐Yes	0. ☐ No	2. ☐ N/A
4. Patient rooms*(specify who)* _____	1. ☐Yes	0. ☐ No	2. ☐ N/A
5. Physicians' cabinets (*specify who)* _____	1. ☐Yes	0. ☐ No	2. ☐ N/A
6. Other(*Specify*) _____	1. ☐Yes		0.☐No
Please choose one observation location inside the observation site by your convenience, spend approximately 15 minutes in that location and answer to the following questions. Location name_____			
13. Do you smell of tobacco smoke?	1. ☐Yes		0.☐No
14. How many people are in that location? Specify patients, visitors, family members, or TB physicians	# of people (15 min) _____		
15. How many smokers are in that location? Specify patients, visitors, family members, or TB physicians	# of smokers (15 min) _____		

Medical Records Review Checklist: Clinical Records (1)

	Standards	***Yes***	***No***	***Comment***
	Clinical Records			
1.	Patient clinical records are maintained through the use of an identifier unique to the patient or some other effective method			
2.	Authenticated dated reports of all examinations are included in the patient's clinical record			
3.	Standardized diagnosis codes are used			
4.	Standardized procedure codes are used			
5.	Standardized definitions are used			
6.	Standardized symbols are used			
7.	Patient clinical records contain adequate information to identify the patient			
8.	Patient clinical records contain adequate information to support any diagnosis, care and treatment			
9.	Patient clinical records contain adequate information to document the course and results of care and treatment			
10.	The author and the date of each entry can be identified, and when required by the organization, the time of each entry can be identified			
11.	The care and procedures provided to each patient is written in the patients' record			
12.	There is uniform recording of informed consent			
13.	The planned care is documented in the patient record			
14.	Individuals other than the patient, granting consent are noted in the patients record			
15.	Patient clinical records contain adequate information to support any diagnosis, care, and treatment			
16.	Medications prescribed and/or administered within the ambulatory care organization are noted in the patient's record			
17.	Medications adverse effects are documented in the patient's record			
18.	Educational needs assessment findings are recorded in the patient's record			
19.	This assessment findings are documented:			
	a) Patients beliefs and values			
	b) Literacy, educational level and language			
	c) Emotional barriers and motivations			
	d) Physical and cognitive limitations			
	e) Willingness to receive information			
20.	There is uniform recording of patient education by all staff			
21.	Assessment findings are documented in a uniform manner and uniform location in the patient's record			
22.	The patient's records are up to date			
23.	Assessment findings are documented in a uniform manner and uniform location in the patient's record			
	These questions should be clarified with the TB doctor and write the number in the appropriate column.			

24.	How many patients have been treated since 2019 January-February in the TB cabinet?			
25.	How many of those patients final diagnosis has been made			
	a) In the TB cabinet			
	b) At the National Tuberculosis Center (Abovyan TB Hospital)			
	c) In another hospital			

Medical Records Review Checklist: TB Treatment Cards (2)

	TB treatment cards *Review TB treatment cards for a cohort of patients, including patients currently being treated and patients who have completed treatment. Cross-check the TB treatment cards against the TB treatment register and the laboratory register to ensure that information has been properly recorded on the treatment card*			
1.	TB treatment cards include :			
	a) information on referrals			
	b) information on HIV care			
	c) information on date and results of HIV test			
	d) information on being a migrant worker			
	e) information on anti-retroviral treatment			
	f) information on the date when co-tremoxazole preventive therapy started			
	g) information on dates of radiography and results			
	h) complete patient addresses or information where to locate the patient is provided.			
2.	Information from the TB treatment register and the laboratory register has been correctly recorded on the TB treatment card.			
3.	Medication administration is recorded for each dose			
4.	Medication information is kept in the patient's record			
5.	Administered medications are noted in the patient's record			
6.	Adverse effects of treatment are reported in the TB treatment card			
	TB treatment register			
7.	Childhood TB cases have been recorded in the TB treatment registers			
8.	Patients are entered in the TB treatment register in numerical and chronological order, starting with 1 at the beginning of the calendar year			
9.	Smear-positive (SS+) cases recorded in the **laboratory register** are recorded in the **TB treatment register.** *Check if any smear-positive patients are missing from the TB treatment register.*			

10.	The diagnosis and results of follow-up sputum examinations have been recorded accurately in the TB treatment register			
11.	Sputum-smear microscopy results are correctly transcribed from the laboratory register to the TB treatment register *Randomly choose a number of patients and confirm whether their results at the time of diagnosis, at 2 months or 3 months of treatment, at 5 months of treatment, and at 6 months or 8 months of treatment have been correctly transcribed from the laboratory register to the TB treatment register.*			

Policy Review Checklist

	Standard measurable element	**Policy Name**	**Yes**	**No**	**Comment**
	International Patient Safety Goals (IPSG)				
1.	Policy on patients identification is established				
2.	Policy describes how the patients are identified, that is how the identifiers are developed				
3.	Policy describes how the patients are identified for administering medications				
4.	Policy describes how the patients are identified for taking sputum, blood and other specimens for clinical testing				
5.	Policies and procedures support consistent practice in verifying the accuracy of verbal and telephone communication				
6.	Policy describes how the patients are identified for provision of treatments and procedures				
7.	Policies and procedures are developed to support continued reduction of health care–associated infections				
8.	Policies identify screening and diagnostic tests standard for treatment				
	Access and Continuity of Care (ACC)				
9.	Transfers of patients are based on criteria developed by the ambulatory care organization to address patients' needs for continuing care				
10.	The process addresses how responsibility for continuing care is moved to another practitioner or setting				
11.	The process addresses who is responsible for the patient during transfer				
12.	The process addresses the situation in which transfer is not possible				
13.	The ambulatory care organization has a process through which it communicates to patients and				

	patients' families about ongoing health needs and needed care and services				
	Patients and Family Rights (PFR)				
14.	Policies and procedures guide and support patient and family rights in the organization				
15.	The ambulatory care organization develops and implements a clearly defined informed consent process				
16.	The organization defines how a general consent is documented in the patient's record				
17.	The organization identifies its vulnerable patient groups				
18.	Children, disabled individuals, the elderly, and others identified by the organization are protected				
19.	The organization identifies patient and family responsibilities in the care process				
20.	The responsibilities identified include at least:				
	a) the full disclosure of health information by the patient;				
	b) cooperation during examinations and procedures;				
	c) respect for the organization's staff and other patients;				
	d) respect for the organization's policies and procedures related to smoking, infection prevention and control, and environmental care; and				
	e) compliance with instructions for self-care by the patient, including taking medications and attending follow-up appointments.				
21.	The organization has a process to inform patients of their rights and responsibilities when written communication is not effective or appropriate				
22.	The ambulatory care organization has a process for when others can grant informed consent				
23.	Policies and procedures indicate who may grant consent when the patient is unable to do so				
24.	Policies and procedures include a list of high-risk procedures and treatments for which consent is required				
25.	The ambulatory care organization develops and implements a process to respond to a patient's request for additional information on the health care practitioner responsible for his or her care				
	Assessment of Patients (AOP)				

26.	The ambulatory care organization develops and implements an initial assessment process to identify the health care needs of all patients				
27.	The ambulatory care organization identifies who performs which assessments				
28.	The scope and content of initial assessments conducted by each clinical discipline are defined in writing				
29.	The ambulatory care organization identifies the assessments process for those patients whose needs do not match the organization's mission and resources who require a referral or transfer to another organization				
30.	The scope and content of reassessments conducted by each clinical discipline are defined in writing				
31.	Policies and procedures describe how patients medical needs are defined				
32.	Policies define time frames for performing assessments for all settings and services				
33.	Time frames for performing reassessments are established for all clinical disciplines and services				
34.	The organization has established the expected report time for laboratory test results				
35.	All smear examinations performed in the laboratory have been recorded in the laboratory register (previous month)				
36.	The following fields have been included in the register and have been completed for newly diagnosed and registered patients: a) date the specimen was received b) name of the patient c) address of the patient d) name of the referring facility e) reason for sputum-smear microscopy f) results basic management unit and TB laboratory register number				
37.	Written policies and procedures address the handling and disposal of infectious and hazardous materials				
38.	There is a documented quality control program in the laboratory				
39.	The program includes biosafety rules for the use of laboratory coats, gowns, or uniforms				
40.	The laboratory safety program includes rules prohibiting eating, drinking, smoking, applying				

	cosmetics, manipulating contact lenses, and mouth pipetting				
41.	For radiology and diagnostic imaging services on site, there is a documented quality control program that demonstrates quality control checks on each type of imaging service performed *Skip to Q 47, if there is no radiology service in the facility.*				
42.	The quality control program includes instrument calibration equipment performance and evaluation, and test performance				
43.	There is a radiation safety management program is in place, which is compliant with applicable standards, laws, and regulations				
44.	The radiation safety program is compliant with the facility management and infection control programs, including reporting to the organization's safety structure at least annually and when any safety events occur				
45.	The radiation safety program ensures availability of safety protective devices appropriate to the practices and hazards encountered				
	Care of Patients (COP)				
46.	Ambulatory care organization leadership identifies high-risk patients and services and develops relevant policies and procedures of care				
47.	The care of immune-suppressed patients is guided by appropriate policies and procedures				
48.	The care of patients on dialysis is guided by appropriate policies and procedures				
49.	The care of frail, dependent elderly patients is guided by appropriate policies and procedures				
50.	The care of young, dependent children is guided by appropriate policies and procedures				
51.	The care of patients receiving chemotherapy or other high-risk medications is guided by appropriate policies and procedures				
	Medication Management and Use (MMU)				
52.	The ambulatory care organization develops a program to guide medication management and use that meets applicable laws and regulations.				
53.	The program addresses the following:				
	a) what medications are available within the ambulatory care organization;				
	b) the procurement process;				

	c) the proper and safe storage and labeling of medications;				
	d) how medications will be prescribed and dispensed; (*Also see* MOI.9)				
	e) the safety and sanitation of medication preparation and dispensing areas;				
	f) the qualifications of those who can prescribe, dispense, and administer medications;				
	g) medication administration and medication monitoring;				
	h) the management of sample medications;				
	i) what emergency medications are available within the ambulatory care organization and how they are securely stored; (*Also see* FMS.3)				
	j) the medication recall process, including patient notification and the inadvertent use of medications known to be expired;				
	k) medication safety practices such as medication error reporting and adverse drug reaction reporting;				
	l) sources of contemporary drug information.				
54.	Policy identifies those medication adverse effects that are to be recorded in the patient's record				
55.	Policy identifies those medication adverse effects that must be reported to the organization				
56.	Policy or procedure defines medication errors and near misses				
57.	The ambulatory care organization establishes and implements a process for reporting and acting on medication errors and near misses				
	Quality and Patient Safety (QPS)				
58.	The quality and patient safety program includes all patients, staff, and visitors				
59.	The quality and patient safety program unites all quality and safety activities of the ambulatory care organization				
60.	The PHC leaders have established a definition of a sentinel event that at least includes:				
	a) an unanticipated death, including, but not limited to • death that is unrelated to the natural course of the patient's illness or underlying condition (**for example**, death from a postoperative infection or a health care–associated infection); • death of a full-term infant; and • suicide;				

	b) major permanent loss of function unrelated to the patient's natural course of illness or underlying condition;				
	c) transmission of a chronic or fatal disease or illness as a result of infusing blood or blood products or transplanting contaminated organs or tissues;				
	d) infant abduction or an infant sent home with the wrong parents; and				
	e) rape, workplace violence such as assault (leading to death or permanent loss of function), or homicide (willful killing) of a patient, staff member, practitioner, medical student, trainee, visitor, or vendor while on organization property.				
61.	The ambulatory care organization establishes a definition of a near miss				
62.	The ambulatory care organization defines the type of events to be reported				
63.	The ambulatory care organization establishes the process for the reporting of near misses				
	Prevention and Control of Infections (PCI)				
64.	The ambulatory care organization designs and implements an infection prevention and control program to reduce the risk of health care–associated infections in patients and staff that is based on the organization's size, geographic location, services, patients, and staff				
65.	The program is based on current scientific knowledge, accepted practice guidelines, and local laws and regulations				
66.	The program is based on standards from national or local agencies and publications and professional organizations that address environmental sanitation and cleanliness				
67.	The organization has identified those processes associated with infection risk				
68.	The organization identifies those situations for which gloves and/or masks/or respirators are required				
69.	The organization identifies those situations for which hand washing and hand disinfection or surface disinfecting procedures are required				
70.	The organization has adopted hand-hygiene guidelines from an authoritative source				
71.	The organization identifies which processes require policies, procedures, staff education, practice changes,				

	evidence-based activities, and other strategies to support risk reduction				
72.	There is a policy/guideline for medical waste management				
73.	Policy and/or procedure guides elimination or limitation of smoking				
74.	There is a smoking limitation policy applying to:				
	a) patients				
	b) staff				
75.	There is a respiratory protection program, which includes:				
a)	Physicians				
b)	Nurses				
c)	Administrators				
d)	Laboratory personnel				
e)	Construction or renovation staff				
f)	Janitorial staff				
g)	Maintenance or engineering staff				
h)	Transportation staff				
	Governance, Leadership and Direction (GLD)				
76.	The organization's governance structure is described in the written documents				
77.	Those responsible for governance and managing are identified by title or name				
78.	Governance responsibilities and accountabilities are described in the documents				
79.	There is an annual documented performance evaluation of governance				
80.	There is a policy on staff recruitment, retention, and continuing education				
	Staff Qualification and Education (SQE)				
81.	There is a written strategy for staffing the ambulatory care organization in a manner that complies with local laws and regulations				
82.	The number and types of staff are identified in the strategy using a recognized staffing method				
83.	The strategy addresses the assignment and reassignment of staff				
84.	There is a staff health and safety program (incorporated into the quality and safety program) that is responsive to urgent and non-urgent staff needs through direct treatment and referral.				

85.	The epidemiologically significant infections are identified by the organization				
86.	The staff at high risk for exposure to and transmission of infections are included in the vaccination and immunization program				
87.	Policy and regulations define required credentials for each medical staff member				
88.	Policy describes process for the review of each medical staff member's credential file				
89.	Policy/procedure lists the required contents of personnel files				
	Management of Information (MOI)				
90.	Policy establishes those health care practitioners who have access to the patient's record				
91.	There is a process that addresses how entries in the patient clinical record are corrected or overwritten				
92.	A written policy addresses the privacy and confidentiality of information, consistent with laws and regulations.				
93.	Policy determines the format and location of entries in the patient records.				
94.	Policy determines specific content of patient clinical record				
95.	Those authorized to have access to the patient clinical record are identified in organization policy				
96.	Those authorized to make entries in the patient clinical record are identified in organization policy				
97.	The ambulatory care organization develops and implements processes to ensure the accuracy, consistency, and completeness of data and information				
98.	There is a written guidance document that defines the requirements for developing and maintaining policies, procedures, and programs, including at least items a) through h) in the intent				
99.	There are standardized formats for all similar documents; **for example**, all policies				
100.	The requirements of the guidance document are implemented and evident in the policies, procedures				

APPENDIX 2: List of facilities targeted in the Result Area 1

#	Marz	TB cabinet / PHC facility
1.	**Yerevan**	Arshakunyats Policlinic
2.		Nor Arabkir MC
3.		No. 12 Policlinic
4.		Davitashen No. 20 Policlinic
5.		Nor Aresh Policlinic
6.	**Shirak**	Enrico Matte Policlinic
7.		Gyumri No. 1 Policlinic
8.		Gyumri No. 2 Policlinic
9.		Akhuryan MC
10.		Artik MC
11.		Berlin Policlinic
12.	**Aragatsotn**	Ashtarak MC
13.		Aparan MC
14.	**Armavir**	Armavir MC
15.		Metsamor MC
16.	**Ararat**	Masis MC
17.		Ararat MC
18.	**Lori**	Stepanavan MC
19.		Vanadzor No. 1. Policlinic
20.		Alaverdi MC
21.		Vanadzor No. 5 Policlinic
22.	**Tavush**	Ijevan MC
23.		Noyemberyan MC
24.	**Gegharkunik**	Gavar MC
25.		Sevan MC
26.	**Syunik**	Kapan MC
27.		Goris MC
28.	**Kotayk**	Abovyan MC
29.		Hrazdan MC
30.	**Vayots Dzor**	Vayk MC

APPENDIX 3: IRB approval for the Result Area 1

AUA American University of Armenia

January 31, 2019

PRINCIPAL INVESTIGATOR: Vahe Khachadourian, MD, MPH, PhD(c)
CO-INVESTIGATOR(S): Nune Truzyan, DVM, MPH, Lusine Musheghyan, MA, MPH, Lusine Aslanyan, BS, MPH Saten Hovhannsiyan, MD, MPH
STUDENT INVESTIGATOR(S): N/A

TITLE: Institutionalization of Patient-Centered Tuberculosis (TB) Treatment in Armenia. Result Area 1: Strategy for improved quality and safety of TB service delivery at PHC level endorsed by stakeholders.

SPONSORING AGENCY: USAID

PROTOCOL #: AUA-2019-003

Vahe Khachadourian, MD, MPH, PhD(c); Nune Truzyan, DVM, MPH
Via Email(s): vkhachadourian@aua.am , tnune@aua.am

Dear Dr. Khachadourian and Ms. Truzyan,

The above referenced protocol was reviewed and approved by the Vice Chair of the Institutional Review Board of the American University of Armenia using the expedited procedure set forth in 45 CFR 46.110, category 6,7, on January 31, 2019. This study will be due for continuing review on or before January 31, 2020. Annual continuing reviews will be required for this proposal. The proposed study can proceed as it is approved by the AUA IRB. However, please note, the IRB must be kept apprised of any and all changes in the research that may have an impact on the level and type of IRB review needed for a specific proposal. You are required to notify the AUA IRB if any changes are proposed in the study that might alter its IRB status and consent procedures. New procedures that may have an impact on the risk-to-benefit ratio cannot be initiated until IRB approval has been given. Please retain this letter as documentation of the IRB's determination regarding your proposal. Please contact me, at akopyank@aua.am with a copy to auairb@aua.am, should you have any questions about the information in this letter. Thank you.

Sincerely,

Kristina Akopyan, MD, MPH
Vice Chair, AUA IRB
Institutional Research Manager
Office of Institutional Research and Assessment, AUA

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